DRAFT DOCUMENT

ONLINE DEVELOPMENTAL TENDER FOR PROCUREMENT OF VACCINE FOR UNIVERSAL IMMUNIZATION PROGRAM (UIP)

Tender No: CMSS/PROC/2024-25/UIP/032
(National Competitive Bidding)
(FOR CLASS-I and CLASS-II LOCAL SUPPLIERS ONLY)
(DEVELOPMENTAL TENDER)

CENTRAL MEDICAL SERVICES SOCIETY
(An Autonomous Society Under Ministry of Health & Family Welfare, Govt. of India)
2nd Floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Marg, Teen Murti Marg,
Chankayapuri, New Delhi-110021
Phone: 011-21410905, 21410906
Website: www.cmss.gov.in, email- dgceocmss@cmss.gov.in, gmproc1@cmss.gov.in, agmproc2@cmss.gov.in

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Notice Inviting Tender (NIT)

CENTRAL MEDICAL SERVICES SOCIETY

(An Autonomous Society Under Ministry of Health & Family Welfare, Govt. of India)
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website: cmss.gov.in, email- dgceocmss@cmss.gov.in, gmproc1@cmss.gov.in, agmproc4@cmss.gov.in

NOTICE INVITING E-TENDER
(E-PROCUREMENT)
Tender No- CMSS/PROC/2024-25/UIP/032, Dated 17.10.2024

1. The Central Medical Services Society, an autonomous body under Ministry of Health and Family welfare, Government of India, invites online tenders in prescribed format on Central Public Procurement Portal (CPPP), from eligible and qualified tenderers for supply of following goods for National AIDS Control Organization Program:

Schedule No.	Name of Item	Quantity to be procured	Unit of Measurement	EMD in Rs. (For 100%)	EMD in Rs. (For 50%)
I	**MR Vaccine**	1,54,37,500	Doses	17907500	8953750
II	**IPV**	7,50,000	Doses	2855100	1427550
III	**RVV**	2,17,68,750	Doses	29370397.5	14685198.75
IV	**bOPV (Routine Immunization) & bOPV (Pulse Polio)**	7,95,00,000	Doses	12354300	6177150
V	**TD vaccine**	1,30,00,000	Doses	2527200	1263600

Note:

i. This bid is reserved for Class I and Class II bidders only as per Government of India Public Procurement (Preference to Make in India) Order dated 16th September 2020). Only manufacturers are authorized to participate in the bidding process.

ii. Manufacturer who gets technically qualified and whose price bid is opened against CMSS regular tender no. CMSS/PROC/2024-25/UIP/001 dtd. 22.07.2024 & tender no. CMSS/PROC/2024-25/UIP/007 dtd. 12.09.2024 will not be eligible to participate in this developmental tender for the items for which they are technically qualified against aforesaid tender. This developmental tender is only for those manufacturers who do not meet prescribed eligibility criteria of aforesaid regular tender but have credential/ meet requirements for subject developmental tender.

2. Tender timelines are as under:

Sr. No.	Description	Scheduled date
(a)	Availability of tender documents on CPPP for download	17/10/2024
(b)	Last date and time for receipt of pre-bid queries, if any	30/10/2024 till 5:00 PM
(c)	Pre-bid meeting date, time and venue	25/10/2024 at 12 Noon Venue- Conference Hall, CMSS HQ New Delhi
(d)	Last date and time for bid submission	18/11/2024 till 01:00 PM
(e)	Last date and time for submission of original documents	18/11/2024 till 02:00 PM
(f)	Date and time for tender opening (technical bid)	18/11/2024 till 04:30 PM

3. Further details of the NIT along with the terms and conditions, tender document, other specification and Corrigendum (if any) can be published and downloaded from the e-procurement website https://eprocure.gov.in /eprocure/app'.

4. **As per directives of Government of India, the tender is published on GeM platform with GeM terms and conditions. However, in case of ambiguity or contradiction in terms and conditions of GeM bid, the clauses of the tender document uploaded in Additional Terms and Conditions (ATC) shall prevail.**

DG&CEO

SECTION II: INSTRUCTIONS TO BIDDERS (ITB)

1. Scope of Bid	**1.1 Scope of Bid** Purchaser as defined in Bid Data Sheet invites bid for supply of goods as stipulated in "Schedule of Requirement" conforming to specification as indicated in the "Technical Specification and Quality Assurance" and as per terms and conditions as indicated in GCC (General Condition of contract) read with SCC (Special Condition of Contract). The Bids should be submitted as per instruction given below and in the prescribed bidding forms. **1.2 Interpretations, Definitions, Abbreviations and Document Conventions** General Conditions of Contract (GCC), details Tenets of interpretation (GCC-clause 1.1), Definitions (GCC-clause 1.2), Document conventions (GCC-clause 1.3) and Abbreviations (GCC-clause 1.4), which shall also apply to the rest of the Tender Document.
Procuring Entity - Rights and Disclaimers	**2.1 The Procuring Entity** Bids are to be addressed to the DG & CEO CMSS, complete details given in Bid Data Sheet, herein after called the Tender Inviting Authority. The Tender Inviting Authority is the designated officer for uploading and clarifying this Tender Document. The contract may designate, as required, Inspection Agency/ Officer and interim/ ultimate Consignee(s) and Paying authority who shall discharge designated function during contract execution. **2.2 Right to Intellectual Property and confidentiality:** **1.** The Tender Document and associated correspondence are subject to copyright laws and shall always remain the property of the Procuring Entity and must not be shared with third parties or reproduced, whether in whole or part, without the Procuring Entity's prior written consent. **2.** However, Bidders may share these to prepare and submit its bid with its employees, subcontractor(s), or holding Company. Bidders shall obtain from them an undertaking of confidentiality similar to that imposed on Bidder under this clause. **3.** This condition shall also apply to bidders who do not submit a bid after downloading it or who are not awarded a contract in the process. **4.** The obligation of the Bidders under sub-clauses above, however, shall not apply to information that: i. now or hereafter is or enters the public domain through no fault of Bidder; ii. is legally possessed by Bidder at the relevant time and was not previously obtained, directly or indirectly, from the Procuring Entity; or

iii. otherwise lawfully becomes available to Bidder from a third party that has no obligation of confidentiality.

5. The provisions of this clause shall survive completion or termination for whatever reason of the Tender Process or the contract.

2.3 2.3 Right to reject any or all Bids

The Procuring Entity reserves its right to accept or reject any or all Bids, abandon/ cancel the Tender process, and issue another tender for the same or similar Goods at any time before the award of the contract. It would have no liability to the affected Bidder or Bidders or any obligation to inform the affected Bidder or Bidders of the grounds for such action(s).

2.4 Disclaimers

2.4.1 Regarding Purpose of the Tender Document

The Tender Document is neither an agreement nor an offer to prospective Bidder(s) or any other party hereunder. The purpose of the Tender Document is to provide the Bidder(s) with information to assist them in participation in this Tender Process.

2.4.2 Regarding Documents/ guidelines

The Tender Document, ensuing communications, and Contracts shall determine the legal and commercial relationship between the bidders/ contractors and the Procuring Entity. No other Government or Procuring Entity's document/ guidelines/ Manuals including its Procurement Manual (for internal and official use of its officers), notwithstanding any mention thereof in the Tender Document, shall have any locus-standii in such a relationship. Therefore, such documents/ guidelines/ Manuals shall not be admissible in any legal or dispute resolution or grievance redressal proceedings.

2.4.3 Regarding Information Provided

Information contained in the Tender Document or subsequently provided to the Bidder(s) is on the terms and conditions set out in the Tender Document or subject to which that was provided. Similar terms apply to information provided verbally or in documentary or any other form, directly or indirectly, by the Procuring Entity or any of its employees or associated agencies.

2.4.4 Regarding Tender Document:

1. The Tender Document does not purport to contain all the information Bidder(s) may require. It may not address the needs of all Bidders. They should conduct due diligence, investigation, and analysis, check the information's accuracy, reliability, and completeness, and obtain independent advice from appropriate sources. Information provided in the Tender Document to the Bidder(s) is on a wide range of matters, some of which may depend

	upon interpreting the law. The information given is not intended to be an exhaustive account of statutory requirements and should not be regarded as a complete or authoritative statement of law. The Procuring Entity, its employees and other associated agencies accept no responsibility for the accuracy or otherwise for any interpretation or opinion on law expressed herein. The Procuring Entity, its employees and other associated agencies make no representation or warranty for the accuracy, adequacy, correctness, completeness or reliability, assessment, assumption, statement, or information in the Tender Document. They have no legal liability, whether resulting from negligence or otherwise, for any loss, damages, cost, or expense that may arise from/ incurred/ suffered howsoever caused to any person, including any Bidder, on such account.
3. Eligibility and Qualification Criteria for Participation in this Tender	**3.1 Bidder** Subject to provisions in this Tender Document, participation in this Tender Process is open to all bidders who fulfill the eligibility criteria detailed in this bid document. Bidder should meet (as on the date of his bid submission and should continue to meet till the award of the contract) the 'Eligibility Criteria' detailed in this bid document. Bidder shall submit a declaration about the 'Eligibility Criteria' compliance in Form 1.2 – Eligibility Declarations. **3.2 Eligibility of bidders from specified countries** Entities having beneficial ownership in land border sharing countries, as defined in Department of Expenditure Order No. F.7/10/2021-PPD dated 23.02.2023, as amended from time to time, shall be eligible to bid only if they are registered with competent authority in accordance with the provisions of the Order. **3.3 Conflict of Interest -** Any bidder having a conflict of interest, which substantially affects fair competition, shall not be eligible to bid in this tender. Bids found to have a conflict of interest shall be rejected as nonresponsive. Bidder shall be required to declare the absence of such conflict of interest in Form 1.2 - Eligibility Declarations. A bidder in this Tender Process shall be considered to have a conflict of interest if the bidder: 1. directly or indirectly controls, is controlled by or is under common control with another Bidder; or 2. receives or have received any direct or indirect subsidy/ financial stake from another bidder; or 3. has the same legal representative as another bidder for purposes of this bid; or 4. has a relationship with another bidder, directly or through common third parties, that puts it in a position to have access to information

about or influence the bid of another Bidder or influence the decisions of the Procuring Entity regarding this Tender process; or

5. Participates in more than one bid in this tender process. Participation in any capacity by a Bidder (including the participation of a Bidder as sub-contractor in another bid or vice-versa) in more than one bid shall result in the disqualification of all bids in which he is a party. However, this does not limit the participation of a non-bidder firm as a sub-contractor in more than one bid; or
6. would be providing goods, works, or non-consulting services resulting from or directly related to consulting services that it provided (or were provided by any affiliate that directly or indirectly controls, is controlled by, or is under common control with that firm), for the procurement planning (inter-alia preparation of feasibility/ cost estimates/ Detailed Project Report (DPR), design/ technical specifications, terms of reference (ToR) / Activity Schedule/ schedule of requirements or the Tender Document etc) of this Tender process; or
7. has a close business or family relationship with a staff of the Procuring Organization who: (i) are directly or indirectly involved in the preparation of the Tender document or specifications of the Tender Process, and/or the evaluation of bids; or (ii) would be involved in the implementation or supervision of resulting Contract unless the conflict stemming from such relationship has been resolved in a manner acceptable to the Procuring Entity throughout the Tender process and execution of the Contract.

3.4 **Eligibility of Distributors/ Agents/ Resellers –** Unless otherwise stipulated in Bid Data Sheet, only manufacturers of the quoted items are authorized to participate in this bid. Distributors/ Agents/ Resellers are not eligible to bid.

3.5 Eligibility of Class-I/ Class-II/ Non-local Suppliers - As detailed in Bid Data Sheet.

1. **Minimum local content requirement for bidder's** classification as Class-I/ Class-II local Suppliers shall be as detailed in Bid Data Sheet.
2. The 'Class-I local Supplier'/ 'Class-II local Supplier' at the time of tender, bidding, or solicitation are required to indicate the percentage of local content and provide self-certification that the item offered meets the local content requirement for 'Class-I local Supplier'/ 'Class-II local Supplier' as the case may be. In cases of procurement for a tender value above Rs. 10 crores, the 'Class-I local Supplier'/ 'Class-II local Supplier' shall be required to

	provide a certificate, in the prescribed format, from the statutory auditor of the company (in the case of companies) or a practicing cost accountant or practicing chartered accountant (in respect of Contractors other than companies) giving the percentage of local content. Bids with false declarations regarding Local contents shall be rejected as responsive, in addition to punitive actions under the MII orders and for violating the Code of Integrity as per the Tender Document. 3. Failure to comply with declared local content shall attract penalty as prescribed in GCC 10.1.7 **3.6 Eligibility of Non-MSE entities** (MSE means Micro and Small Enterprises) **-** As detailed in Bid Data Sheet. **3.7 Debarred/ black listed bidders –** In accordance with DoE guidelines vide OM No F.1/20/2018/PPD dt. 02.11.2021, the bidder should not be debarred, in general or for the goods tendered, by CMSS, MoH&FW and DoE on the date of tender opening and on the date of award of contract. Aforesaid debarred bidders are not eligible to bid. **Qualification Criteria** – Only the bidders, who meet the qualification criteria as detailed in Section IV of the bid document shall be considered for award of contract. Bidders are required to submit supporting documents, as indicated in Section IV "Qualification Criteria".
4. Purchase Preference Policies of the Government	**4.1 Support to local manufacturers** Policies of the Government to support local manufacturers shall apply to this procurement. Accordingly, the provisions of Public Procurement (Preference to Make in India) Order 2017 dated 19.07.2024, as amended from time to time, shall apply to this procurement. In accordance with aforesaid provisions: 1. If the nodal Ministry has notified the item as having sufficient local capacity and competition, and to be procured exclusively from Class-I local suppliers, under Para 3(a) of PPP-MII Order, only Class-I local suppliers shall be eligible to submit a bid and be considered. 2. If the item is not reserved for procurement exclusively from Class-I local suppliers and if Class-II/ Non-local suppliers are also eligible to participate in the tender, as per ITB 3.5, purchase preference shall be given to Class-I local suppliers over Class-II/ Non-local suppliers provided its quoted rates fall within 20% margin of purchase preference, in accordance with PPP-MII Order dated 19.07.2024. The 'Class-I local Supplier'/ 'Class-II local Supplier' availing aforesaid benefit are required to indicate at the time of tender, bidding, or solicitation the percentage of local content and provide self-

	certification that the item offered meets the local content requirement for 'Class-I local Supplier'/ 'Class-II local Supplier', as the case may be. In cases of procurement for a tender value above Rs. 10 crores, the 'Class-I local Supplier'/ 'Class-II local Supplier' shall be required to provide a certificate, in the prescribed format, from the statutory auditor of the company (in the case of companies) or a practicing cost accountant or practicing chartered accountant (in respect of Contractors other than companies) giving the percentage of local content. Bids with false declarations regarding Local contents shall be rejected as responsive, in addition to punitive actions under the MII orders and for violating the Code of Integrity as per the Tender Document. **4.2 Support to MSEs** Policies of the Government to support Micro and Small Industries shall apply to this procurement. Accordingly, the provisions of M/o MSME Public Procurement Policy for the Micro and Small Enterprises (MSEs) Order, 2012, as amended from time to time shall apply to this procurement. In accordance with aforesaid provisions: 1. MSEs shall be exempted from payment of Earnest Money. They shall be required only to submit Bid Securing Declaration. 2. If the item is reserved for exclusive purchase from Micro and Small Enterprises (MSEs) as per the Public Procurement Policy for the Micro and Small Enterprises Order, 2012, only MSEs shall be eligible to submit a bid and be considered. 3. If the item is not reserved for procurement exclusively from MSEs and if Medium/ Large enterprises are also eligible to participate in the tender, purchase preference shall be given to MSEs over Medium/ Large enterprises provided its quoted rates fall within 15% margin of purchase preference, in accordance with Public Procurement Policy for the Micro and Small Enterprises (MSEs) Order, 2012. 4. Relaxation in Prior Turnover and Experience: The prior turnover and prior experience requirement for MSEs enterprises shall be as indicated in Qualification Criteria/ Section IV. 5. In accordance with M/o MSME Gazette Notification No S.O. 2119 (E) dt. 26th June 2020, " In case of reverse-graduation of an enterprise, whether as a result of re-classification or due to actual changes in investment in plant and machinery or equipment or turnover or both, and whether the enterprise is registered under the Act or not, the enterprise will continue in its present category till the closure of the financial year and it will be given the benefit of the changed status only with effect from 1st April of the financial year following the year in which such change took place."

	6. In accordance with M/o MSME Gazette Notification No S.O. 4926 (E) dt. 18th October 2022, "In case of an upward change in terms of investment in plant and machinery or equipment or turnover or both, and consequent re-classification, an enterprise shall continue to avail of all non - tax benefits of the category (micro or small or medium) it was in before the re-classification, for a period of three years from the date of such upward change." MSEs interested in availing aforesaid benefits must enclose in Form 1.2 with their offer the Udhyam Registration Certificate with the Udhyam Registration Number as proof of their being MSE registered on the Udhyam Registration Portal. The certificate should be valid on the date of bid submission. **4.3 Support to Start-up Enterprises** - Policies of the Government to support Start-ups shall apply to this procurement. Accordingly, in accordance with Department of Expenditure OM No F.20\212014-PPD dated 25.07.2016 and its subsequent clarifications: 1. **Exemption from submission of Bid Security:** DPIIT registered Start-ups shall be exempted from payment of Earnest Money. They shall be required only to submit Bid Securing Declaration. 2. **Relaxation in Prior Turnover and Experience:** The prior turnover and prior experience requirement for DPIIT registered start-up enterprises shall be as indicated in Qualification Criteria/ Section IV. **4.4** The guidelines regarding concurrent applicability of "Public Procurement (Preference to Make in India) Order 2017" and "Public Procurement Policy for the Micro and Small Enterprises (MSEs) Order, 2012" for simultaneous purchase preference to both Class-I local suppliers and MSE suppliers are detailed as under: 1. The applicability of "Public Procurement Policy for MSEs Order 2012" (PPP MSE Order) and "Public Procurement (Preference to Make in India) Order 2017" (PPP-MII Order) in various scenarios, involving simultaneous purchase preference to MSEs and Class-I local suppliers respectively, shall be in accordance with Department of Expenditure OM No. F.1/4/2021-PPD dated 18.05.2023 read with "Public Procurement (Preference to Make in India) Order 2017" and "Public Procurement Policy for the Micro and Small Enterprises (MSEs) Order, 2012", as amended till date.
5. The Goods, Eligible Goods and Basis of Evaluation	**5.1 Eligible Goods –Origin and Minimum Local Content** Unless otherwise stipulated in the Tender Document, all 'Goods' and 'incidental Works/ Service' to be supplied under the contract must conform to i) restrictions on certain countries with land-borders with India

	(ITB-clause 3.2; ii) minimum local content (Make in India Policy (ITB-clause 3.5 and 4.1); iii) Procurement Policy for the Micro and Small Enterprises (MSEs) Order, 2012 (ITB-clause 3.6 and 4.2). If Bidder avails benefits under any preferential policy as Class-I Local Supplier or as MSE or Start-up enterprise, the Goods must not circumvent the provisions relating to such benefits. **5.2 Basis of Evaluation for Schedules** 5.2.1 Unless otherwise stipulated in Bid data sheet, if there is more than one schedule in Section V: Schedule of Requirements, evaluation of financial ranking of bids shall be done separately for each schedule, and Bidder has the option to submit its quotation for any one or more schedules. 5.2.2 Bidder shall submit bid for minimum 50% of the scheduled quantity, unless otherwise defined in the bid data sheet.

6. Bid Prices, Taxes and Duties	**6.1 Prices** **6.1.1 Competitive and Independent Prices** a. The prices should be arrived at independently, without restricting competition, any consultation, communication, or agreement with any other bidder or competitor relating to: i. those prices; or ii. the intention to submit an offer; or iii. The methods or factors used to calculate the prices offered. b. The prices should neither be nor shall be knowingly disclosed by the Bidder, directly or indirectly, to any other bidder or competitor before bid opening or contract award unless otherwise required by law. **6.1.2 Undue profiteering** **1. Controlled Price, if any or MRP:** The price quoted by Bidder shall not be higher than the controlled price fixed by law for the Goods, if any, or where there is no controlled price, it shall not exceed the prices or contravene the norms for fixation of prices if any, laid down by Government or where the Government has fixed no such prices or norms, it shall not exceed the price appearing in any agreement, if any, relating to price regulation by any industry. In any case, save for special reasons stated in the bid, if any, the price charged shall not be higher than the Maximum Retail Price (MRP). **2. Undue profiteering:** If the price quoted is higher than the controlled price in the sub-clause above, Bidder shall specifically mention this fact in his bid giving reasons for quoting a higher price(s). If he fails to do so or makes any misstatement, it shall be lawful for the Procuring Entity either to revise the price at any stage to bring it in conformity with the sub-clause (1) above or to terminate the contract for default as per the contract and avail all the remedies available therein in addition to other punitive actions for violation of Code of Integrity. **6.1.3 Price Components** 1. Bidder shall indicate in the Price Schedule all the specified components of prices shown therein, including the unit prices and total bid prices. 2. The prices in the corresponding price schedule shall be entered separately in the following manner: a. The price of the Goods quoted ex-factory, ex-showroom, ex-warehouse or off-the-shelf, as applicable, shall be assumed to include all taxes and duties like GST, customs duty, etc. already paid or

payable on the components and raw material used in the manufacture or assembly of the Goods.

b. Any GST, which shall be payable on the Goods in India if the contract is awarded.

c. Charges towards inland transportation, insurance, and other local costs incidental to the delivery of the Goods to their final destination as stipulated in Section V: Schedule of Requirements.

6.1.4 Price Schedule

1. Bidders are to upload only the downloaded Price Schedule (in excel format) after entering the relevant fields without any alteration/ deletion/ modification of other portions of the excel sheet. All the columns shown in the price schedule should be filled up as required. If any column does not apply to a Bidder, he should clarify the same.

2. Bidders shall fill in their rates other than zero value in the specified cells without keeping it blank.

3. The quoted price shall be considered to include all relevant financial implications, including inter-alia the scope of the Goods to be supplied, location of the bidder, location of the consignee(s), terms of delivery, extant rules and regulations relating to taxes, duties, customs, transportation, environment, labour etc. in India.

6.1.5 Provisions of GST

1. Break up of different price elements, i.e., as per GST Act, shall be indicated separately, along with its associated HSN code and GST rate.

2. While quoting the basic rate, the bidder should offset the input credit available/ to be availed as per the GST Act.

3. Please refer to ITB-clause 6.3 for further details.

6.1.6 Currencies of Bid and Payment

1. The currency of bid and payment shall be quoted by Bidder entirely in Indian Rupees. All payments shall be made in Indian Rupees only.

6.1.7 Non-compliance

Tenders, where prices are quoted in any other way, shall be rejected as nonresponsive.

6.2.2 Firm/ Variable Price

1. Firm Price

Prices quoted by Bidder shall remain firm and fixed during the currency of the contract and not subject to variation on any account.

6.2.3 Exchange Rate Variation- Deleted

6.3 Goods and Services Tax (GST)

6.3.1 GST Registration Status:

1. All the bidders/ Bidders should ensure that they are GST compliant and their quoted tax structure/ rates as per GST Act/ Rules. Bidder should be registered under GST and furnish GSTIN number and GST Registration Certificate in their offer unless they are specifically exempted from registration under specific notification/ circular/ section/ rule issued by statutory authorities.

2. GST Registration Number (15-digit GSTIN).

If the bidder has multiple business verticals in a state and has separate registration for each vertical, the GSTIN of each vertical is concerned with the supply and service involved, as per the scope of Schedule of Requirements and Price Schedule quoted. If the supply/ service provided is from multiple states, the bidder should mention GST registration numbers for each state separately.

3. Composition scheme:

If the Bidder has opted for a composition levy under Section 10 of CGST, he should declare the fact while bidding along with GSTIN and GST registration certificate.

4. Exemption from Registration:

If a bidder is not liable to take GST registration, i.e., having turnover below threshold, he shall submit undertaking/ indemnification against tax liability. Bidder claiming exemption in this respect shall submit a valid certificate from practising Chartered Accountant (CA)/ Cost Accountant with Unique Document Identification Number (DIN) to the effect that Bidder fulfils all conditions prescribed in notification exempting him from registration. Such bidder/ dealer shall not charge any GST and/ or GST Cess in the bill/ invoice. In such case, applicable GST shall be deposited under Reverse Charge Mechanism (RCM) or otherwise as per GST Act by the Procuring Entity directly to concerned authorities. Bidder should note that his offer would be loaded with the payable GST under the RCM. Further, Bidder should notify and submit to the Procuring Entity within 15 days from the date of becoming liable to registration under GST.

5. The principal place of business for purchase (CMSS) is Delhi. CMSS has GSTN registration no in 18 states including Delhi, as per details given below:

S No.	LOCATION	STATE	GSTIN	Address
1	AGARTALA	TRIPURA	16AABAC6275 F1ZV	CMSS, CWC

					Complex, Hapania, Near ONGC complex, Opposite of Satsangha Ashram, Agartala, Tripura Pin-799014
	2	AHMEDABAD	GUJRAT	24AABAC6275F1ZY	CMSS, Central warehousing corporation premises, Opposite P&T Colony, Teen Batti Road, Near Shahalam Gate, Shahalam, Ahmedabad, Gujarat Pin- 380028
	3	BANGLORE	KARNATAKA	29AABAC6275F1ZO	CMSS, Ministry of Health & Family Welfare, Central warehousing corporation premises, APMC Yard, Yeshwanthapur, Bangalore, Pin- 560 022
	4	BHOPAL	MADHYA PRADESH	23AABAC6275F1Z0	CMSS, Central

					warehousing corporation premises, Godown no. 1A, Near railway cabin no. 3, Chhola road, Nishatpura, District: Bhopal Pin-462 010. Landline No. 0755-2508050
	5	BHUBANESWAR-JAJPUR	ODISHA	21AABAC6275F1Z4	CMSS, 326, Khata No-456/948 Mouza-Johal, PO/PS-PAHALA, District – Khurda, Bhubaneswar, Odisha-751032.
	6	CHENNAI	TAMIL NADU	33AABAC6275F1ZZ	CMSS C/o Central warehousing corporation Warehouse no: 11C Opposite to Varadharaja Theatre Chitlapakkam, Chrompet, Chennai Pin- 600064
	7	DELHI	DELHI	07AABAC6275F1ZU	CMSS, Khata No -

					81, Village-Bamnoli, Sector -28, Dwaraka, Delhi-110075.
	8	GUWAHATI	ASAM	18AABAC6275F1ZR	CMSS, EPIP Complex, CWC premises, Opp. Emami, Amingaon, Guwahati, Pin- 781 031
	9	HYDERABAD	TELANGANA	36AABAC6275F1ZT	CMSS Block No. A3 Go down C W C Nampally Hyderabad Pin- 500001 Landline No. 040-29705969
	10	JAIPUR	RAJASTHAN	08AABAC6275F1ZS	CMSS C/O CWC, Plot No.-SPL-1296, EPIP, Sitapura Ind. Area, Goner Road, Jaipur, Rajasthan-Pin- 302022
	11	KOLKATTA	WEST BENGAL	19AABAC6275F1ZP	CMSS C/o Central Warehousing Corporation, Bonhooghly

					, RIC Estate, Kolkata, West Bengal-700108
	12	LUCKNOW	UTTAR PRADESH	09AABAC6275F1ZQ	CMSS C/o Central Warehousing Corporation, Naveen Galla Mandi, Sitapur Road Lucknow UP-226020
	13	MUMBAI	MAHARASHTRA	27AABAC6275F1ZS	CMSS C/O-Central Warehousing Corporation, GN. 01, Regional Office Mumbai, Sector-20, NR, Turbe RLY Station, Vashi - Navi Mumbai-400703 Landline No. 022-27830009.
	14	PATNA	BIHAR	10AABAC6275F1Z7	CMSS C/O-Central Warehousing Corporation, Katra Bazar, Bazar Samiti, Patna City

					Pin - 800008.
	15	RAIPUR	CHHATISGARH	22AABAC6275F1Z2	CMSS, C/O- Central Warehousing Corporation, Near Harish Petrol Pump, Rauabhata, Birgaon, Raipur, Pin-493221
	16	RANCHI	JHARKHAND	20AABAC6275F1Z6	CMSS C/O- Central Warehousing Corporation, Near OTC ground, Ranchi, Pin no. 834005
	17	TRIVANDRUM	KERAL	32AABAC6275F1Z1	CMSS C/O- Central Warehousing Corporation Kinfra Aplarel Park Menamkulam, Trivandrum Kerala Pin-695586 Landline No. 0471-2704470
	18	ZIRAKHPUR	PUNJAB	03AABAC6275F1Z2	CMSS, Ground Floor, Warehouse No.

				B014/3433, Godown Area. 35 Feet Road, Village Bhabat, Thana Zirakpur, SAS NAGAR, Punjab Pin-140603

i) Supplier supplying goods to CMSS warehouses or any of its consignee having delivery address within the state listed above, the supplier to issue tax invoice to CMSS, using the registration number of that state only.

ii) Supplier supplying goods directly to any consignee having delivery address in a state other than the 18 states mentioned above, the supplier to issue tax invoice to CMSS using the registration number of its principal place of Business i.e. Delhi GSTIN - 07AABAC6275F1ZU only.

The Billing –to Address will be
Central Medical Services Society
2nd Floor, Vishwa Yuvak Kendra,
Teen Murti Marg, Chanakyapuri,
New Delhi-110021.
GSTIN-**07AABAC6275F1ZU**

(iii) And, the Shipping–to Address will be the address of the consignee given in the Purchase order.

6.3.2 HSN Code and GST Rate:

4. It shall be the responsibility of Bidder to ensure that they quote the exact HSN Code and corresponding GST rate for the goods being offered by them.

5. As per the GST Act, the bid and contract must show the GST Tax Rates (and GST Cess if applicable) and GST Amount explicitly and separate from the bid/ contract price (exclusive of GST). If the price is stated to be inclusive of GST, the current rate included in the price must be declared by the bidder.

6. If a Bidder asks for GST (and GST Cess if applicable) to be paid extra, the rate and nature of such taxes applicable should be shown

	separately. Bidders should quote 'GST' if payable extra on the total basic rate of each cost element and quote GST in '%' inclusive of cess. **7.** If GST, other taxes, duties are not specified, or column is left blank in the price schedule, it shall be presumed that no such tax/ levy is applicable or payable by the Procuring Entity. **8.** Applicability to Imported Goods/ Services: Following the implementation of GST, the import of commodities shall not be subject to such erstwhile applicable duties like safeguard duty, education cess, basic customs duty, anti-dumping duty, etc. All these supplementary custom duties are subsumed under GST. The supply of commodities or services or both, if imported into India, shall be considered as supply under inter-state commerce/ trade and shall attract integrated tax (IGST). The IGST rate and GST cess shall be applicable on the 'Custom Assessable Value' plus the 'Basic Customs duty applicable thereon'. **6.4 Payments** **6.4.1 General** Payment terms as laid down in clause GCC 10.3 shall be applicable. **6.4.2 No Advance Payments** No advance payment of any type (Mobilization, secured advances etc.), shall be made by the Procuring Entity to the contractor.
7. Downloading the Tender Document; Corrigenda and Clarifications	**7.1 Downloading the Tender Document** The Tender Document shall be published and be available for download. The Bidders can download the Tender Document after the date and time of the start of availability till the deadline for availability. If the office happens to be closed on the deadline for the availability of the Tender Document, the deadline shall not be extended. **7.2 Corrigenda/ Addenda to Tender Document** Before the deadline for submitting bids, the Procuring Entity may update, amend, modify, or supplement the information, assessment or assumptions contained in the Tender Document by issuing a corrigenda and addenda. The corrigenda and addenda shall be published in the same manner as the original Tender Document. Without any liability or obligation, the Portal may send intimation of such corrigenda/ addenda to bidders who have downloaded the document under their login. However, the bidders' responsibility is to check the website(s) for any corrigenda/ addenda. No, separate communication shall be sent by procuring entity to the bidders regarding corrigendum/addendum. Any corrigendum or addendum thus issued shall be considered a part of the Tender Document. To give reasonable time to the prospective bidders to take such corrigendum/ addendum into account in preparing their bids, the Procuring Entity may suitably extend the deadline for the bid submission,

	as necessary. After the procuring entity makes such modifications, any Bidder who has submitted his bid in response to the original invitation shall have the opportunity to either withdraw his bid or re-submit his bid superseding the original bid within the extended time of submission as per ITB-clause 10.4.1 below. **7.3 Clarification on the Tender Document** A Bidder may seek clarification of the Tender Document from Office/ Contact Person/ e-procurement Help Desk as mentioned in BDS, provided the clarifications are raised before the clarification end date mentioned in BDS (or if not mentioned, within 7 days before the deadline for the bid submission). The Procuring Entity shall respond within 5 working days of receipt of such a request for clarification. The query and clarification shall be shared on the portal with all the prospective bidders. No separate communication shall be sent to the bidders. Accordingly, bidders are advised to regularly visit the portal for any update. Any modification of the Tender Document that may become necessary due to the clarification shall be made by the Procuring Entity through an Addendum/ Corrigendum issue under the sub-clause above.
8. Pre-bid Conference	1. Prospective bidders interested in participating in this tender may attend a Pre-bid conference to clarify techno-commercial conditions of the Tenders at the venue, date and time specified in Bid Data Sheet. Participation in the Pre-bid conference is restricted to prospective bidders who have downloaded the Tender Document. 2. Participation is not mandatory. However, if a bidder chooses not to (or fails to) participate in the Pre-bid conference or does not submit a written query, it shall be assumed that they have no issues regarding the techno/ commercial conditions. 3. The date and time by which the written queries for the Pre-bid must reach the authority and the last date for registration for participation in the Pre-bid conference are also mentioned in the Bid Data Sheet. If the dates are not mentioned, such date and time shall be 7 days before the date and time of the pre-bid conference. 4. Delegates participating in the Pre-bid conference must provide a photo identity and an "Authorization for attending a Pre-bid Conference" from their Company/ principals; else, they shall not be allowed to participate. The pre-bid conference may also be held online at the discretion of the Procuring Entity. 5. After the Pre-bid conference, Minutes of the Pre-bid conference shall be published on the Procuring Entity's portal. If required, a clarification letter and corrigendum to Tender Document shall be issued, containing amendments of various provisions of the Tender Document, which shall form part of the Tender Document. As per ITB-clause para under 7.2 above, to give reasonable time to the

	prospective bidders to take such clarifications into account in preparing their bids, the Procuring Entity may suitably extend, as necessary, the deadline for the bid submission. No separate communication shall be sent to the prospective bidders regarding their pre-bid queries/ any other clarification. Purchaser's response to the queries/ clarifications shall be uploaded only on the portal. Accordingly, bidders are advised to regularly visit the portal for any update.
9. Preparation of Bids	**9.1 The bid** **9.1.1 Language of the bid** The bid submitted by Bidder and all subsequent correspondence and documents relating to the bid exchanged between Bidder and the Procuring Entity shall be written in English Language. However, the language of any printed literature furnished by Bidder in connection with its bid may be written in any other language provided a translation accompanies the same in the bid language. For purposes of interpretation of the bid, translation in the language of the bid shall prevail. **9.1.2 Acquaintance with Local Conditions and Factors** The Bidder, at his own cost, responsibility, and risk, is encouraged to visit, examine, and familiarize himself with all the site/ local conditions and factors. The Bidder acknowledges that before the submission of the bid, he has, after a complete and careful examination, made an independent evaluation of the Site/ local conditions, the legal, environmental, infrastructure, logistics, communications and any other conditions or factors of which would have any effect on the price to be quoted by him or affecting performance/ completion of the contract. Bidders shall themselves be responsible for compliance with Rules, Regulations, Laws and Acts in force from time to time at relevant places. On such matters, the Procuring Entity shall have no responsibility and shall not entertain any request from the bidders in these regards. **9.1.3 Cost of Bidding** The Bidder(s) shall bear all direct or consequential costs, losses and expenditure associated with or relating to the preparation, submission, and subsequent processing of their Bids, including but not limited to preparation, copying, postage, delivery fees, expenses associated with any submission of samples, demonstrations, or presentations which the Procuring Entity may require, or any other costs incurred in connection with or relating to their Bids. All such costs, losses and expenses shall remain with the Bidder(s), and the Procuring Entity shall not be liable in any manner whatsoever for the same or any other costs, losses and expenses incurred by a Bidder(s) for participation in the Tender Process, regardless of the conduct or outcome of the Tender Process.

9.1.4 Interpretation of Provisions of the Tender Document

The provisions in the Tender Document must be interpreted in the context in which these appear. Any interpretation of these provisions far removed from such context or other contrived or in between-the-lines interpretation is unacceptable.

9.1.5 Quote Quantities/ Prices in both Numerals and Words

Although the software on the Portal may convert quantities/ rates/ amounts in numerical digits in Bids to words, the bidders are advised to ensure that there is no ambiguity in this regard.

9.1.6 Alternative Bids not Allowed

Conditional offers, alternative offers, multiple bids by a bidder shall not be considered. The Portal shall permit only one bid to be uploaded.

9.2 Documents comprising the bid:

9.2.1 Techno-commercial bid/ Cover

"Technical Bid" shall include inter-alia the original or scanned copies of duly signed or digitally signed copies of the following documents in pdf format. Pdf documents should not be password protected. If so, stipulated in BDS, specified originals or self-certified copies of originals shall also be required to be physically submitted as per instruction contained therein. No price details should be given or hinted at in the Technical bid:

1. Form 7: Documents relating to Bid Security: Scanned copy of Bid Securing Declaration (applicable for MSEs and Startups)/ EMD (applicable for all other bidders i.e. other than MSEs and Startups), as applicable, is to be uploaded along with electronic bid. The original documents are to be deposited with the Tender Inviting Authority within timelines as prescribed in the Bid Data Sheet. Failure to deposit the original documents by the specified last date shall result in summarily rejection of bid;
    a. Form 7: Bid Securing Declaration Format
    b. Form 7A: EMD Bank Guarantee Format

2. Form 1: bid Form (to serve as covering letter and declarations applicable for both the technical bid and financial bid);
    a. Form 1.1: Bidder Information;
    b. Form 1.2: Eligibility Declarations;

    Following documents are to be attached mandatorily:

    i. Self-attested copy of registration certificate/ Partnership deed, as the case may be.

	ii. Self-attested copy of PAN iii. Self-attested copy of GSTIN Registration iv. Self-attested copy of Power of Attorney authorizing signatories to sign the bid. v. Self-attested copy of Registration Certificate for entities having beneficial ownership in land border sharing countries, if applicable. vi. Self-attested copy of MSME Registration, if applicable. vii. Self-attested copy of Startup Registration, if applicable viii. Any other document stipulated in the bid document to establish bidder's eligibility to participate in the bidding process. c. Form 1.3: Local content Declaration from Statutory Auditors for purchases above Rs. 10 Crore. **3.** Form 4: 'Qualification Criteria – Compliance and Deviations': Unless otherwise stipulated in Bid Data Sheet; Following documentary evidence to establish the Bidder's qualifications as stipulated in Section IV: Qualification Criteria, apart from any other document listed explicitly in the bid document may also be attached. a. Valid Manufacturing license b. Valid WHO GMP Certificate c. Valid COPP Certificate d. Market Standing Certificate for last 02 years e. Non-Conviction Certificate for last 02 years f. Certificate of Annual Production Capacity g. Performance Statement in support of having supplied same or similar items in the past in the Form 4.1 h. Annual Turnover Statement of previous years in the Form 4.2 i. Audited Annual Reports of previous years j. Any other document stipulated in Section -IV: "Qualification Criteria"/ Bid document. **4.** Form 2: Schedule of Requirements – Compliance and Deviation: Bidders should fill this form to detail the Schedules of Goods offered by them, maintaining the same numbering and structure. They may add additional details not covered elsewhere in their bid. They should highlight here any deviations/ exceptions/ reservations regarding Section V: 'Schedule of Requirements' in tabular format. Even in case of no deviation, please fill in confirmations and nil deviation statements. If mentioned elsewhere in the bid, such deviations shall not be recognized and shall be null and void. **5.** Form 3 - Technical Specifications and Quality Assurance – Compliance and Deviation: Bidder is required to provide clause by clause compliance/ deviation Statement in a tabular form relating to all parameters of Technical Specifications, Quality Assurance. Even in case of no deviation, please fill in confirmations and nil deviation statements. If mentioned elsewhere in the bid, such deviations shall

	not be recognized and shall be null and void. Unless otherwise stipulated in Bid Data Sheet; Bidder shall upload following documents with the compliance statement, along with any other supporting documents explicitly stipulated in bid documents: i. Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life. However, For the drugs recently introduced drugs in the county (introduced in the last two years), the requirement for Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life shall be waived off. Point no (iii) shall be applicable. ii. Only for the drugs introduced in Indian Pharmacopoeia in the recent past (last 2yrs), Long Term (Real Time) Stability Data for previously approved Pharmacopoeia or In-house Standards shall be accepted, as the case may be. iii. Accelerated Stability data for a period of 6 months in specified packing for at least 3 batches and available long term (Real Time) stability data as available for the quoted product shall be submitted. iv. Certificate of Analysis of one batch of the quoted product should be submitted. a. Any other document as stipulated in the Section VI: "Technical Specifications and Quality Assurance"/ Bid document. **6.** Form 5 - Terms and Conditions – Compliance and Deviation: Bidder must comply with the entire commercial and other clauses of this Tender Document. Any deviations should be listed in a tabular form without ambiguity or conditionality. Even in case of no deviation, please fill in confirmations and nil deviation statements. If mentioned elsewhere in the bid, such deviations shall not be recognized and shall be null and void. **7.** Form 6- Bidder must upload the Bid Summary in the format as prescribed in Form 6 of the bid document to confirm that he has complied with all the instructions in the Tender Document, and nothing is inadvertently left out. This summary is only for general guidance and may not be comprehensive, and does not absolve Bidder from complying with all the requirements stipulated elsewhere in the Tender Document. **8.** Any other format/ form, not covered above but part of bid document/ considered relevant by the bidder **9.2.2 Financial bid/ Cover** "Financial bid" shall comprise the Price Schedule (To be submitted

	separately as an excel sheet) considering all financially relevant details, including Taxes and Duties as per ITB-clause 6.3. No additional technical details, which have not been brought out in the technical bid shall be brought out in the Financial bid. **9.3 Bid Validity** 1. Unless specified to the contrary in the BDS, Bids shall remain valid for a period not less than 150 days from the deadline for the bid Opening stipulated in BDS. A bid valid for a shorter period shall be rejected as nonresponsive. 2. In case the day upto which the bids are to remain valid falls on/ subsequently declared a holiday or closed day for the Procuring Entity, the bid validity shall automatically be deemed to be extended upto the next working day. 3. In exceptional circumstances, before the expiry of the original time limit, the Procuring Entity may request the bidders to extend the validity period for a specified additional period. The request and the bidders' responses shall be made in writing or electronically. A bidder may agree to or reject the request. A bidder who has agreed to the Procuring Entity's request for extension of bid validity, in no case, he shall be permitted to modify his bid. **9.4 Bid Security - Related Documents** 1. Bidders shall submit Earnest Money Deposit (EMD) for the amount as indicated in **Bid Data Sheet**. 2. The EMD shall be paid by Account payee Demand Draft/ Fixed Deposit Receipt/ Banker's Cheque /Bank Guarantee or RTGS/NEFT/Insurance Surety Bonds. 3. For EMD fund transfer, purchaser's bank account details are as under: **Beneficiary Name: Central Medical Services Society** **A/C No. : 50100729160644** **Bank Name: HDFC Bank** **Branch: SAFDARJUNG ENCLAVE-DEER PARK, New Delhi** **IFSC Code: HDFC0000503** 4. EMD Bank Guarantee format is given in **Section – IX/ Form: 7A**. The name of beneficiary in Bank Guarantee shall be **Central Medical Services Society**.EMD shall remain valid for 45 days beyond the validity period for the bid and will be extended accordingly beyond any extension subsequently requested by purchaser. The Bank guarantee shall be issued by

	a Commercial bank in India to make it enforceable and acceptable to the purchaser. 5. Offers of the firms submitted without EMD / EMD for a shorter period/EMD for an amount lesser than the amount as demanded will summarily rejected. 6. The EMD will be forfeited, if the bidder withdraws or amends, impairs or derogates from the tender in any respect within the period of validity of his Tender 7. The EMD will be refunded to the successful bidder/s within 30 days from the date of signing the contract agreement and on the deposit of the Performance Security. 8. The EMD furnished by all unsuccessful tenderers will be returned as early as possible after the expiration of the period of tender validity but not later than 30 days of the award of the contract. 9. For bidders falling in the category of MSEs and Startup, EMD requirement has been waived off as detailed in ITB Section 4.2 and 4.3 respectively. In lieu of Bid Security, such Bidders shall furnish Bid Securing Declaration (BSD) as Form 7: The BSD is required to protect the Procuring Entity against the risk of the Bidder's unwarranted conduct as amplified under the sub-clause below. a) The BSD provides for automatic suspension of the Bidder from being eligible for bidding in any tender in Ministry/ Department of Procuring Organisation for 2 years from the date of such enforcement. This declaration shall stand enforced if Bidder breaches the following obligation(s) under the tender conditions: i. withdraws or amends his bid or impairs or derogates from the bid in any respect within the period of validity of its bid; .or ii. after having been notified within the period of bid validity of the acceptance of his bid by the Procuring Entity: iii. refuses to or fails to submit the original documents for scrutiny or the required Performance Security within the stipulated time as per the conditions of the Tender Document. iv. fails or refuses to sign the contract. 10. Unsuccessful Bidders' bid-Securing Declaration shall expire, if the contract is not awarded to them, upon: a) receipt by Bidder of the Procuring Entity's notification i. of cancellation of the entire tender process or rejection of all bids or ii. of the name of the successful bidder or

	b) forty-five days after the expiration of the bid validity or any extension thereof 11. The bid-Securing Declaration of the successful bidder shall stand expired only when Bidder has furnished the required Performance Security and signed the Agreement. **9.5 Non-compliance with these provisions** Bids are liable to be **rejected as nonresponsive** if a Bidder: 1. fails to provide and/ or comply with the required information, instructions etc., incorporated in the Tender Document or gives evasive information/ reply against any such stipulations. furnishes wrong and/ or misguiding data, statement(s) etc. In such a situation, besides rejection of the bid as nonresponsive, it is liable to attract other punitive actions under relevant provisions of the Tender Document for violation of the Code of Integrity.

10. Signing and Uploading of Bids	**10.1 Relationship between Bidder and e-Procurement Portal** The Procuring Entity is neither a party nor a principal in the relationship between Bidder and the organization hosting the e-procurement portal (hereinafter called the Portal). Bidders must acquaint and train themselves with the rules, regulations, procedures, and implied conditions/ agreements of the Portal. Bidders intending to participate in the bid shall be required to register in the Portal. Bidders shall settle clarifications and disputes, if any, regarding the Portal directly with them. In case of conflict between provisions of the Portal with the Tender Document, provisions of the Portal shall prevail. Bidders may study the resources provided by the Portal for Bidders. **10.2 Signing of bid** The individual signing/ digitally signing the bid or any other connected documents should submit an authenticated copy of the document(s), which authorizes the signatory to commit and submit bids on behalf of the bidder in Form 1.1: Bidder Information. **10.3 Submission/ uploading of Bids.** **10.3.1 Submission/ Uploading to the Portal** 1. No manual Bids shall be made available or accepted for submission (except for originals of scanned copies as per sub-clause 6 below). In the case of downloaded documents, Bidder must not make any changes to the contents of the documents while uploading, except for filling the required information – otherwise, the bid shall be rejected as nonresponsive. 2. Bids shall be received only *Online* on or before the deadline for the bid submission as notified in BDS. 3. Only one copy of the bid can be uploaded, and Bidder shall digitally sign all statements, documents, certificates uploaded by him, owning sole and complete responsibility for their correctness/ authenticity as per the provisions of the IT Act 2000 as amended from time to time. 4. Bidder need not sign or up-load the Bid documents above while uploading his bid unless otherwise instructed in the Tender Document. It is assumed that Bidder commits itself to comply with all the Sections and documents uploaded by the Tender Inviting Officer. 5. Bidder must upload scanned copies of originals (or self-attested copies of originals – as specified). Uploaded Pdf documents should not be password protected. Bidder should ensure the clarity/ legibility of the scanned documents uploaded by him. 6. If stipulated in the BDS, copies/ originals of such specified uploaded scanned documents must also be physically submitted sealed in cover to TIA. Failure to do so is likely to result in the bid being rejected as non-responsive. If the office is closed on the deadline for physical submission of originals, it shall stand extended to the next working

	day at the same time and venue. The Procuring Entity reserves its right to call for verification originals of all such self-certified documents from the Bidders at any stage of evaluation. 7. Regarding the protected Price Schedule (excel format, Cover-2), Bidder shall write his name in the space provided in the specified location only. Bidder shall type rates in the figure only in the rate column of respective item(s) without any blank cell or Zero values in the rate column, without any alteration/ deletion/ modification of other portions of the excel sheet. If space is inadequate, Bidder may upload additional documents under "Additional Documents" in the "bid Cover Content." 8. The date and time of the deadline for the bid submission shall remain unaltered even if the specified date is declared a holiday for the Tender Inviting Officer. 9. The date and time of the e-Procurement server clock, which is also displayed on the dashboard of the bidders, shall be taken as the reference time for deciding the closing time of bid submission. Bidders are advised to ensure they submit their bid within the deadline and time of bid submission, taking the server clock as a reference, failing which the portal shall not accept the Bids. No request on the account that the server clock was not showing the correct time and that a particular bidder could not submit their bid because of this shall be entertained. Failure or defects on the internet or heavy traffic at the server shall not be accepted as a reason for a complaint. The Procuring Entity shall not be responsible for any failure, malfunction or breakdown of the electronic system used during the e-Tender Process. 10. All Bids uploaded by Bidder to the portal shall get automatically encrypted. The encrypted bid can only be decrypted/ opened by the authorised persons on or after the due date and time. The bidder should ensure the correctness of the bid before uploading and take a printout of the system generated submission summary to confirm successful bid upload. 11. The Procuring Entity may extend the deadline for bids submission by issuing an amendment as per ITB-clause 7.2 above, in which case all rights and obligations of the Procuring Entity and the bidders previously subject to the original deadline shall then be subject to the new deadline for the bid submission. 12. Bid submitted through modalities other than those stipulated in BDS shall be liable to be rejected as nonresponsive. **10.3.2 Implied acceptance of procedures by Bidders** Submission of bid in response to the Tender Document is deemed to be acceptance of the e-Procurement and tender procedures and conditions of the Tender Document. **10.3.3 Late Bids** The bidder shall not be able to submit his bid after the expiry of the

	deadline for the bid submission (as per server time). Therefore, in eProcurement, a situation of Late Tender does not arise. **10.4 Modification, Resubmission and Withdrawal of Bids** **10.4.1 Modification & Resubmission** Once submitted in e-Procurement, Bidder cannot view or modify his bid since it is locked by encryption. However, resubmission of the bid by the bidders for any number of times superseding earlier bid(s) before the date and time of submission is allowed. Resubmission of a bid shall require uploading of all documents, including financial bid afresh. The system shall consider only the last bid submitted as the valid bid. **10.4.2 Withdrawal** 1. The bidder may withdraw his bid before the bid submission deadline, and it shall be marked as withdrawn and shall not get opened during the Bid opening. No bid should be withdrawn after the deadline for the bid submission and before the expiry of the bid validity period. If a Bidder withdraws the bid during this period, the Procuring Entity shall be within its right to forfeit EMD/ enforce Bid Securing Declaration, as applicable, in addition to other punitive actions provided in the Tender Document for such misdemeanor.

11. Bid Opening	The date & time of the opening bid is as stipulated in BDS. Bids cannot be opened before the specified date & time, even by the Tender Inviting Officer, the Procurement Officer, or the Publisher. If the specified date of Bid Opening falls on is subsequently declared a holiday or closed day for the Procuring Entity, the Bids shall be opened at the appointed time on the next working day.

12. Evaluation of Bids and Award of Contract	**12.1 General norms** **12.1.1 Evaluation based only on declared criteria.** The evaluation shall be based upon scrutiny and examination of all relevant data and details submitted by Bidder in its/ his bid and other allied information deemed appropriate by Procuring Entity. Evaluation of bids shall be based only on the criteria/ conditions included in the Tender Document. **12.1.2 Deviations/ Reservations / Omissions - Substantive or Minor** 1. During the evaluation of Bids, the following definitions apply: a. "Deviation" is a departure from the requirements specified in the Tender Document; b. "Reservation" is the setting of limiting conditions or withholding from complete acceptance of the requirements specified in the Tender Document; and c. "Omission" is the failure to submit part or all of the information or documentation required in the Tender Document. **2** A deviation/ reservation/ omission from the requirements of the Tender Document shall be considered as a substantive deviation as per the following norm, and the rest shall be considered as Minor deviation: **a.** which affects in any substantive way the scope, quality, or performance of the product; **b.** which limits in any substantive way, inconsistent with the Tender Document, the Procuring Entity's rights or the Bidder's obligations under the contract; or **c.** Whose rectification would unfairly affect the competitive position of other Bidders presenting substantively responsive Bids. **11.** The decision of the Procuring Entity shall be final in this regard. Bids with substantive deviations shall be rejected as nonresponsive. **12.** Variations and deviations and other offered benefits (techno-commercial or financial) above the scope/ quantum of the Goods specified in the Tender Document shall not influence evaluation Bids. If the bid is otherwise successful, such benefits shall be availed by the Procuring Entity, and these would become part of the contract. **13.** The Procuring Entity reserves the right to accept or reject bids with any minor deviations. Wherever necessary; the Procuring Entity shall convey its observation as per ITB-clause 12.1.3 below, on such 'minor' issues to Bidder by registered/ speed post/ electronically etc. asking Bidder to respond by a specified date. If Bidder does not reply by the specified date or gives an evasive reply without clarifying the point at issue in clear terms, that bid shall be liable to be rejected as nonresponsive.

12.1.3 Clarification of Bids and shortfall documents

1. During the evaluation of Techno commercial or Financial Bids, the Procuring Entity may, at its discretion, but without any obligation to do so, ask Bidder to clarify its bid by a specified date. Bidder should answer the clarification within that specified date. The request for clarification shall be submitted in writing or electronically, and no change in prices or substance of the bid shall be sought, offered, or permitted that may grant any undue advantage to such bidder. Any clarification submitted by a Bidder regarding its Bid that is not in response to a request by the Purchasing Entity shall not be considered.
2. If discrepancies exist between the uploaded scanned copies and the Originals submitted by the bidder, the original copy's text, etc., shall prevail. Any substantive discrepancy shall be construed as a violation of the Code of Integrity, and the bid shall be liable to be rejected as nonresponsive in addition to other punitive actions under the Tender Document for violation of the Code of Conduct.
3. The Procuring Entity reserves its right to, but without any obligation to do so, to seek any shortfall information/ documents only in case of historical documents which pre-existed at the time of the Bid Opening, and which have not undergone change since then and does not grant any undue advantage to any bidder. There is a provision on the portal for requesting Short-fall documents from the bidders. The system allows taking the shortfall documents from any bidders only once after the technical bid opening.

12.1.4 Contacting Procuring Entity during the evaluation

From the time of bid submission to awarding the contract, no Bidder shall contact the Procuring Entity on any matter relating to the submitted bid. If a Bidder needs to contact the Procuring Entity for any reason relating to this tender and/ or its bid, it should do so only in writing or electronically. Any effort by a Bidder to influence the Procuring Entity during the processing of bids, evaluation, bid comparison or award decisions shall be construed as a violation of the Code of Integrity, and bid shall be liable to be rejected as nonresponsive in addition to other punitive actions for violation of Code of Integrity as per the Tender Document.

12.2 Evaluation of Bids

12.2.1 Preliminary Examination of Bids - Determining Responsiveness

A substantively responsive bid is complete and conforms to the Tender Document's essential terms, conditions, and requirements, without substantive deviation, reservation, or omission. Only substantively responsive bids shall be considered for further evaluation. Unless

otherwise stipulated in the BDS, the following are some of the crucial aspects for which a bid shall be liable to be rejected as nonresponsive:

1. The bid is not in the prescribed format or is not submitted as per the stipulations in the Tender Document.
2. Required EMD/ Bid Securing Declaration, applicable, has not been provided.
3. Bids with EMD for a shorter period/lesser amount as demanded will be summarily rejected.
4. Bidder is not eligible to participate in the bid as per laid down eligibility criteria;
5. The Goods offered are not eligible as per the provision of this tender.
6. Bidder has quoted conditional bids or more than one bid or alternative bids unless permitted explicitly in the BDS.
7. The bid validity is shorter than the required period.
8. The bid departs from the essential requirements stipulated in the bidding document;
9. Against a schedule in Section V: Schedule of Requirement, Bidder has not quoted the entire Goods as stipulated in that schedule.
10. Non-submission or submission of illegible scanned copies of stipulated documents/ declarations.

12.2.2 The evaluation process

Unless otherwise stated, this Tender Process is for two covers Bids. Initially, only the techno-commercial bids shall be opened on the stipulated date of opening of bids. After that, the techno-commercial evaluation shall be done whether these bids meet the eligibility & qualification criteria and techno-commercial aspects. Subsequent opening of financial bids and financial evaluation shall be done only of bids declared successful in techno-commercial evaluation.

12.3 Techno-commercial Evaluation

Only substantively responsive bids shall be evaluated for techno-commercial evaluation. In evaluating the techno-commercial bid, conformity to the eligibility/ qualification criteria, technical specifications, and Quality Assurance; and commercial conditions of the offered Goods to those in the Tender Document is ascertained. Additional factors incorporated in the Tender Document shall also be considered in the manner indicated therein. Bids with substantive techno-commercial deviations shall be rejected as nonresponsive. Procuring entity reserves its right to consider and allow minor deviations in technical and Commercial Conditions as per ITB-clause 12.1.2.

12.3.1 Evaluation of eligibility

Procuring Entity shall determine, to its satisfaction, whether the Bidders are eligible as per ITB-clause 3 above to participate in the Tender Process as per submission in Form 1.2: Eligibility Declarations in Form 1: bid

	Form. Tenders that do not meet the required eligibility criteria prescribed shall be rejected as nonresponsive. **12.3.2 Evaluation of Qualification Criteria** Procuring Entity shall determine, to its satisfaction, whether the Bidders are qualified and capable in all respects to perform the contract satisfactorily as per submission in Form 4. This determination shall, inter-alia, consider the Bidder's financial, technical and production or other prescribed capabilities for satisfying requirements incorporated in the Tender Document. The determination shall not consider the qualifications of other firms such as the Bidder's subsidiaries, parent entities, affiliates, subcontractors (other than specialized subcontractors if permitted in the bidding document), or any other firm(s) different from the Bidder. **12.3.3 Evaluation of Conformity to Schedule of Requirements and Technical Specifications/ Quality Assurance** Procuring Entity shall evaluate schedule-wise conformity of the description, scope of supply, quantity, delivery schedules, terms of delivery, transportation of the offered goods to Section V- Schedule of requirements as per submissions in Form 2: 'Schedule of Requirements - Compliance'. Technical specifications, drawings, quality assurance and other technical terms and conditions of the Bids shall be examined, as per Form 3: 'Technical Specifications and Quality Assurance - Compliance'. Unless otherwise stated in the BDS, alternative offers/ makes/ models shall not be considered. **12.3.4 Evaluation of Conformity to Commercial and Other Clauses** Bidder must comply with all the Commercial and other clauses of the Tender Document as per submissions in Form 5. The Procuring Entity shall also evaluate the commercial conditions quoted by Bidder to confirm that all terms and conditions stipulated in the Tender Document have been accepted without substantive omissions/ reservations/ exception/ deviation by the Bidder. Deviations from or objections or reservations to critical provisions such as those concerning Governing laws and Jurisdiction (GCC Clause 3), Contractor's Obligations and Restrictions of its Rights (GCC Clause 5), Performance Bond/ Security (GCC Clause 5.8), Warranty/ Guarantee (GCC Clause 6.7), Force Majeure (GCC Clause 9.13), Taxes & Duties (GCC Clause 10.2) and Code of Integrity (GCC Clause 13) will be deemed to be a material deviation. **12.3.5 Declaration of Techno-commercially Suitable Bidders and Opening of Financial Bids** Bids that succeed in the above techno-commercial evaluation shall be considered techno-commercially suitable, and financial evaluation shall be done only of such Bids. The list of such techno-commercially suitable bidders and date/time and venue for the opening of their financial bids shall be declared on the Portal in accordance with ITB-clause 12.2.2 as per the type of Tender Processes.

	12.4 Evaluation of Financial Bids and Ranking of Bids **12.4.1 Ranking of Financial Bids** 1. Unless otherwise stipulated, evaluation of the financial bids shall be on the price criteria only. Financial Bids of all Techno-commercially suitable bids are evaluated and ranked to determine the lowest priced bidder. 2. Unless otherwise stipulated, the comparison of the responsive Bids shall be on total outgo from the Procuring Entity's pocket, to be paid to the contractor or any third party, including all elements of costs as per the terms of the proposed contract, duly delivered, commissioned, etc. as the case may be, including any taxes, duties, levies etc., freight, transit Insurance, loading/ unloading/ stacking, insurance etc. 3. The bid for a schedule shall not be considered if the complete requirements prescribed in that schedule are not included in the bid; 4. If any bidder offers conditional discounts/ rebates in his bid or suo motu discounts and rebates after the Bid Opening (techno-commercial or financial), such rebates/ discounts shall not be considered for ranking the offer. But if such a bidder does become L-1 without discounts/ rebates, such discounts/ rebates shall be availed and incorporated in the contracts; 5. Unless announced beforehand, the quoted price shall not be loaded based on deviations in the techno-commercial conditions. If it is so declared, such loading of the financial bid shall be done as per the relevant provisions; 6. As per policies of the Government, from time to time, the Procuring Entity reserves its option to give purchase preferences to eligible categories of Bidders as indicated in the Tender Document. 7. evaluation of Bids shall include and consider the following taxes/ duties, as per ITB-clause 6.3 above: a. GST & other similar duties, which shall be contractually payable, on the Goods if a contract is awarded on the bidder; b. The offers shall be evaluated based on the GST rate quoted by each bidder, and the same shall be used for determining the inter-se ranking. The Procuring Entity shall not be responsible for any misclassification of HSN Number or incorrect GST rate if quoted by the bidder. Any increase in GST rate due to misclassification of HSN number shall have to be absorbed by the supplier; and c. If GST is quoted extra, but with the provision that it shall be charged as applicable at the time of delivery, the offer shall be evaluated for comparison purposes by loading the maximum existing rate of GST for the product/ HSN code. 8. **Price Variation:** Deleted

9. **Ambiguous Financial bid:** If the financial bid is ambiguous and leads to two equally valid total price amounts, it shall be rejected as nonresponsive.

12.4.2 Global Tender Enquiry (GTE, International Competitive Bidding)- Deleted

12.4.3 Evaluation Process in Tender cum e-Reverse Auction- Deleted

12.4.4 Cartel Formation/ Pool Rates

1. If Procuring Entity decides this to be a case of Cartel/ Pool Rates, leading to "Appreciable Adverse Effect on Competition" (AAEC) as identified in Competition Act, 2002, as amended from time to time, it reserves its rights to:
   a) order any quantity on any one or more bidders without assigning any reason thereof.

   And/ or

   b) consider it as a violation of the Code of Integrity and reject the bid(s) as nonresponsive in addition to other punitive actions provided in this regard in the Tender Document. In addition to such remedies, the Procuring Entity also reserves the right to refer the matter to the Competition Commission of India (CCI) for obtaining necessary relief. In addition, the attention of the bidders is drawn to Chapter VI of the "The Competition Act 2002", which deals with Penalties. Such actions shall be in addition to other rights and remedies available to the Procuring Entity under the contract and Law.

12.4.5 Reasonableness of Rates Received

Procuring Entity shall evaluate whether the rates received in the Bids in the zone of consideration are reasonable. If the rates received are considered abnormally low or unreasonably high, it reserves its right to take action as per the following sub-clauses, or as per ITB-clause 2.3, reject any or all Bids; abandon/ cancel the Tender process and issue another tender for the identical or similar Goods.

12.4.6 Consideration of Abnormally Low Bids

An Abnormally Low bid is one in which the bid price, in combination with other elements of the bid, appears so low that it raises substantive concerns as to the Bidder's capability to perform the contract at the offered price. Procuring Entity shall in such cases seek written clarifications from

	the Bidder, including detailed price analyses of its bid price concerning scope, schedule, allocation of risks and responsibilities, and any other requirements of the Tender Document. If, after evaluating the price analyses, procuring entity determines that Bidder has substantively failed to demonstrate its capability to deliver the contract at the offered price, the Procuring Entity shall reject the bid/ proposal, and evaluation shall proceed with the next ranked bidder. **12.4.7 Price Negotiation** Usually, there shall be no price negotiations. However, the Procuring Entity reserves its right to negotiate with the lowest acceptable bidder (L-1), who is techno-commercially suitable for supplying bulk quantity and on whom the contract would have been placed but for the decision to negotiate.

13. Award of Contract	**13.1The Procuring Entity's Rights** **13.1.1 Right to Vary Quantities at the Time of Award** Unless otherwise stipulated in Bid Data Sheet, at the time of contract award, the Procuring Entity reserves the right to increase or decrease, without any change in the unit prices or other terms and conditions of the bid and the Tender Document, the quantity of Goods originally stipulated in Section V: Schedule of Requirements, provided this increase/ decrease does not exceed 25 (twenty-five) percent of tendered quantity (or any other percentage indicated in the Tender Document). **13.1.2 Parallel Contracts or Splitting of Award** 1. After the Price Bid opening, the lowest offer will be declared as the L1 bidder. CMSS reserves right to negotiate prices with L1 bidder in justified cases. 2. If two or more than two bidders are declared as lowest bidders for the same item(s) (i.e. emerge L1), such bidders will be eligible for placement of Purchase Orders for equal proportion of tendered quantities (50:50 or 33.33:33.33:33.33) for such item(s) for which they are declared as lowest (L1). 3. In all other cases, unless stipulated otherwise in bid data sheet, in order to maintain uninterrupted supplies, CMSS will place orders with minimum of two bidders for tendered product with 70% of the orders given to L1 and the balance 30% to the next Matched Lowest bidder. 4. Accordingly, CMSS will counter offer the lowest rate (L1 rate) to other bidders in the order of their ranking i.e. L2, L3 and so on will be asked to match the L1 price. In case there is no L2 /matched bidder, 100% of the tendered quantity can be offered to L1 bidder. Quantity beyond quoted quantity including delivery schedule thereof will be ordered on mutual consent. Also, delivery schedule for quantity in consideration in accordance with Para 13.1.1 above will be with mutual consent. 5. In case L1 bidder has quoted for 50% quantity, the balance quantity will be offered to L2 and L3 bidders for 30% and 20% quantity respectively. In case, there is no L3/matched bidder, 70% of tendered quantity shall be offered to L1 bidder on mutual consent. However, if L1 bidder does not agree to supply 70% of tendered quantity, balance 50% quantity may be offered to L2/matched bidder in case. **13.1.3 Deleted** **13.2 Letter of Award (Acceptance - LoA) and Signing of Contract** **13.2.1 Selection of Successful Bidder(s)**

	The Procuring Entity shall award the contract to the Bidder(s) whose bid(s) is Techno-commercially suitable and bid price(s) is lowest and reasonable, as per evaluation criteria detailed in the Tender Document. **13.2.2 Verification of Original Documents** The Procuring Entity may, at its discretion, ask Bidder to submit for verification the originals of all such documents whose scanned copies were submitted online along with the technical bid. If so decided, the photocopies of such self-certified documents shall be verified and signed by the competent officer and kept in the records as part of the contract agreement. If the Bidder fails to provide such originals or in case of substantive discrepancies in such documents, it shall be construed as a violation of the Code of Integrity. Such bid shall be liable to be rejected as nonresponsive in addition to other punitive actions in the Tender Document. **13.2.3 Letter of Award (LoA)** **1.** The Bidder, whose bid has been accepted, shall be notified of the award by the Procuring Entity before the expiration of the Bid-Validity period by written or electronic means. This notification (hereinafter and in the Conditions of Contract called the "Letter of Award - LoA") shall state the sum (hereinafter and in the contract called the "Contract Price") that the Procuring Entity shall pay the contractor in consideration of the supply of the Goods. The Letter of Award (LoA) shall constitute the legal formation of the contract, subject only to the furnishing of performance security as per the provisions of the sub-clause below. **2.** It shall be mandatory for the successful bidder to be registered on GeM and obtain a unique GeM Seller ID before the placement of LoA or the contract. This ID shall be incorporated in the contract. **13.2.4 Performance Security** 1. Within 14 days of receipt of the Letter of Award (LoA, or the contract if LoA has been skipped), performance Security as per details in GCC-5.8 shall be submitted by the contractor to the Procuring Entity. 2. If the contractor, having been called upon by the Procuring Entity to furnish Performance Security, fails to do so within the specified period, it shall be lawful for the Procuring Entity at its discretion to annul the award, besides taking any other administrative punitive action. 3. If the bidder, whose bid is the lowest evaluated bid withdraws or whose bid has been accepted, fails to sign the procurement contract as may be required or fails to provide the security as may be required for the performance of the contract or otherwise withdraws from the procurement process, the Procuring Entity shall cancel the procurement process. If the Procuring Entity is

	satisfied that it is not a case of cartelization and that the integrity of the procurement process has been maintained may offer the next successful bidder an opportunity to match the financial bid of the first successful bidder, and if the offer is accepted, award the contract to the next successful bidder at the price bid of the first successful bidder. **13.2.5 Signing of Contract** 1. Within seven working days of receiving performance security, the Procuring Entity shall send the Long Term Agreement (LTA) form duly completed and signed, in duplicate, by registered/ speed post or by suitable digital means to the successful Bidder. 2. The successful Bidder shall return the original copy of the LTA, duly signed and dated, within seven days from the date of its receipt, to the Procuring Entity by registered/ speed post or by a suitable digital means. 3. Purchase Orders, containing complete details including consignee wise allocation, against LTA shall be issued separately by tender inviting authority. There can be multiple purchase orders against the LTA quantity. 4. The format of LOA, LTA, Purchase Order is given at format -1, 1A & 1B respectively **13.2.6 Return of EMD/ Expiry of bid Declaring Declarations –** In accordance with ITB 9.4 above, the EMD shall be returned back within 30 days of award of contract and receipt of Performance Security from successful bidder. Bid Securing declaration submitted by MSEs/ Startups shall also expire on award of contract and receipt of Performance Security from successful bidder. **13.2.7 Publication of Tender Result** The name and address of the successful Bidder(s) receiving the contract(s) shall be published in the Portal and notice board/ bulletin/website of the Procuring Entity.

14. Grievance Redressal/ Complaint Procedure	1. Bidder has the right to submit a complaint or seek de-briefing regarding the rejection of his bid, in writing or electronically, within 03 days of declaration of techno-commercial or financial evaluation results. The complaint shall be addressed to the Head of Procurement. 2. Within 03 days of receipt of the complaint, the Tender Inviting Officer shall acknowledge the receipt in writing to the complainant indicating that it has been received, and the response shall be sent in due course after a detailed examination. 3. The Tender Inviting Officer shall convey the final decision to the complainant within 15 days of receiving the complaint. No response shall be given regarding the confidential process of evaluating bids and awarding the contract before the award is notified, although the complaint shall be kept in view during such a process. However, no response shall be given regarding the following topics explicitly excluded from such complaint process: a. Only a bidder who has participated in the concerned Tender Process, i.e., pre-qualification, bidder registration or bidding, as the case may be, can make such representation. b. Only a directly affected bidder can represent in this regard. i. In case a technical bid has been evaluated before the opening of the financial bid, an application for review concerning the financial bid may be filed only by a bidder whose technical bid is found to be acceptable. c. Following decisions of the Procuring Entity shall not be subject to review: i. Determination of the need for procurement. ii. Complaints against specifications except under the premise that they are either vague or too specific to limit competition iii. Selection of the mode of procurement or bidding system; iv. Choice of the selection procedure. v. Provisions limiting the participation of bidders in the Tender Process, in terms of policies of the Government vi. Provisions regarding purchase preferences to specific categories of bidders in terms of policies of the Government vii. The decision to enter into negotiations with the L-1 bidder; and viii. Cancellation of the Tender Process except where it is intended to subsequently re-tender the same Goods.

15. Code of Integrity in Public Procurement, Misdemeanours and Penalties:	Procuring authorities, bidders, suppliers, contractors, and consultants should observe the highest standard of integrity and not indulge in prohibited practices or other misdemeanours, either directly or indirectly, at any stage during the Tender Process or during the execution of resultant contracts. GCC-clause 13 (including the penalties prescribed therein) shall be considered to be part of this clause of ITB (even though it is not being reproduced here for the sake of brevity) and shall apply mutadis mutandis during the pre-award tender process.
16. Integrity Pact	1. Unless otherwise stipulated in the BDS, the Integrity Pact is part of the contract and its conditions bind the parties concerned. Accordingly, Bidders will have to sign Integrity Pact with the procuring entity as per Form 1.4. Only those vendors/bidders who commit themselves to such a pact with the buyer would be considered competent enough to participate in the tender process. In other words, entering into this Pact would be an eligibility criterion. 2. The pact envisages an agreement between the prospective vendors/bidders and the buyer, committing the persons/officials of both sides not to resort to any corrupt practices in any aspect/stage of procurement process and the contract. Only those vendors/bidders who commit themselves to such a pact with the buyer would be considered competent enough to participate in the tender process. In other words, entering into this Pact would be an eligibility criterion. The essential ingredients of the Pact include: a) Promise on the part of the Procuring Entity to treat all bidders with equity and reason and not to seek or accept any benefit that is not legally available; b) Promise on the part of bidders not to offer any benefit to the employees of the Procuring Entity not available legally; c) Promise on the part of Bidders not to enter into any undisclosed agreement or understanding with other bidders with respect to prices, specifications, certifications, subsidiary contracts, etc. d) Promise on the part of Bidders not to pass any information provided by Principal as part of business relationship to others and also not to commit any offence under Prevention of Corruption Act, 1988 or Indian Penal Code141 (IPC) 1860; e) Foreign bidders are to disclose the name and address of agents and representatives in India, and Indian Bidders are to disclose their foreign principals or allied firms; f) Bidders to disclose the payments to be made by them to agents / brokers or any other intermediary; g) Bidders are to disclose any transgressions with any other public / government organization that may impinge on the anti-corruption

	principle. The date of such transgression, for the purpose of disclosure by the bidders in this regard, would be the date on

	which the competent authority took cognizance of the said transgression. The period for which such transgression(s) is/ are to be reported by the bidders shall be the last three years to be reckoned from the date of bid submission. The transgression(s) for which cognizance was taken even before the specified period of three years but is pending conclusion shall also be reported by the bidders. h) Any violation of the Integrity Pact would be considered as a violation of the Code of Integrity and would entail punitive provisions thereof including disqualification of the bidders and exclusion from future business dealings, as per the of GFR, 2017, PC Act, 1988 and other Financial Rules/ Guidelines, etc., as may be applicable to the organization concerned; 3. The integrity Pact would be implemented through a panel of Independent External Monitors (IEMs). The particulars of all IEMs, including their email IDs, are mentioned in BDS. 4. A person signing the Integrity Pact shall not approach the Courts while representing the matters to IEMs, and they shall await their decision. 5. In the case of a joint venture, all the partners of the joint venture should sign the Integrity Pact. In the case of sub-contracting, the principal contractor shall take responsibility for the sub-contractor's adoption of the integrity pact. It is to be ensured that all sub-contractors also sign the Integrity Pact. In the case of sub- contractors, the integrity pact shall be a tri-partite arrangement to be signed by the Organization, the contractor, and the sub-contractor. With respect to a particular contract, the Integrity Pact shall be operative from the date both parties sign it. 6. **Role of IEMs in Integrity Pact Contracts**: a) Bidders or their authorised representative may address to the IEMs all the representations/grievances/complaints related to any discrimination on account of lack of fair play in modes of procurement and tendering systems, tendering method, eligibility conditions, bid evaluation criteria, commercial terms & conditions, choice of technology/specifications etc. b) The entire panel of IEMs should examine the matter jointly, who would investigate the records, conduct an examination, and submit their joint recommendations to the Management of the Procuring Entity. If the entire panel is unavailable for unavoidable reasons, the available IEM(s) shall examine the complaints. Consent of the IEM(s), who may not be available, shall be taken on record. The IEMs would be provided access to all documents/records of the tender for which a complaint or issue is raised before them, as and when warranted. c) The role of IEM is advisory, and the advice of IEM is non-binding on the Organization; however, their advice would help properly implement the Integrity Pact.

	7. In case of any dispute between the management and the contractor relating to those contracts where an Integrity Pact is applicable, in case both the parties are agreeable, they may try to settle the dispute through mediation before the panel of IEMs in a time-bound manner. If required, the organisations may adopt any mediation rules for this purpose. However, no more than five meetings shall be held for dispute resolution. Both parties shall equally share the fees/expenses on dispute resolution. If the dispute remains unresolved even after mediation by the panel of IEMs, the organisation may take further action as per the terms & conditions of the contract.

SECTION III: BID DATA SHEET (BDS)

<table>
<tr><th>Reference ITB Section</th><th>Description</th></tr>
<tr><td>ITB 1.1</td><td>Purchaser- The Central Medical Services Society, an autonomous body under Ministry of Health and Family welfare, Government of India.</td></tr>
<tr><td>ITB 2.1</td><td>Tender Inviting Authority – DG & CEO, Central Medical Services Society, Ministry of Health and Family welfare, Government of India, New Delhi
Address: 2nd floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Road, Opposite Police Station Chanakaya Puri,
New Delhi-110021
Telephones: 011-21410905, 21410906</td></tr>
<tr><td>ITB 3.4</td><td>No change</td></tr>
<tr><td>ITB 3.5</td><td>In accordance with DPIIT Public Procurement (Preference to Make in India) Order, 2017 dated 19.07.2024 read with DOP Circular F.No.31026/36/2016-MD dated 16.02.2021 as amended till date, only Class-I and Class II local suppliers, as defined in aforesaid notifications are eligible to bid.

Minimum local content requirement for bidders- classification as Class-I/ Class-II local Suppliers shall be as per the DOP Circular F.No.31026/65/2020-MD dated 30.12.2020 as amended till date. Accordingly, **Class I Local Supplier** means a supplier or service provider, whose goods, services or works offered for procurement, has local content equal to or more than 80%. **Class II Local Supplier** means a supplier or service provider, whose goods, services or works offered for procurement, has local content more than 50% but less than 80%.</td></tr>
<tr><td>ITB 3.6</td><td>MSEs (Micro & Small Enterprises) and Non- MSEs entities are eligible to bid.</td></tr>
<tr><td>ITB 5.2.1</td><td>No change</td></tr>
<tr><td>ITB 5.2.2</td><td>No change</td></tr>
<tr><td>ITB 6.1</td><td><u>PRICE SCHEDULE:</u>
Since, the said tender is being floated on GeM portal and it does not allow for BOQ based bidding. Therefore, Price Schedule as on GeM portal shall prevail as there no need to upload price bid separately in “excel format” as mentioned in clause 6.1.4.</td></tr>
<tr><td>ITB 7.3</td><td>All clarifications to the tender document should be addressed to Tender Inviting Authority. An email, seeking clarification to the bid document, should be sent at email id. agmproc2@cmss.gov.in; with copy to gmproc1@cmss.gov.in and dgceocmss@cmss.gov.ins</td></tr>
<tr><td>ITB 8</td><td>Tender timelines are as under:
<table>
<tr><th>Sr. No.</th><th>Descriptions</th><th>Scheduled date</th></tr>
<tr><td>(a)</td><td>Availability of tender documents on GeM for download</td><td>16/10/2024</td></tr>
</table>
</td></tr>
</table>

	(b)	Last date and time for receipt of pre-bid queries, if any	30/10/2024 till 5:00 PM The pre-bid queries should be addressed to Tender Inviting Authority at email Id agmproc2@cmss.gov.in with copy to gmproc1@cmss.gov.in and dgceocmss@cmss.gov.in , mgrproc2@cmss.gov.in
	(c)	Pre-bid meeting date, time and venue	25/10/2024 at 11:30 AM Venue- Conference Hall, CMSS HQ New Delhi
	(d)	Last date and time for online bid submission	18/11/2024 till 01:00 PM
	(e)	Last date and time for submission of Original Bid Securing Declaration/ EMD	18/11/2024 till 02:00 PM
	(f)	Date and time for tender opening (technical bid)	18/11/2024 till 03:00 PM

ITB 9.4 Schedule wise EMD shall be as under:

Sr. No.	Schedule No.	EMD Amount in INR for 100%	EMD Amount in INR for 50%
(a)	MR Vaccine	1,79,07,500 (Rupees one crore seventy nine lakhs seventy thousand five hundred Only)	89,53,750.00 (Rupees eighty nine lakhs fifty three thousand seven hundred and fifty Only)
(b)	IPV	28,55,100 (Rupees twenty eight lakhs fifty five thousand one hundred Only)	14,27,550.00 (Rupees fourteen lakhs twenty seven thousand five hundred and fifty Only)
(c)	RVV	2,93,70,398 (Rupees two crore ninety three lakhs seventy thousand three hundred and ninety eight Only)	1,46,85,198.75 (Rupees one crore forty six lakhs eighty five thousand one hundred and ninety nine Only)
(d)	bOPV (Routine Immunization) & bOPV (Pulse Polio)	1,23,54,300 (Rupees one crore twenty three lakhs fifty four thousand three hundred Only)	61,77,150.00 (Rupees sixty one lakhs seventy seven thousand one hundred and fifty Only)

	(e)	TD vaccine	25,27,200 (Rupees twenty five lakhs twenty seven thousand two hundred Only)	12,63,600.00 (Rupees twelve lakhs sixty three thousand and six hundred Only)

"ITB 9.2.1 Sub-para 1" and "10.3.1 Sub-para 6"	Original copies of Bid Securing Declaration (applicable for MSEs and Startups)/ Earnest Money Deposit (applicable for all other bidders i.e., other than MSEs and Startups), as applicable, is to be submitted in a sealed cover. The envelope should be superscribed as Bid Securing Declaration/ Earnest Money Deposit against Tender No. CMSS/PROC/2024-26/UIP/024 Dated 06/09.2024 Scheduled to be opened on 27/06/2024 at 04:00 PM. The documents should be sent in person/ courier so as reach the Tender Inviting Authority by the scheduled date and time, as indicated in Bid Data Sheet at ITB 8.
ITB 9.2.1.3	**Additional Clause in Bid date sheet:** 1. Being development tender, Market standing certificate and performance statement for past supplies as stipulated in 9.2.1.3(d) &(g) respectively, shall not be applicable for this tender. 2. This developmental tender is only for those manufacturers who are not able to meet prescribed eligibility criteria of corresponding regular tender but have credentials/meet requirements for development tender. Hence, bidders who are technically qualified and whose price bids are opened for regular tender schedule, will not be eligible for corresponding developmental tender schedules. However, if a bidder is not eligible for a regular tender schedule for a particular manufacturing site (but qualifies for other manufacturing site), it can bid for developmental tender for the manufacturing site for which it is not eligible for regular tender.
ITB 9.2.1.5	No Change
ITB 10	**The bid is published on GeM Portal. Accordingly, bidders are requested to submit their bid online on GeM Portal. In case of any contradiction in terms and conditions stipulated in this bid document and the terms of and conditions of GeM portal, the clauses of this tender document shall prevail.**
ITB 10.3.1 (sub clause 7)	**<u>PRICE SCHEDULE:</u>** Since, the said tender is being floated on GeM portal and does not allow for BOQ based bidding. Therefore, Price Schedule as on GeM portal shall prevail as there no need to upload price bid separately in *"excel format"* as mentioned in clause 10, sub clause 7.
ITB 13.1.2 (3)	No Change
ITB 16.1	No Change
ITB 16.3	IEM's : Name and Contact Details are as under:

	a) Sh. B. Siddhartha Kumar, Email Id : bsiddharthak_66@rediffmail.com b) Sh. Arun Kumar Sinha Email Id: aksinha2@yahoo.com

SECTION-IV -QUALIFICATION CRITERIA

a) Tenderer must be a manufacturer of quoted Vaccine.

b) Tenderer must submit own manufacturing license in the indicated pharmacopeia (as indicated in technical specification) valid on the date of tender opening (technical bid). If the tendered Vaccine is in Indian Pharmacopoeia (IP), then the manufacturing license has to be submitted in IP only.

For Vaccines that are not available in IP, other official Pharmacopeia (s) are applicable. If a Vaccine is not available in any of the official pharmacopeias, 'In House' standards are applicable as per the Drugs and Cosmetics Act 1940 and the Rules therein.

Bidder is requested to submit an undertaking that the Vaccine is not available in IP or any other approved pharmacopeia.

Note:

1. License certificate should be for the same manufacturing premises from which quoted goods have been offered for supply.
2. Loan license, Contract manufacturing license etc. shall not be considered.
3. License for export of goods shall not be considered.

c) Tenderer must submit WHO GMP certificate valid on the date of tender opening (technical bid).

d) Tenderer must submit Certificate of Pharmaceutical Product (COPP) as recommended by WHO in any of the pharmacopeia (IP/BP/USP) or In-house Standards valid on the date of tender opening (technical bid).

e) Tenderer must submit Non-Conviction Certificate issued by the Licensing Authority certifying that the tenderer has not been convicted for the last two financial years i.e. 2021-22 and 2022-23 or 2022-23 and 2023-24.

Note:

1. Unless otherwise stipulated in the Non-Conviction Certificate, the said certificate issued on a particular date shall be treated valid certificate for the financial year in which it is issued. For example, Non-Conviction Certificate issued on 15.07.2022 shall be treated as Non-Conviction Certificate for the FY 22-23 only.
2. Non-Conviction Certificate should be for the same manufacturing premises from which quoted goods have been offered for supply.

f) The tenderer must have annual production capacity greater than or at least equal to the total quantity that is being quoted for the specific schedule ($\geq$ 100%). Annual capacity certificate, issued by the licensing authority, must be submitted along with the bid.

g) The tenderer must have average annual turnover of last three FY i.e. 2020-21, 2021-22 and 2022-23 or 2021-22, 2022-23 and 2023-24 more than the followings:

Schedule No	**Amount (in Rs.) for quoted qty of 100%**	**Amount (in Rs.) for quoted qty of 50%**
V	35,81,50,000.00	17,90,75,000.00
VI	5,71,02,000.00	2,85,51,000.00
VII	58,74,07,950.00	29,37,03,975.00
VIII	24,70,86,000.00	12,35,43,000.00
IX	5,05,44,000.00	2,52,72,000.00

Annual turnover statement for last three financial years i.e. 2020-21, 2021-22 and 2022-23 or 2021-22, 2022-23 and 2023-24 should be furnished in the format given in Section IX Form 4.2 duly certified by the practicing Chartered Accountant. The certifying Chartered Accountant must indicate the details along with its UDIN. The MSEs and Startups bidders are exempted from aforesaid minimum turnover requirement.

h) Copies of the audited Annual reports including the Balance Sheet and Profit and Loss Account along with all the annexure for the last three years i.e. 2020-21, 2021-22 and 2022-23 or 2021-22, 2022-23 and 2023-24 duly certified by a practicing Chartered Accountant, where ever applicable.

SECTION V
SCHEDULE OF REQUIREMENTS

LIST OF PRODUCT & THEIR TECHNICAL SPECIFICATIONS

Sch. No.	Item Name	Total Tentative Quantity	Unit	Detailed Technical Specifications of the Goods/Drugs	Order Distribution Criteria	Inspection Methodology (PDI/Non-PDI)	Consignee Location
I	MR Vaccine	1,54,37,500	Doses	Section VI	Refer ITB 13.1.2	Refer GCC clause no. 7.1.7	Direct to Consignee
II	IPV	7,50,000	Doses	Section VI			
III	RVV	2,17,68,750	Doses	Section VI			
IV	bOPV (Routine Immunization) & bOPV (Pulse Polio)	7,95,00,000	Doses	Section VI			
V	TD vaccine	1,30,00,000	Doses	Section VI			

(Please refer Technical specifications attached in SECTION VI)

Delivery Terms:

(a) The delivery shall be on DDP (Destination basis).

(b) Delivery Schedule

Tentative monthly Quantity of vaccine required (in Lakh doses)						
S.No	Month & Year	MR	IPV	RVV	bOPV (RI)	Td
1	May-24					
2	Jun-24					
3	Jul-24					
4	Aug-24					
5	Sep-24					
6	Oct-24					
7	Nov-24					
8	Dec-24					
9	Jan-25				30	
10	Feb-25				11.25	

11	Mar-25			16.6875	30	
12	Apr-25	9.375		16.5	30	16.25
13	May-25	10		16.5	30	16.25
14	Jun-25	12.5		16.5	30	16.25
15	Jul-25	12.5		16.5	30	16.25
16	Aug-25	13.75		16.5	118.75	16.25
17	Sep-25	13.75		16.5	30	12.5
18	Oct-25	13.75		16.5	30	12.5
19	Nov-25	13.75		16.5		12.5
20	Dec-25	13.75		16.5		11.25
21	Jan-26	13.75		17.5	425	
22	Feb-26	13.75	3.75	17.5		
23	Mar-26	13.75	3.75	17.5		
Total		**154.375**	**7.5**	**217.6875**	**795**	**130**

A. Delivery Locations:

The details of Consignee addresses are indicated below:

S.No.	Name of GMSD	Consignee Name and Address of States/GMSD
EAST ZONE		
1	Kolkata	State EPI Officer (H&FW/RCH)/, Health & Family Welfare Department.Govt. Vaccine Institute, Tata Road, Namkum. Jharkhand. Contact: State Immunization Officer, Dr. Dayal , Mob.-No.-7004985784, Mr. Mohit-SVLM-9934994416 rijharkhand2022@gmail.com
2	Kolkata	State EPI Offcer/ Joint Director (Immunization), Directorate of Family Welfare, 2nd Floor, SMCS Cell, HOD Building, Unit- V, Bhubneshwar - 751 001. **Odisha**. Contact: Dr. Tapas Kumar Patra, State EPI Officer-9437224520, , Mr. Ravi-SVLM-9556992600 ri.odisha.dfwo@gmail.com, svlmodisha2013@gmail.com
3	Kolkata	**Official Communication Address:** Joint Director(RCH)/Asstt. Director (EPI)/(MCH)/ADM/Senior CMO (SAG)/ Dy. Director(MCH), Directorate of Health Services, State Family Welfare Bureau, Swasthya Bhawan, A-wing, 3rd Floor, GN-29, Sector- V, Salt Lake City,Kolkata-700091. **West Bengal**. Contact: adhs.epi2017@gmail.com **Consignment Supply Address:**

		Central Family Welfare Store, Bagbazar. 541-B Rabindra Sarani, Kolkata-700003, Nearest landmark-Laxmi Aprtment, Near Kumortoli, Contact No- 8697119350/9830515748
4	Kolkata	Joint Director (UIP), Directorate of Health Services (FW), Swasthya Bhawan, Hengrabari, Guwahati - 781036, **(Assam)** Contact: Mr. B.K Chaudhary (CCO)-9435401095, SVLM- Mr. Jayanta-9954218270, uipassam@gmail.com
5	Kolkata	State Immunization Officer, State Vaccine Store, NMCH campus, Agamkuan, Patna - 800007 **(Bihar)** Contact : Er. Alok Ranjan, SCCC-cum-I/c SVS Contact No.- 8002900900, Ms. Rani-SVLM-9473197728/7033586782 ribihar2013@gmail.com
6	Kolkata	Sr. Chief Medical Officer (SAG)/ The ADM/ The DDG (MS) **Government Medical Store Depot** 9, Clyde Row Hastings **Kolkata**-700 022. Contact: Mr. Dibyendu Patra, 09874738131, 033-22236125, gmsdkol@yahoo.com
WEST ZONE		
1	Mumbai	Regional Deputy Director, Health & Medical Services, Civil Hospital Compound, **Gandhi Nagar, (Gujarat)** Contact: Mr K B Patel- 9925367924/9687630148, Mr. Idrish Mansuri-9825978399, pharma.health.rddgandhinagar@gmail.com, Tel- 079-23245320, email- rdd.health.gandhinagar@gmail.com
2	Mumbai	Administrative Officer/ Regional Deputy Director, Health & Medical Services New Civil Hospital Campus,Near Dhobi Ghat, Majura gate, ring road, **Surat (Gujarat)-395001** Contact: Smitaben M Patel ,Pharmacist, 09428183312, 7984065673 tel- 0261-2460673, email - rdd.health.surat@gmail.com, pharma.health.rddsurat@gmail.com
3	Mumbai	Regional Deputy Director /Joint Director, Health & Medical Services, Vaccine Institute, Old Padra Road, **Vadodara - 390016 (Gujarat)** Contact: Mayank N Tailor, Pharmacist 09904260875, Tel- 0265-2356183/84, email - rdd.health.vadodara@gmail.com
4	Mumbai	Regional Deputy Director, Health & Medical Services, Rftcp Campus, Opposite Government Press, Race Course Road, **Rajkot (Gujarat)** Contact: Mr Rajani Bai Dobariya, Mobile- 09925514808 tel- 0281-2459488/2440599 email- rdd.health.rajkot@gmail.com
5	Mumbai	The Director (Health & Family Welfare)/SEPIO, Directorate (H&FW), Old Nursing Hostel, Mantralaya Parisar, **Raipur, Chattisgarh.** Contact: Dr.V R Bhagat, SEPIO, 9424189899,7987459407. immunizationcg@gmail.com.Mr Spandan Bhanjadeo, 7008223961
6	Mumbai	Regional Director Health Services, Kilol Park, Bhopal near Peetetoral Pump, District **Bhopal, Madhya Pradesh**- 462002. Contact Person: Regional JD - 9425377064, Mr. Neeraj Shukla mob-9826016431ddimmmp@gmail.com, neerajjdhs@yahoo.com, djdhsbpl@yahoo.co.in

7	Mumbai	Regional Director Health Services, M.T.H. Compound, Near Indore Press Club, Indore District **Indore- 452001, Madhya Pradesh**. Contact Person: RJD -9826022885, Manish Ghaghoria mob- 9425050335, ddimmmp@gmail.com, manishghanghoria@yahoo.com, rjdhealthindmp@mp.nic.in
8	Mumbai	Regional Director Health Services, Regional Health and Family Welfare Training Center Campus, City Center, Gwalior District **Gwalior-474002, Madhya Pradesh** Contact Person: RJD - 9425196667, Abhay Kulshreshtha, mob- 9827548319, ddimmmp@gmail.com, abhayjdhsstore@gmail.com,rjdhealthgwamp@mp.nic.in
9	Mumbai	Regional Director Health Services, Indra Market, Near Railway Station, Jabalpur District, **Jabalpur- 482001 Madhya Pradesh** Contact Person: RJD - 9424387300, Suresh Kosta, mob- 9770408451, korivikram1971@gmail.com, ddimmmp@gmail.com, rjdhealthjabmp@mp.nic.in,
10	Mumbai	Asstt. Director/Additional Director of Health Services (EPI), State Family Welfare Bureau, Kutumb Kalyan Bhawan, Behind **Pune Railway station, Pune - 411 0011**. Maharashtra. Contact: Mr. Umesh Jadhav, 7972166028, pulsepolio1@gmail.com
11	Mumbai	**Director-CDTL,I/C Government Medical Store Depot, (Government of India),Post Box No.4514, Belasis Road, Mumbai Central, Mumbai-400008.Ph.No.022-23078365, 23082091-92Mr. Nitin Khobare - 9594382912 gmsdmumbai-mohfw@nic.in, gmsdmumbaiun@yahoo.com , Mr.Chetan-7506988591**
NORTH ZONE		
1	Karnal	SPO Medical Store,Directorate of Family welfare, Rajiv Gandhi Superspeciality Hospital Utility Block,Tahirpur, **Delhi**-110093 Contact no.- Dr. B K Tyagi- 9599144457 Mr. Mohit - 9818320276.Ms. Bhawna- 8130915066 rch.immunization@gmail.com, cmsdfw2@gmail.com, spomedstore@gmail.com
2	Karnal	State EPI officer/Deputy Director(Child health)/District Immunization officer, LNJP Hospital, regional store, Kurukshetra- 136119, **Haryana** Dr. V.S. Ahlawat (SEPIO), Mob-8168429732, 09468195073 /Mr. Rajiv (TA), Mob. 9464270250,/ Geetika- 9914004177, Dr. Rajeev Seth- 9464270250 Dr. Anupama (DIO KKR) , Mob. 8708163814, dhs.ddmch@hry.nic.in
3	Karnal	State EPI officer, Department of Health & Family Welfare, Offset press building, opposite Govt. High School, Sector 24-A, Chandigargh, Punjab Contact: Mr. Sarabjit- 9317881377, Dr. Balwinder Kaur - 9876223500 ripunjab@gmail.com
4	Karnal	Project Director (Immunization), Directorate Of Medical Health & FW Services, Swasthya Bhawan, Tilak Marg, C-Scheme, **Jaipur**-302005 (Rajasthan) Phone: 0141-2225715 Contact: Dr. Raghuraj Singh 7374004404 and Shri Surender Singh - 9414060377, pd-immu-rj@gov.in, pdimmunization2016@gmail.com
5	Karnal	District Reproductive & Child Health Officer, Medical Health Services, Swasthya Bhawan, Village Bari Udaipur (Rajasthan) Contact: Dr.Ashok Aditya 9829065941 and Shri Akram Khan 9358009904, email- rcho-uda-rj@nic.in

6	Karnal	Jt. Director/ JT Director EPI, Medical health Welfare Services, Vaccine Depot Lucknow, Jagat Narain Road, Silver Jubilee Maternity Hospital, **Lucknow UP**. Contact- Atul Nigam- 9453965895, Prashant Misra- 8601244555, upsepio1@gmail.com, coldchainup@gmail.com.
7	Karnal	Addl. Director, Medical Health Welfare Services, Vaccine Depot Agra, Near ESI Hospital , Halwai ki Bagichi , Agra - (Uttar Pradesh) Contact: Lokesh Kumar, Store Incharge- 9412330448 svsagra22@gmail.com
8	Karnal	Addl. Director Medical Health Welfare Services Vaccine Depot Varanasi, Pt. Deen Dayal Upadhayay Campus Varanasi (Uttar Pradesh) Contact:Sandeep Tripathi- 7905864910, 9450810800, advaranasi2013@gmail.com
9	Karnal	Addl. Director, Medical Health Welfare Services Vaccine Depot Meerut, Medical College Campus, Garh Road Meerut (UTTAR PRADESH),PN Dangwal- 8218695801- store Incharge addmrt@gmail.com
10	Karnal	Additional Director, Health & Family Welfare, Gorakhpur mandal near BRD Medical College, Gorakhpur. (UTTAR PRADESH) Contact: DP Singh- 7652058073, 9415173901, adgkpp@gmail.com
11	Karnal	Additional Director, Health & Family Welfare, Bareilly mandal, near Mental Hospital, Bareilly. (UTTAR PRADESH) Contact: Sarvesh Kumar- 9411248416, 6395584176, adbly2016@gmail.com
12	Karnal	Additional Director, Health & Family Welfare, Kanpur mandal, Ramadevi, Kanpur. (UTTAR PRADESH) Contact: Arvind- 9369207293, addknp5@gmail.com
13	Karnal	Additional Director, Health & Family Welfare, Ayodhya mandal, Darshan nagar, Ayodhya (UTTAR PRADESH) Contact: SP Chaudhrai- 9532633485, 6307398193, Amardeep- 8115110534, adsvsayodhya@gmail.com, adhealthayodhya@gmail.com
14	Karnal	Additional Director Medical Health & Family welfare, Jhansi Division, Jhansi Drugware House, CMO Office Campus, opposite to kunj vihari mandir, gwalior road, Jhansi (UTTAR PRADESH) Gopal Chand Mishra- 9651150338, 7860728447, addjhansi2@gmail.com
15	Karnal	The Medical officer, Incharge Government Medical Store Depot Karnal, Opposite Telephone Exchange, PB No. 8, Karnal, Pin Code -132001(Haryana), Contact No. 0184-2252328/2272175, Dr. Barla Vidya Sagar - 7981188919 Mr. Dilbag Singh (Depot Superintendent) - 8950068851
South Zone		
1	Chennai	State Cold Chain Officer, State Vaccine Store, CHC Gannavaram Compound, Opp: TDP Party Office, Gannavaram-01, Krishna District, PIN-521101. **Andhra Pradesh** Contact: Mr Devanandam, 9398312902, 7330733911 jdchichfwap@gmail.com, cco.chfw@gmail.com

2	Chennai	Consignee details: **Administrative office address:** The Project Director (RCH),1st floor, Arogya Soudha, Directorate of Health & Family welfare Services, Magadi Road , Bangalore -560023 **Store address :** Project Director (RCH),Directorate of Health and Family welfare Services,1st Floor, Arogya Soudha State Vaccine Store,KHB colony, Magadi Road,Baswehwaranagar, **Bangalore , Karnataka-560079** Contact: Dr. B.N.Rajani, Deputy Director(Immunization) - 9449843358, Mr. Vasu - 9901059653,Mr. Rajendra - 7975869217, Smt. Beena - 9663546816, Mr. S.N. Vijaykumar - 9880759439 pdrchkar@gmail.com, ddimmkar@gmail.com
3	Chennai	Assistant Director, Vaccine Institute, Belagavi, State Vaccine store-II, Vaccine depot compound, 2nd railway gate, Tilakawadi, **Belagavi, Karnataka**-590006. Contact Person Mob No- Shri Rajakumar R Kamble, FDA-6366401315, Shri M J santaji, Pharmacy officer-9480422316 Dr Mahesh Koni, District Health and F W Officer-9449843039, Dr Chetan K.-9449843184, , Maruthi-9480422316 Email-advaccineinstitutebelagavi@gmail.com dhobelgaum@gmail.com, rchobelgaum@gmail.com
4	Chennai	District Medical Officer Of Health Ernakulam, Regional Vaccine Store **Ernakulam -682 001,Kerala** Contact: Mr.Jos Benroy,(Store I/C) Mobile- 9895798887 Fax- 0484-2369567 email-rvsdmoekm@gmail.com
5	Chennai	District Medical Officer Of Health, Regional Vaccine Store Civil Station **Kozhikode,Kerala** Contact: Mr. Anil K T (Store I/C) Mobile-8592865540 email- fwstorekozhikode@gmail.com
6	Chennai	District Medical Officer Of Health, Regional Vaccine Store, Tvm, Red Cross Road, Opp. Ophthalmic Hospital, **Thiruvananthapuram,Kerala** Contact: Mrs. Rajasree(store in charge) , Mobile 9496194681, Tel : 0471-2471291 email-vaccinestoredmohtvm@gmail.com
7	Chennai	Joint Director(CH&I), O/O Commissioner Of Family Welfare, DM&HS Campus, Sultan Bazar,Kothi, **Hyderabad - 500 095.Telangana** Contact: Mr. Kaleemuddin - SVLM, 7330733165, jdchisection@gmail.com, svlmtshyd@gmail.com.
8	Chennai	The Joint Director (Immunization) & Of Public Health &State Epi Officer, Department Of Public Health & Preventive Medicine, 359, Anna Salai, Dms Compound, Teynampet, Chennai - 6 **Tamil Nadu** Contact:Mr. Subramanyam CCO, 09444757815, 04424336674; dphimm@nic.in

9	Chennai	**The Asst. Director, Deputy assitant directore general, Government Medical Store Depot no. 37, Naval Hospital road, Periamet, Chennai-600003, Contact Ms. Poovazhaki, 9840812159, isschennai2009@gmail.com**

CMSS reserve to right the change the consignee at any time if required.

SECTION VI
TECHNICAL SPECIFICATIONS AND QUALITY ASSURANCE

As given by Programme Division

Annexure

Minutes of Bivalent Oral Polio Vaccine (bOPV) Technical Specifications Committee virtual meeting
3rd July 2020, Nirman Bhawan

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Technical Specifications committee for Bivalent Oral Polio Vaccine (bOPV) meeting was held under the chairpersonship of Dr. Promila Gupta, Principal Consultant, DGHS through a virtual platform, on 3rd July, 2020 at Nirman Bhawan at 11 am in view of COVID-19. Representatives from Drug Controller General of India (DCGI), Indian Council of Medical Research (ICMR), Dept. of Biotechnology, Department of Procurement, Immunization Division (MoHFW), WHO-NPSP, UNICEF and ITSU participated in the meeting. The agenda of the meeting was to discuss the amendments to the technical specification of the bOPV vaccine in tender document, proposed by M/s Panacea Biotec.

The meeting initiated with a brief introduction to the objective of the meeting by Joint Commissioner (Imm.), MoHFW, wherein the following was informed to the group:

> The group was informed that a letter was received from M/s Panacea Biotec on 3rd March 2020 requesting for amendments in technical specification of bOPV vaccine in tender document.

Each point was discussed one by one and after getting the inputs from the group, a decision was finally taken by the chair as per details given below:

Observation from Immunization Division, MOHFW:				
S. No.	Point No.	As mentioned in Technical Specification	Proposed Amendment	Recommendations from Technical Specification Committee and suggested changes to be done in Technical Specification document
1	A. Specific Requirements (Refer page No.1 of 8 of Technical Specification)	Description: "The estimated mean virus titre for a single human dose of **trivalent** OPV must not be less than $10^{6.0}$ infectious units (CCID50) for Type 1, and $10^{5.8}$ infectious units (CCID50) for Type 3.	The estimated mean virus titre for a single human dose of **bivalent** OPV must not be less than $10^{6.0}$ infectious units (CCID50) for Type 1, and $10^{5.8}$ infectious units (CCID50) for Type 3.	Accepted the proposed amendment from **trivalent** to **bivalent**.

Dr Pritish Talwar. ITSU

10/8/2020

Points proposed from M/s Panacea Biotec:				
S. No.	Point No.	As mentioned in Technical Specification	Proposed Amendment	Recommendations from Technical Specification Committee and suggested changes to be done in Technical Specification document
1	**A. Specific Requirements** (Refer page No.2 of 8 of Technical Specification)	Dosage size: "Each dose containing of 0.1 ml or 2 drops containing the specified virus concentration of **three** virus types."	"Each dose containing of 0.1 ml or 2 drops containing the specified virus concentration of **two** virus types."	Accepted the proposed amendment from **three** to **two**. The statement may be change to "Each dose of 0.1 ml (2 drops) containing the specified virus concentration of **two** virus types."
2	**A. Specific Requirements** (Refer page No.2 of 8 of Technical Specification)	**Filling Volume:** Each 10- dose vial should contain 1 ml **(may be up to 5 ml depending on concentration) plus 15 % overfill.** Each 20- dose vial should contain 2 ml **(may be up to 10 ml depending on concentration) plus 15 % overfill.**	Each 10- dose vial should contain 1 ml Each 20- dose vial should contain 2 ml	Each vaccine vial should contain an overfill to the extent that the extractable volume delivered is as per claimed doses.
3	**B. Quality Assurance** (Refer page No.4 of 8 of Technical Specification)	Evidence: "The supplier shall retain a sample of twenty (20) vials from each lot shipped for **two years** beyond the printed expiration date."	"The supplier shall retain a sample of twenty (20) vials from each lot shipped **for period of 3 months** beyond the printed expiration date."	The committee accepted that the retain sample should be as per "Good manufacturing practices for premises and materials under Schedule M (part 1) of Drugs and Cosmetics Act, 1940 & Rules 1945 of India, Sub-section 16.7".

Points proposed from M/s Panacea Biotec:				
S. No.	Point No.	As mentioned in Technical Specification	Proposed Amendment	Recommendations from Technical Specification Committee and suggested changes to be done in Technical Specification document
4	**C. Packing** (Refer page No.5 of 8 of Technical Specification)	Over Packing: "The containers must have adequate insulation and or sufficient refrigerant to ensure that the warmest storage temperature of the vaccine does not rise above +8 °C in continuous outside ambient temperatures of + 43 °C during transit and for a period of at least 48 hours **after arrival at airport of destination."**	"The containers must have adequate insulation and or sufficient refrigerant to ensure that the warmest storage temperature of the vaccine does not rise above +8 °C in continuous outside ambient temperatures of + 43 °C for a period of at least 48 hours.	Committee did not agree for any changes in this section, as this has been in practice since last many years to ensure vaccine quality.
5	E. Documentation (Refer page No.8 of 8 of Technical Specification)	"Throughout shipment, pending reshipment and prior to collection by the consignee, the vaccine must be stored at -15 °C to -25 °C."	**i) For vaccine consignments packed in dry ice:** "Throughout shipment, pending reshipment and prior to collection by the consignee, the vaccine must be stored at -15 °C to -25 °C." **ii) For vaccine consignments packed in ice packs:** "Throughout shipment, pending reshipment and prior to collection by the consignee, the warmest storage temperature of the vaccine does not rise above +8 °C "	Committee did not agree for any changes in this section, as this has been in practice since last many years to ensure vaccine quality.

The meeting ended with a vote of thanks to the Chair.

List of participants:

1. Dr. Promila Gupta, Principal Consultant, DGHS, MoHFW and chair of the meeting
2. Dr. Pradeep Haldar, Advisor (RCH), MoHFW
3. Dr. Veena Dhawan, Joint Commissioner (Imm.), MoHFW
4. Mr. R Chandrashekhar, DDCI, Drug Controller General of India (DCGI)
5. Dr. Nivedita Gupta, Scientist F, ICMR
6. Mr. D.V.K. Rao, Deputy Secretary, Procurement division, MoHFW
7. Dr. Danish Ahmed, NPO Immunization, WHO
8. Mr. Dheeraj Bhatt, Health Officer, UNICEF
9. Dr. Pritu Dhalaria, Director, ITSU
10. Dr. Chirag Valia, Technical Consultant, Immunization division, MoHFW

Representative from Department of Biotechnology could not attend the meeting.

Mr. Chandrashekhar R
DDCI, CDSCO

Dr. Pradeep Haldar
Advisor (RCH), MoHFW

Dr. Nivedita Gupta
Scientist F, ICMR

Dr. Veena Dhawan
Joint Commissioner (Imm)
MoHFW

Mr. D. V. K. Rao
Dy Secretary, Procurement,
MoHFW

Dr. Danish Ahmed,
NPO Immunization, WHO

Dr. Pritu Dhalaria,
Director, ITSU

@. Approval taken through mail.
Mr. Dheeraj Bhatt,
Health Officer, UNICEF

10/8/2020
Dr. Promila Gupta
Chairperson
Principal Consultant, DGHS,
MoHFW

Note: As per the approved minutes, changes have been done in Technical Specification for Oral Polio Bivalent Vaccine (bOPV) which is submitted with this document for signature.

4

Annexure

Technical Specification
Oral Polio Bivalent Vaccine (bOPV) Specifications
(For NCB/ICB)

A. Specific requirements

Item:

Bivalent Poliovirus vaccine, live, oral shall meet the requirements as per Indian Pharmacopoeia (I.P.) and Rule-122B of Drugs and Cosmetics Act, 1945.

The vaccine shall be currently registered in the country of manufacture and shall meet all requirements of the licensing authority of the country of manufacture. The vaccine also shall be currently registered in the country of use (India) and shall meet all the requirements of the licensing authority of the country of use.

Descriptions:

Bivalent Poliomyelitis vaccine, oral is a preparation of live attenuated strains of poliovirus (*Sabin*), type 1 and 3, of known history and originally obtained from the WHO or any other source approved by WHO and grown in suitable approved cell cultures. The monovalent poliovirus vaccine bulk of each type (Type 1 and Type 3) is tested for consistency of virus characteristics to ensure that the vaccine virus has not undergone changes during its multiplication in cell cultures in comparison with the respective Standard Reference virus. The final vaccine is constituted by combining appropriate dilutions of the two monovalent vaccines. The estimated mean virus titre for a single human dose of bivalent OPV must not be less than $10^{6.0}$ infectious units (CCID50) for type 1 and $10^{5.8}$ infectious units (CCID50) for Type 3.

Protocol and testing:

Complete Test Protocol along with samples of all batches should be sent to the Head of the Polio Vaccine testing laboratory i.e. Central Drugs Laboratory, Kasauli-173204;
For local manufacturers:
Complete Test Protocol and samples are taken and sent by the Inspecting Officer duly sealed and signed by him or his authorized representative.
The vaccine should be dispatched to the consignee only on clearance from the Central Drugs Laboratory, Kasauli. The vaccine will be released on the basis of Protocol scrutiny and testing of the vaccine by Central Drugs Laboratory, Kasauli. Each batch should be accompanied with a certificate from the manufacturer that the vaccine meets the I.P. requirements.

Dosage size:

For primary immunization, three doses of Bivalent oral Poliomyelitis vaccine (bOPV) at the interval of 4 to 6 weeks, each dose of 0.1 ml (2 drops) containing the specified virus concentration of two virus types. In all

Dr Rishi Shukla IP 1 2751

10/8/2020

NPSP WHO

institutional deliveries an oral dose at the time of birth. Additional dose/doses may be required in accordance with the National Immunization Policy.

Dose Package:

Vials of 10 or 20 doses with sterile dropper, container must protect vaccine from exposure to light.

Filling Volume:

Each vaccine vial should contain an overfill to the extent that the extractable volume delivered is as per claimed doses.

Storage temperature:

Shall be kept continuously in final containers at below -20°C when thawed it should be kept between 2 to 8°C and use within 4 months.

Shelf-life:

Not more than 2 years if stored continuously at temperature below -20°C after the last titration, at least 18 months must remain after shipment. The supplier will provide manufacturer's stability test data substantiating 24 months shelf life in the proposed vial/ampoule.

Labelling:

The label on each vial shall conform to the requirements of I.P. and shall appear in the language of English.
All labeling shall be in indelible ink and shall withstand immersion in water and remain intact.
All labels shall state the name of the vaccine, name of the manufacturer, address of manufacturer, lot number, designation(s) of the strain(s) of poliovirus contained in the vaccine, minimum amount of virus of each type contained in one recommended human dose, cell substrate used for the preparation of the vaccine, nature and amount of any stabilizer present in the vaccine, mode for administration (the fact that the vaccine is not to be injected) expiry date, storage temperature and any other marking that is appropriate.

VVM:

The label on each vial should include a Vaccine Vial Monitor (VVM) designed to meet the heat stability curve of the vaccine supplied. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond and acceptable level.

The Vaccine Vial Monitor (VVM) shall be as per WHO Specifications (please refer to Annexure I).

Labeling for secondary packaging:
A label must be affixed either to the top and/or front surface of the secondary packages. It should indicate the type of vaccine, the name of the manufacturer, presentation, batch number, date of manufacture, date of expiry, quantity and storage conditions.

Labeling for tertiary packaging (insulated packaging):
The external surface of insulated packages should be either white or in the natural color of corrugated carton. Dark colors must be avoided.
All labels on tertiary packaging must be attached to all four sides.
Vaccine Rush:
A label must be affixed to all four sides of the vaccine package in English/Hindi.

Numbering of tertiary packaging:
All boxes should be numbered consecutively. Shipping documents should be included in the box labeled number 1, and this box should be clearly labeled with the words
"Containing vaccine shipping documents".

Additional Labelling:
All the containers and other outer containers shall be marked with the statement "CGS NOT FOR SALE" in English.
All labels on containers i.e. vials/ampoules, cartons, tubes etc as well as outer dropper should be marked with the statement "CGS NOT FOR SALE" in bold red letters in English.

Containers:
IP Type I glass amber coloured tamper proof vials or plastic container for parenteral preparation.

Closures:
Vaccine vials shall be fitted with closures that conform to IP requirements for injectable preparations.

Dropper:
Should be sterile duly supported with the testing certificate.

Printed materials:
Two (2) information sheets, printed in English and Hindi, shall be included in each secondary package and shall include information as per Annexure II.

B. **Quality assurance**

Compliance:

The Supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of the specification and related documents; (b) meet I.P./Internationally (WHO) recognized standard for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller; (d) are free from defects in workmanship and in materials and (e) the product has been manufactured cGMP included in Schedule M.

Evidence:

The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned.
The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for shipment.
The Supplier shall provide a copy of **Validation record** with regards to process validation demonstrating batch to batch consistency and to confirm that the packaging complies with WHO requirements.
The Supplier shall provide a copy of the Certificate of Analysis for each lot and that of a dropper intended for shipment.
The Supplier shall provide to the Purchaser a copy of the approval of each source material, constituent material and component for each lot intended for shipment.
The Supplier shall retain a sample as per "Good manufacturing practices for premises and materials under Schedule M (part 1) of Drugs and Cosmetics Act, 1940 & Rules 1945 of India"
Chemical, Physical and biological test data for in-process and finished product testing must be on record for each lot shipped and must be available to Purchaser's representatives when requested.

Inspection:

The Purchaser may inspect and sample, or cause to be sampled, the product at the Supplier's factory and/or warehouse at a mutually agreeable time prior to the shipment of the product.

Testing:

The Purchaser may cause independent laboratory testing to be performed as deemed necessary to assure that the goods conform to the prescribed requirements. The said laboratory testing shall be of the Purchaser's choice if suitably equipped and qualified to conduct quality assurance tests on biological products.

C. Packing

Prior to and at the time of packing, the vaccines must be kept within the storage temperature limits recommended by the manufacturer.

Storage:

Supplier shall state storage volume occupied per infant dose of vaccine (storage volume includes the vaccine vial, packet containing the vaccine vial and any intermediate packaging).

Inner boxes:

_____(number) individual glass vials or ampoules shall be contained in sturdy white cardboard boxes (of not less than 300 GSM) outfitted with individual segments for protecting and separating each vial.

Temperature monitoring devices:

To be included in all vaccine shipments to document whether temperature limits have been exceeded.
One electronic temperature device is included in each and every international vaccine shipping carton (Please refer to Annex III).

Vaccine manufacturer is required to validate their packaging twice for a period of 48 hours that the warmest temperature in the insulated package does not rise above +8°C in continuous outside temperature +43°C.

Over packing:

Box shall be over packed so that the vaccine remains refrigerated below +8 degrees C. The containers must be suitable for export shipping in accordance with *WHO guidelines on the international packaging and shipping of vaccines (WHO/V&B/01.05)*. The containers must have adequate insulation and or sufficient refrigerant to ensure that the warmest storage temperature of the vaccine does not rise above +8°C in continuous outside ambient temperature of +43°C during transit and for a period of at least 48 hours after arrival at the airport of destination.
Additional cushioning shall be provided, sufficient to protect the vials from breakage during transit and handling.

Exterior shipping carton:

Product and printed materials, packaged as specified above, shall be packed in weather-resistant, triple-wall corrugated fiberboard cartons with a bursting test strength of no less than 1900 kPa. The overall dimensions of the exterior shipping cartons should be such that the product does not become damaged during transportation and storage.

Each international shipping carton should weigh less than 50 kg. It is important that individual boxes are not too heavy during transport as they are frequently loaded and offloaded manually at airports and intermediate stores.

D. Markings

All containers and invoices must bear the name of vaccine, expiry dates of the vaccine and appropriate storage temperature.

Advance notice of arrival and advance shipping documentation:
Copies of the documentation for the goods to be shipped must be sent at least seven days in advance of arrival of the shipment. In the case of an individual contract for a specific destination that requires a longer period of advance notice a longer period should apply. The consignee(s) shall be intimated well in advance by registered letter/e-mail/telephone including mobile no., so that vaccines are collected from airport immediately after arrival. Copy of the communication from the supplying firm shall be endorsed to the Assistant Commissioner (I) and Deputy Director (UIP), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi for information.

The documentation must include the following:

- Pre-advice defined by the Purchaser
- Airway bill (AWB);
- Supplier's invoice;
- Packing list;
- Lot release certificate (LRC) issued by the national regulatory authority (NRA) of the country of manufacture for each lot of vaccine supplied; and
- Any other document, certificate of instruction specified in the individual order.

The documents should be sent by e-mail and fax by the freight forwarder or the manufacturer to the consignee, the Purchaser, and any other parties specified in the individual contract.

The pre-advice must contain the following information:

- Purchase order reference;
- Consignee requisition reference;
- Number of packages, gross weight (in kilograms) and volume (in cubic meters);
- Type of vaccine, total number of vials and number of doses per vial/ampoule/tube;
- Value of shipment (in Indian Rupees and/or US $);
- AWB and flight number(s);
- Date and time for place of departure, transit (if applicable) and arrival;
- Instructions for collection;
- Any other information specified in the individual contract must also be included for the consignee.

The following information shall be stated on the airway bill:

- Consignee's name, address telephone number (including mobile no.) and e-mail ID;
- Purchase order reference;
- Consignee's requisition reference;
- Type of vaccine and quantity;

- Instructions to "Telephone consignee upon arrival (*repeat telephone number*)";
- Handling information; **"Medicines-Vaccine-for Human use-Highly perishable-Not to be delayed."**

The following instruction should be stated in the AWB **"Throughout shipment pending reshipment and prior to collection by the consignee, the vaccine must be stored at -15°C to -25°C"**

F. Dispatch

Vaccines should travel by a direct route wherever possible; road transport may be used if accompanied by attendant. Where trans-shipment is unavoidable, the journey should be planned through airports that:

a) have cold storage facilities, and
b) are located in countries with a temperate climate.

The maximum transit time from the manufacturer to arrival at the airport of final destination must not exceed 48 hours.

Shipments should be scheduled to arrive outside weekends and/or public holidays in the recipient country and airline bookings should be made well ahead of the date of departure.

- Vaccines must not be transported with radioactive products, fish or meat;
- Correct cold-chain procedures must be observed during transit, warehousing and shipping (i.e. all vaccines must be kept in temperature-controlled environments at all times throughout the shipment process);
- Reactivation of the refrigeration process of shipments must be performed in accordance with the instructions of the supplier of each shipment whenever deemed necessary.

G. References

1) Indian Pharmacopoeia 2007, Indian Pharmacopoeia Commission, Government of India, Ministry of Health & Family Welfare, Ghaziabad.

2) British Pharmacopoeia 2007, Volume III, page 42

3) Guidelines of the international packaging and shipping of vaccines. WHO 2005; Department of Immunization, Vaccine and Biologicals, WHO/IVB/05.23.

4) Procurement of vaccines for public-sector programmes – A reference manual. WHO/IVB/03.16;2004.

5) WHO Expert Committee on Biological Standardization; 40th Report; Technical Report Series 800; WHO 1990.

Mr. Chandrashekhar R
DDCI, CDSCO

Dr. Pradeep Haldar
Advisor (RCH), MoHFW

Dr. Nivedita Gupta
Scientist F, ICMR

Dr. Veena Dhawan
Joint Commissioner (Imm.),
MoHFW

Mr. D. V. K. Rao
Dy Secretary, Procurement,
MoHFW

@. Approved token through mail

Dr. Danish Ahmed,
NPO Immunization, WHO

Dr. Pritu Dhalaria,
Director, ITSU

Mr. Dheeraj Bhatt,
Health Officer, UNICEF

Dr. Promila Gupta
Chairperson
Principal Consultant, DGHS,
MoHFW

T13011/38/2011-Imm
Government of India
Ministry of Health and Family Welfare
Immunization Division
***

Nirman Bhawan, New Delhi
Dated: 1st April 2020

OFFICE MEMORANDUM

Subject: Rotavirus vaccine (RVV) technical specifications-reg.

In reference to the subject cited above, this is to inform that a meeting of Rotavirus Vaccine Technical Specification Committee was held on 11th March 2020 under chairpersonship of Dr. A.K. Gadpayle, Addl. DGHS/Principal Consultant to discuss the technical specifications for Rotavirus vaccine.

The committee has examined the specifications and in view of the availability of fully liquid RVV (Rotasiil-liquid), and the existing programmatic challenges between currently used presentations, the committee agreed to amend the technical specifications. The minutes of the meeting and revised technical specifications are annexed.

In view of the above, it is requested that the revised technical specifications of RVV to be used for further tender processes.

Encl:- As above (06 pages)

(Dr. Pradeep Haldar)
Advisor (RCH)

Deputy Secretary (Proc.), MoHFW

Copy to:

1. PPS to Joint Secretary (RCH), MoHFW
2. PPS to Joint Secretary (Proc), MoHFW
3. PPS to Addl. DGHS/Principal Consultant, MoHFW
4. PS to Addl. Commissioner (Imm.), MoHFW
5. PA to Joint Commissioner (UIP), MoHFW
6. PS to Joint Commissioner (Imm), MoHFW
7. Members of RVV Technical Specification Committee (as per RVV Technical Specification Committee Meeting)

Minutes of Rotavirus vaccine (RVV) Technical Specifications Committee Meeting
11th March 2020, 342-B A Wing, Nirman Bhawan

Technical Specifications committee for Rotavirus vaccine met under the chairpersonship of Addl. DGHS/ Principal Consultant, Dr. A.K. Gadpayle on 11th March 2020 at Nirman Bhawan at 12pm. Representatives from Ministry of Health & Family Welfare (MoHFW), Central Drugs Standard Control Organisation (CDSCO), Dept. of Biotechnology, UNICEF-India, JSI and ITSU participated in the meeting. The agenda of the meeting was to amend Rotavirus vaccine technical specifications.

The meeting initiated with a brief from Joint Commissioner (Imm.), MoHFW, wherein the following was informed to the group:

- The group was informed that in 2016, RVV was introduced in 4 states- Himachal Pradesh, Odisha, Haryana and Andhra Pradesh. It was expanded to another 5 states by 2017 namely, Tripura, Rajasthan, Madhya Pradesh, Assam and Tamil Nadu. At the time of introduction of rotavirus vaccine, liquid frozen RVV (Rotavac) from M/s Bharat Biotech was available and was used in mentioned 9 states. In 2018, as another indigenous RVV was available, a freeze dried lyophilized RVV (Rotasiil) from M/s Serum Institute of India which was introduced in state of Jharkhand.
- As per STSC (Standing Technical Sub-Committee) of National Technical Advisory Group on Immunization (NTAGI), both the vaccines have similar efficacy, however, programmatic challenges exist in their implementation.
- The programmatic challenges between the two presentations of vaccines was highlighted.
- In 2019, under the 100 days agenda of Government of India, RVV was scaled up to the entire country; and decision was taken that the liquid frozen RVV (Rotavac) and freeze dried lyophilized RVV (Rotasiil) be used in different states in view of the operational differences.
- Recently one of the manufacturers of RVV (M/s Serum Institute of India), which is providing freeze dried lyophilized vaccine Rotasiil, has communicated that the fully liquid rotavirus vaccine manufactured by them has been licensed. The manufacturer has also intended to offer fully liquid RVV (Rotasiil-liquid) for UIP tender.

In view of the availability of fully liquid RVV (Rotasiil-liquid), and the existing programmatic challenges between currently used presentations, the group agreed to amend the technical specifications and suggested changes which are tabulated below:

Particular	Technical specifications developed in July 2015	Changes made in Oct 2017 for 9 states using liquid frozen (Rotavac)	Changes suggested for revised RVV technical specification
Dosage Size	The dose should be packed as single or multiple dose vials as approved by DCG (I). The preferred pack size should be as per the requirements of the national programme.	The dose should be packed as single or multiple dose vials as approved by DCG (I). The preferred pack size for 9 states (Andhra Pradesh, Haryana, Himachal Pradesh, Odisha, Assam, Madhya Pradesh, Rajasthan, Tamil Nadu and	The doses should be packed as single/multiple dose in packaging as approved by DCG (I). The preferred pack size should be as per the requirements of the national programme.

Particular	Technical specifications developed in July 2015	Changes made in Oct 2017 for 9 states using liquid frozen (Rotavac)	Changes suggested for revised RVV technical specification
		Tripura) should be 5/10 dose as per the requirements of the national programme.	
Dose Package	The vaccine can be presented as liquid frozen or liquid or lyophilized vaccine to be reconstituted with a diluent on a prefilled oral applicator (wherever applicable for the vaccine type), containing the requisite amount of live attenuated RV strains as approved by the DCGI . The vaccines are available as single or multidose vials	The vaccine can be presented as liquid frozen or liquid containing the requisite amount of live attenuated RV strains as approved by the DCGI	The vaccine can be presented as liquid frozen or liquid vaccine, containing the requisite amount of live attenuated RV strains as approved by the DCGI.
Storage Temperature	The vaccine should be stored at 2 to 8 degree or at -20 degree or any other temperature as approved by DCG(I), depending on the type of vaccine. Diluent in oral applicator is to be stored at 2 to 8 degree or as any other temperature approved by DCG(I), and should be discarded if frozen"	The vaccine should be stored at 2 to 8 degree or at -20 degree or any other temperature as approved by DCG(I), depending on the type of vaccine"	The vaccine should be stored at 2 to 8 degree C or at -20 degree C depending on the type of vaccine.
Container	IP Type I glass tamper proof vials	IP Type I glass tamper proof vials	Packages/containers as approved by DCGI.
Shelf life	At least 24 months from date of manufacture when stored at recommended temperatures and at least 5/6th of shelf life must remain after shipment. The supplier will provide manufacturer's stability test data substantiating 24 months shelf life in the proposed vial/ampoule/tube.	At least 24 months from date of manufacture when stored at recommended temperatures and at least 5/6th of shelf life must remain after shipment. The supplier will provide manufacturer's stability test data substantiating 24 months shelf life in the proposed vial/ampoule/tube.	At the time of supply to the consignee, the shelf life of vaccine should not have crossed more than 6 months from the date of manufacturing

- Representative from Dept. of Biotechnology suggested informing Standing Technical Sub-Committee (STSC) of NTAGI about the availability of fully liquid RVV (Rotasiil-liquid).

The meeting ended with a vote of thanks to the Chair.

List of participants:

1. Dr. A. K. Gadpayle, Addl. DGHS/ Principal Consultant, MoHFW
2. Dr. Veena Dhawan, Joint Commissioner (Imm.), MoHFW
3. Mr. Chandrashekhar, DDCI, Central Drugs Standard Control Organisation (CDSCO)
4. Dr. Jyoti Logani, Scientist E, Dept. of Biotechnology
5. Dr. Kamakshi Chaithri, Scientist C, Dept. of Biotechnology
6. Dr. Yashika Negi, Immunization Officer, UNICEF
7. Ms. Seema Koshal, Technical Manager, JSI
8. Dr. Vikas Madan, Programme Manager, ITSU
9. Dr. Mayank Shersiya, Senior Consultant, MoHFW

Representative from ICMR and WHO could not attend the meeting.

Dr. A. K. Gadpayle
Addl. DGHS/ Principal Consultant, MoHFW

Mr. Chandrashekhar R
DDCI, CDSCO

Dr. Jyoti Logani
Scientist E, DBT

Dr. Veena Dhawan
Joint Commissioner (Imm.), MoHFW

Ms. Seema Koshal
Technical Manager, JSI

Dr. Yashika Negi
Immunization Officer, UNICEF

Dr. Vikas Madan
Programme Manager, ITSU

Dr. Mayank Shersiya
Senior Consultant, MoHFW

Rotavirus Vaccine Specifications

(For NCB/ICB)

A. Specific requirements

Item:

The manufacturer should have a valid drug manufacturing license. Rota Virus vaccine shall meet the requirements as per the Indian Pharmacopoeia (IP) 2014. The vaccine shall meet all the requirements of Drugs & Cosmetic Act if manufactured in India, however, in case of international transactions, the vaccine shall be registered with Drugs Controller General (India).

Description:

Rotavirus vaccine is a live attenuated, human-bovine reassortant, monovalent or multivalent vaccine which is liquid frozen or liquid for oral use. The vaccine shall contain appropriate amounts of individual components per human dose as approved by the Drugs Controller General of India, if manufactured in India or as approved by regulatory authority in the country of origin. The vaccine shall be registered with the Drugs Controller General of India.

The unit of concentration per human dose varies with the product and it should comply with DCG (I) certification. The companies/manufacturers will provide vaccine efficacy and safety data.

The minimum titers should be as per license approved by DCG (I).

The vaccine should meet the requirements or recommendations to assure the quality, safety, and efficacy of Rotavirus vaccine (human) according to WHO Technical Requirement Specification (TRS) 941, Annex 3 which covers method of production, and preservatives used.

Protocol and testing:

Complete Test Protocol along with samples of all batches should be sent to the Head of the vaccine testing laboratory i.e. Central Drugs Laboratory Kasauli-173204.

Complete Test Protocol and samples are taken and sent by the Inspecting Officer duly sealed and signed by him or his authorized representative.

Dosage schedule:

Vaccine is to be administered orally in doses as approved by DCG (I). The age and dose schedule should be as per the requirements of UIP. Currently under the UIP, the vaccine is given in a 3-dose schedule at 6 weeks, 10 weeks and 14 weeks of age.

Dose package:

The vaccine can be presented as liquid frozen or liquid vaccine, containing the requisite amount of live attenuated RV strains as approved by the DCG (I).

Dose size:

The doses should be packed as single/multiple dose in packaging as approved by DCG (I). The preferred dose size should be as per the requirements of the national programme.

Filling volume:

Final product should contain sufficient overfill to deliver the required volume and number of doses per vial/ampoule/tubes.

Storage temperature:

The vaccine should be stored at 2°C to 8°C or at -20°C depending on the type of vaccine.

Shelf-life:

At the time of supply to the consignee, the shelf life of vaccine should not have crossed more than 6 months from the date of manufacturing.

Labelling:

The label on each vial/ampoule/tube shall conform to the requirements of IP 2014 and shall appear in the English language.

All labelling shall be in indelible ink and shall withstand immersion in water and remain intact.

All labels shall state name of manufacturer, address of manufacturer, lot number, composition, concentration, dose and mode of administration, expiry date and storage temperature.

VVM:

The label on each vial/ampoule/tube should include a Vaccine Vial Monitor (VVM) designed to meet the heat stability curve of the vaccine supplied. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.

Maintain not less than 3 containers of the final lot at an elevated temperature for a defined time period using conditions found suitable for the particular product as approved by the local National Regulatory Authority, as per IP 2014, which should be submitted by the manufacturers to DCG (I).

Each vaccine vial/ampoule/tube has to have a VVM. The Vaccine Vial Monitor (VVM) shall be as per WHO Vaccine Vial Monitor Specifications 2011 (**please refer to annex I**).

Labelling for secondary packaging:

A label must be affixed either to the top and/or front surface of the secondary packages. It should indicate the type of vaccine, the name of the manufacturer,

presentation, batch number, date of manufacture, date of expiry, quantity and storage conditions.

Labelling for tertiary packaging (insulated packaging):
The external surface of insulated packages should be either white or in the natural colour of corrugated carton. Dark colours must be avoided.
All labels on tertiary packaging must be attached to all four sides.

Vaccine Rush: A label must be affixed to all four sides of the vaccine package in English/Hindi.

Numbering of tertiary packaging:
All boxes should be numbered consecutively. Shipping documents should be included in the box labeled number 1, and this box should be clearly labeled with the words **"Containing vaccine shipping documents"**

Additional Labelling:

All the containers and other outer containers shall be marked with the statement "CGS NOT FOR SALE" in English.

All labels on containers i.e. vials/ ampoules, cartons, tubes etc. as well as outer dropper should be marked with the statement "CGS NOT FOR SALE" in bold red letters in English.

Containers:

Packages/containers as approved by DCG (I).

Closures:

Vaccine vials/ampoules/tubes shall be fitted with closures that conform to IP 2014 requirements for oral preparations.

Printed materials:

Two (2) information sheets, printed at least in English and Hindi, shall be included in each secondary package and shall include in formation as per Annexure III

B. **Quality assurance-**

Compliance:

The supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of the specification and related documents; (b) meet I.P. /internationally (WHO) recognized standard for safety, efficacy and quality; (C) are fit for the purposes made known to the seller (d) are free from defects in workmanship and in materials and (e) the product has been manufactured in compliance with cGMP included in Schedule M.

Evidence:

The supplier shall provide objective evidence acceptable to the purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned.
The supplier shall provide a copy of the manufacturing record and procedures to the purchaser for each lot intended for shipment.
The supplier shall provide a copy of **validation record** with regards to process validation demonstrating batch to batch consistency and to confirm that the packaging complies with WHO requirements. The supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment.
The supplier shall provide to the purchaser a copy of the approval of each source material, constituent material and component for each lot intended for shipment.
The supplier shall retain a sample of twenty (20) vials/ampoules/tubes from each lot shipped for two years beyond the printed expiration date. Chemical, physical and biological test data for in-process and finished product testing must be on record for each lot shipped and must be available to purchaser's representatives when requested.

Inspection:

The purchaser may inspect and sample, or cause to be sampled, the product at the supplier's factory and/or warehouse at a mutually agreeable time prior to the shipment of the product.

Testing:

The purchaser may cause independent laboratory testing to be performed as deemed necessary to assure that the goods conform to the prescribed requirements. The said laboratory testing shall be of the purchaser's choice if suitably equipped and qualified to conduct quality assurance tests on biological products.

C. **Packing**

Prior to and at the time of packing, the vaccines must be kept within the storage temperature limits recommended by the manufacturer.

Storage:

Supplier shall state storage volume occupied per infant dose of vaccine (storage volume includes the vaccine vial/ampoule/tube, packet containing the vaccine vial/ampoule/tube and any intermediate packaging).

Inner boxes:

_____ (number) individual glass vials or ampoules or tubes shall be contained in sturdy white cardboard boxes (of not less than 300 GSM) outfitted with individual segments for protecting and separating each vial/ampoule/tube.

Freeze Indicator devices (wherever applicable):

To be included in all vaccine shipments to document that the temperature limits have not been breached during shipment. One electronic temperature device to be included in each shipping carton **(Please refer to Annex II). –**

For vaccine requiring storage at 2°C to 8°C:

Vaccine manufacturer is required to validate their packaging twice for a period of 48 hours i) that the warmest temperature inside the insulated packing does not rise above + 30° C in the continuous outside ambient temperature of + 43° C and ii) that the coolest storage temperature does not fall below + 2° C in the continuous outside temperature of -5°C.

For vaccines requiring shipment storage at -20 degree Celsius, the manufacturer is required to validate the packaging as per CDSCO norms.

Over packing:

Box shall be over packed so that the vaccine remains refrigerated at the recommended temperature for specific vaccine as per CDSCO license. The containers must be suitable for export shipping in accordance with *WHO guidelines on the international packaging and shipping of vaccines* (WHO/IVB/05.23). The containers must have adequate insulation and or sufficient refrigerant to ensure that the warmest storage temperature of the vaccine does not rise above + 30° C in continuous outside ambient temperature of + 43° C during transit and for a period of at least 48 hours after arrival at the consignee point[1].

Additional cushioning shall be provided, sufficient to protect the vials/ampoules/tubes from breakage during transit and handling.

Exterior shipping carton:

Product and printed materials, packaged as specified above, shall be packed in weather-resistant, triple-wall corrugated fiberboard cartons with a bursting test strength of not less than 1900 kPa.

The overall dimensions of the exterior shipping cartons should be such that the product does not become damaged during transportation and storage.

Each shipping carton should weigh less than 50 kg. It is important that individual boxes are not too heavy during transport as they are frequently loaded and offloaded manually at airports and intermediate stores.

D. Markings

All containers and invoices must bear the name of vaccine, batch number, manufacturing date, expiry dates of the vaccine and appropriate storage temperature.

When considering "best practices" for transport and storage of vaccines, reference should be made to current recommended Good Distribution Practices for Biological Products by CDSCO.

Inner boxes:

The inner boxes shall be marked with the following information in a clearly legible manner which is acceptable to the Purchaser:

- Generic name and trade name of the vaccine
- Manufacturer's name and registered address
- Manufacturer's national registration number
- Lot or batch number
- Composition and concentration
- Number of vials/ampoules/tubes contained in box
- Date of manufacture (month and year)
- Expiration date (month and year)
- Instructions for storage and handling[2]
- Place of manufacture (Made in _____)

Exterior shipping cartons:

The following information shall be stenciled or labeled on the exterior shipping cartons on two opposing sides in bold letters, at least '**Arial Font size 14**', high with waterproof ink in a clearly legible manner which is acceptable to the Purchaser:

- Generic name and trade name of the vaccine
- Lot or batch number
- Date of manufacture (month and year)
- Expiration date (month and year)
- Manufacturer's name and registered address
- Manufacturer's national registration number
- Destination country license or registration number
- Consignee's address and emergency phone number including mobile number
- Destination airport
- Contract number
- Number of vials/ampoules/tubes contained in the carton
- Gross weight of each carton (in kg)
- Carton containing ---------- secondary packages
- Instructions for storage and handling2*
- Place of manufacture (Made in _____)

E. Documentation

Supplier shall provide to Purchaser a copy of the batch record, including all quality assurance documentation for the vaccine being supplied.

Advance notice of arrival and advance shipping documentation:

Copies of the documentation for the goods to be shipped must be sent at least seven days in advance of arrival of the shipment. In the case of an individual contract for a specific destination that requires a longer period of advance notice, a longer period should apply.

2*To be provided by Supplier.

The consignee(s) shall be intimated well in advance by registered letter/fax, email and telephone, so that vaccines are received immediately after arrival. Copy of the communication from the supplying firm shall be endorsed to Immunization Division and Procurement Division, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi for information.

The documentation must include the following:

- Pre-advice defined by the Purchaser
- Airway bill (AWB);
- Supplier's invoice;
- Packing list;
- Lot release certificate (LRC) issued by the national regulatory authority (NRA) of the country of manufacture for each lot of vaccine supplied; and

- Any other document, certificate or instruction specified in the individual order

The documents should be sent by e-mail and fax by the freight forwarder or the manufacturer to the consignees, the Purchaser, and any other parties specified in the individual contract.

The pre-advice must contain the following information:

- Purchase order reference;
- Consignee requisition reference;
- Number of packages, gross eight (in cubic meters);
- Type of vaccine, total number of vials/ampoules/tubes and number of doses per vial/ampoule/ tube;
- Date and time for place of departure, transit (if applicable), and arrival;
- Instructions for collection;
- Any other information specified in the individual contract must also be included for the consignee.

The following information shall be stated on the airway bill;

- Consignee's name, address and telephone number (including mobile no.) and e-mail ID;
- Purchase order reference;
- Consignee's requisition reference;
- Type of vaccine and quantity;
- Instructions to: "Telephone consignee upon arrival (repeat telephone number)",
- Handling information: **"Medicines- Vaccine- For human use – Highly Perishable- Not to be delayed"**.

The following instruction should be stated in the AWB: "Throughout shipment, pending reshipment and prior to collection by the consignee, the vaccine must be stored at + 2°C to +8°C

F. Dispatch

Vaccines should travel by a direct route wherever possible; road transport may be used if accompanied by attendant. Where trans-shipment is unavoidable, the journey should be planned through airports that:

a) Have cold storage facilities, and
b) Are located in countries with a temperate climate

The maximum transit time from the manufacturer to arrival at the final destination must not exceed 48 hours.

Shipments should be scheduled to arrive outside weekends and/or public holidays at the consignee points and bookings should be made well ahead of the date of departure.

- Vaccines must not be transported with radioactive products, fish or meat;

- Correct cold-chain procedures must be observed during transit, warehousing and shipping (i.e., all vaccines must be kept in temperature-controlled environments at all times throughout the shipment process);

- Reactivation of the refrigeration process of shipments must be performed in accordance with the instructions of the supplier of each shipment whenever deemed necessary;

G. References

1) Indian Pharmacopoeia 2014, Indian Pharmacopoeia Commission, Government of India; Ministry of Health & Family Welfare, Ghaziabad.

2) Guidelines on the international packaging and shipping of vaccines. WHO 2005; Department of Immunization, Vaccines and Biologicals. WHO/IVB/ 05.23.

3) WHO revised VVM specifications 2011, WHO/PQS/E06/IN05.2.

4) Procurement of vaccines for public-sector programmes- A reference manual. WHO/IVB/03.16; 2004.

5) WHO/IVB/05.23

6) WHO/IVB/04.06

7) WHO/O/UNICEF Product specifications

8) WHO Technical Requirement Specifications (TRS) 941, Annex 3

9) Guidelines on Good Distribution Practices for Biological Products, 2012, CDSCO. (CDSCO/GDP/BP ver:00)

Annexure- I:

SPECIFICATION FOR VACCINE VIAL MONTITORS (VVM)

Specification reference:	**E06/IN05.2**
Product verification protocol:	**E06/IN05.VP.2**
Issue date:	**26 July 2011**
Date of last revision:	**30 November 2006**

1. **Scope:**
   This specification describes the performance requirements for a Vaccine Vial Monitor (VVM) suitable for application to a vaccine vial by a vaccine manufacturer. The product is used to indicate the cumulative heat exposure of a vial of vaccine so that health workers know whether the cumulative heat history of the product has exceeded a pre-set limit.

2. **Normative references:**
   EMAS: *European Union Eco-Management and Audit Scheme.*
   ISO 9001: 2000: *Quality Management Systems – Requirements.*
   ISO 14001: 2004: *Environmental management systems - Requirements with guidance for use.*
   ISO 2859-1: 1999: *Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection.*
   ISO 3951:1989 Sampling procedures for inspection by variables of percent nonconforming
   ISO 5-3:1995 Photography-Density measurements-Part 3: Spectral Conditions

3. **Terms and definitions:**
   AQL: Acceptance Quality Limit

   Active surface: A time-temperature sensitive colour patch whose reaction rate closely matches the stability profile of the vaccine to which the VVM is attached1.

   Spectrodensitometer: The specification for the Start R-I, Indicator OD values, Reference Ring, and OD limits found in E06/IN05.2 are based on measurements with an X-Rite Model 500 series spectrodensitometer. Measurements taken with other instrumentation will require a conversion factor. Due to the small size of the VVM's reference ring and indicator area, it is necessary to modify the target and aperture centring of the spectrodensitometer (as sold by the instrument supplier). The VVM manufacturer will be responsible for providing the service to install the target and centre the aperture. Conversion of spectral data to optical density is defined within ISO 5-3:1995 Photography-Density measurements-Part 3. Spectral Conditions.

   End point: The point at which time-temperature exposure has altered the colour of the active surfaceso that it exactly matches the reference surface. At this point, and thereafter, the vaccine should no longer be used.

   In writing: means communication by letter, fax or email.

   Legal Manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a product or device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

   Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer.

   [1] It is the vaccine manufacturer's responsibility to match the stability profile of their vaccine to the time-temperature profile of one of the four VVM types described in clause 4.2.8 of this specification

   OD: Optical Density.

   Reference surface: A colour patch against which the colour of the active surface can be directly compared.

   Reaction rate: The rate at which the active surface responds to time temperature exposure.

   Reseller: A commercial entity, licensed to act on behalf of a Legal Manufacturer, and which carries product liability and warranty responsibilities no less onerous than those carried by the Legal Manufacturer.

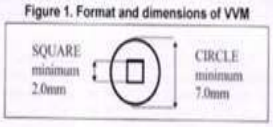
   Start point: The colour of the active surfaceof the VVM at the time when the VVM is received by the vaccine manufacturer[2].

   VVM: Vaccine Vial Monitor comprising, as a minimum, an active surface, a reference surface and the substrate to which these are applied by the VVM manufacturer.

4. **Requirements:**
   4.1 General: Vaccine Vial Monitor suitable for application to a vaccine vial by a vaccine manufacturer.
   The principal purpose of this product is to warn health workers when the cumulative heat exposure of a vial of vaccine has exceeded a pre-set limit, beyond which the vaccine should not be used. This is defined as the end point.
   Before the end point is reached, changes in the appearance of the VVM are used to alert health workers to the fact that heat exposure has occurred. Heat exposed vials can then be used in preference to those that have not been exposed.

   4.2 Performance
   4.2.1 Format and dimensions: The VVM is a circle of colour, minimum diameter 7.0mm with a square of colour, minimum dimensions 2.0 x 2.0mm positioned in the centre of the circle (See Figure 1). Whatever dimensions are chosen, the ratio of the area of the square to the area of the circle (including the square) is to be at least 0.1:1.

Figure 1. Format and dimensions of VVM



   4.2.2 Design: The circle of the VVM comprises a static, reference surface and the square comprises the active surface. The colour change of the active surface is limited to a change of shade, from light to dark. Any colour is permitted for the VVM design, but changes in hue are not permitted.

   4.2.3 Colour density change: The colour density change of the indicator is illustrated in the Figure 2 below. At the start point the colour of the square is lighter than the circle. The end point is indicated when the colour of the square matches the circle. The end point is exceeded when the colour of the square is darker than the circle. The following clauses describe the colour change in more detail.

[2] It is the vaccine manufacturer's responsibility to store the VVMs correctly to prevent any change in the start OD during the period elapsing between the time of receipt of the VVM to the time of its application to the filled vaccine vial.

Figure 2. The colour density change of the indicator

Start point		Square lighter than circle
End point		Square matches the circle
End point exceeded		Square darker than the circle

Note: the central square is the active surface.

4.2.4 Colour at start point and end point:

- At the start point, the colour density of the square as measured by an X-rite Model 500 series spectrodensitometer, must be lighter than the colour shade of the circle by a difference of at least 0.25 OD densitometer units for all VVM except for the VVM2 Dots on Brown Liner where the minimum difference will be 0.23 OD.
- The end point is reached when the difference in the average colour density obtained from readings at least two different points on the circle and the colour density of the square is 0.00 OD, as measured by the densitometer. The end point is exceeded when the colour of the square is darker than the colour of the circle.
- The specifications for the Start R-I and the Indicator OD are shown in Table 1.

Table 1: Start R-I and Indicator OD

Category, Liner	Start R-I	Active Surface Start OD (I)
VVM 30, White and Clear Liner	0.52 ± 0.11	0.09 ± 0.04
VVM 30, Brown Liner	0.49 ± 0.11	0.12 ± 0.04
VVM 14, White and Clear Liner	0.41 ± 0.09	0.10 ± 0.04
VVM 14 Brown Liner	0.38 ± 0.09	0.13 ± 0.04
VVM 7, White Liner	0.41 ± 0.09	0.11 ± 0.04
VVM 7, Brown Liner	0.38 ± 0.09	0.13 ± 0.04
VVM 2, White Liner	0.32 ± 0.07	0.13 ± 0.05
VVM 2, Brown Liner	0.29 ± 0.06	0.16 ± 0.05

4.2.5 Homogeneity of the reference surface: The colour density of one 2mm diameter portion of the circle must be within 0.03 OD of the colour density at any other two 2mm diameter portions of the circle, when measured with a colour densitometer.

4.2.6 Variation of the reference surface within the lot: The colour density of one 2mm diameter portion of the reference circle of one sample must be within 0.03 OD of the colour density of the reference circle of any other sample within the same lot.

4.2.7 Reference surface colours: The colour of the reference area is specified in Table 2.

Table 2: Reference surface colours

Category, Liner	Reference Surface OD (R)
VVM 30, White and Clear Liner	0.61 ± 0.15
VVM 30, Brown Liner	0.61 ± 0.15
VVM 14, White and Clear Liner	0.51 ± 0.13
VVM 14 Brown Liner	0.51 ± 0.13
VVM 7, White Liner	0.52 ± 0.13
VVM 7, Brown Liner	0.51 ± 0.13
VVM 2, White Liner	0.45 ± 0.12
VVM 2, Brown Liner	0.45 ± 0.11

4.2.8 VVM reaction rates: Reaction rates are specific to four different models of VVM, relating to four groups of vaccines according to their heat stability at two specific temperature points (See Table 3).

Table 3: VVM reaction rates by category of heat stability

Category (vaccines)	No. days to end point at +37°C	No. days to end point at +25°C	Time to end point at +5°C
VVM 30: High Stability	30	193	>4 years
VVM 14: Medium Stability	14	90	>3 years
VVM 7: Moderate Stability	7	45	>2 years
VVM 2: Least Stable	2	NA*	225 years

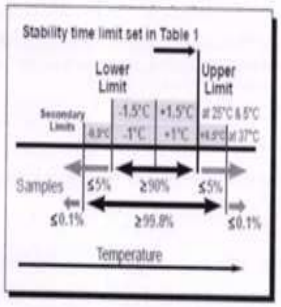
**VVM (Arrhenius) reaction rates determined at two temperature points*

- **At the +37°C specifications, RH 33% +/-5% and RH 75% +/-5%:** At least 90% of VVMs tested should reach the end point at the maximum time in the range of 36 ±1°C. Further, secondary limits are applied to restrict how far beyond the primary specification the TTIs are allowed to be. At least 99.8% of VVMs tested should reach the end point at the maximum time in the range of 36 ±1.5°C.

- **At the 5°C and +25°C specifications (ambient humidity in submerged foil/polythene pouch):** At least 90% of VVMs tested should reach the end point at the maximum time in the range of the specified temperature ±1.5°C.

- **Tolerance:** A tolerance is allowed in the above tests for up to 5% of VVM samples tested to reach the end point at a temperature above the upper limit and 5% at a temperature below the lower limit (See Figure 3).

Figure 3. Stability limit criteria by sample group



- **Allowable range of end points:** Table 4 defines the allowable range of end points such that 90% of a production lot must reach the end point at the specified time within a range of ±1°C and that 99.8% of the lot must reach end point within a range of ±1.5°C.

Table 4: Allowable range of end points

VVM Type	Primary Limits: ±1°C measured at upper limit (including OD tolerance)		Secondary Limits: ±1.5°C measured at upper limit (including OD tolerance)	
	Lower Limit	Upper Limit	Lower Limit AQL= 0.1%	Upper Limit AQL= 0.1%
VVM 30	-0.19	0.03	-0.23	0.06
VVM 14	-0.15	0.03	-0.18	0.06
VVM 7	-0.11	0.03	-0.13	0.05
VVM 2	-0.09	0.03	-0.10	0.04

4.2.9 Global Measurement Accuracy: The allowable total error for measuring the difference between the colours of the circle and square is ± 0.03 OD when using an X-Rite 500 series spectrodensitometer or later qualified model. The measurement error for a single measurement is ± 0.02 OD. Major sources of error are instrument error, both for the circle and the square, repeatability, and variation in end point caused by an allowed temperature variation of ± 0.2°C. 500 series spectrodensitometers require a smaller target than what is provided by the manufacturer (X-Rite). Installation of the smaller target and centering of the aperture must be performed by the VVM manufacturer.

4.2.10 Water Bath Precision and Control: The VVMs should be tested in water baths controlled to within ± 0.2°C. (Any additional 0.1°C variation in temperature control requires an allowance for additional measurement error.)

4.2.11 Reversion: The indicator must not revert to a lighter colour at any point in its life when exposed to conditions likely to be found during normal use. After the endpoint is reached, the square must remain the same colour as the circle or become darker than the circle.

4.2.12 Integrity and location of VVMs:

Before a vial or ampoule is opened, the VVM should not be removable; it should resist removal from the vaccine vial as much as a label meeting current vaccine labeling requirements. In addition, the performance of the VVM should not be changed by soaking in water for 8 hours. Water-exposed samples should conform to within +/-0.04 OD units. The location of the VVM on the vial depends upon whether the vaccine must be discarded at the end of the immunization session in which it is opened, or whether any remaining contents in an opened vial can be retained for use in subsequent sessions. The following cases apply:

- **For multi-dose vials containing a vaccine that can be used in subsequent sessions:** Regardless of the vaccine presentation (liquid, freeze-dried or two vial combinations of liquid and freeze-dried), the VVM must be permanently attached to the label of the vaccine vial and must remain readily observable before, during, and after use, until the entire contents of the vial have been used.
- **For vaccines that must be discarded at the end of the session or within 6 hours, whichever comes first:** The VVM must be attached to the vaccine vial or ampoule and must remain readily observable until the vial or ampoule is opened, but not observable after opening. In order to achieve this requirement, the VVM must be located on the flip-off top of a vial or on the neck of an ampoule.

On a product by product basis, WHO will advise both the vaccine and the VVM manufacturer where the VVM is to be located. Locating the VVM on the bottom of a vial or ampoule is never acceptable – it must always be in a visible location.

4.2.13 Application Surfaces: VVMs must be designed to be applied to the following substrates:

- Glass (e.g., glass vials).
- Paperboard (e.g., primary or secondary packaging).
- Plastic containers of a composition for which permeation of adhesive components is not a risk.

For vial *cap* applications, VVM dots are designed to be applied to smooth, flat surfaces with no embossed areas, recessed areas, or ridges. The use of excessive release agents in the manufacture of the vial caps should be avoided.

Note: Each *user* should ensure there is adequate adhesion of the VVM to the vaccine container. Permanent adhesion may not be guaranteed when the VVM is applied to some plastic materials.

4.3 Traceability: Each roll of VVMs must be labeled with its product identity (part number) together with its lot number[3].

4.4 Physical characteristics: Overall dimensions: As clause 4.2.1, Figure 1.

4.5 Interface requirements:
None.

4.6 Human factors: The colour change must be monotonic in its response to cumulative heat exposure within the limits of the allowed variation. The observer must be able to distinguish between an unchanged indicator, a 50% colour change and the end point of the indicator.

4.7 Materials: The exposed surface of the VVM must not endanger human health. The materials of the VVM must be non-toxic and non-irritant. The VVM must meet any requirements in force concerning toxicity of labels or packaging in the country of manufacture.

4.8 Reliability: All batches of the product must be warranted to conform to the requirements of this specification.

4.9 Servicing provision: The product is to be maintenance-free.

4.10 Disposal and recycling: The product will be disposed of in conjunction with the vial to which it is attached.

4.11 Instructions: An instruction insert, providing vaccine manufacturers with all necessary storage, handling and application directions and traceability directions (with reference to clause 4.3) is to be supplied with every carton. The insert is to be printed in English. If any vaccine manufacturer requires an instruction insert in an additional language, this will be a matter for independent negotiation between the VVM manufacturer and the vaccine manufacturer.

4.12 Training: The VVM manufacturer must provide training for the vaccine manufacturer in order that the manufacturer can correctly handle, apply and test VVMs.

4.13 Verification: In accordance with PQS Verification Protocol **E06/IN05.VP.2.**

5. Packaging:
Materials used for packaging the finished product are to be free of CFC compounds as defined in the Montreal Protocol.

[3] Vaccine manufacturers must keep records of the lot number of the VVMs affixed to each individual batch of vaccine.

6. On-site installation:
VVMs will be applied to vaccine vials by vaccine manufacturers.

7. Product dossier:
The legal manufacturer or reseller is to provide WHO with a pre-qualification dossier containing the following:

- Dossier examination fee in US dollars.
- General information about the legal manufacturer, including name and address.
- Unique identification reference for the product type.
- Full specifications of the product being offered, covering all the requirements set out in this document, including details of product marking and traceability.
- Details of the legal manufacturer's internal AQL sampling procedures in respect of ISO 3951:1989.
- Certified photocopies of the legal manufacturer's ISO 9001 quality system certification.
- Where relevant, certified photocopies of the legal manufacturer's ISO 14001 certification, EMAS registration or registration with an equivalent environmental audit scheme. Conformity with an environmental audit scheme is not mandatory; however preference will be given to manufacturers who are able to demonstrate compliance with good environmental practice.
- Where available, laboratory test report(s) proving conformity with the product specifications.
- A minimum of five samples of each of the four types of VVM shipped with frozen icepacks, together with instruction insert in English language.
- Indicative cost of the product per 10,000, per 100,000 units and per 1,000,000 units EXW (Incoterms 2010).

8. On-site maintenance:

Not applicable.

9. Change notification:

The legal manufacturer or reseller is to advise WHO in writing of any changes which adversely affect the performance of the product, in relation to any of the requirements set out in this specification, after PQS pre-qualification has taken place.

10. Defect reporting:

The legal manufacturer or reseller is to advise WHO and the UN purchasing agencies in writing in the event of safety-related product recalls, component defects and other similar events.

Annex II:

Freeze Indicator Devices

The product will be packed with freezes sensitive vaccines during transport, during storage in fixed locations in a shipping carton, and will be used to warn of exposure to temperature below -5°C.

Performance:

Upper Limit	Lower Limit (without triggering alarm)	Lower Limit (without device failure)
+43°C	-0.5°C	-20°C

Accuracy: +_0.5°C or below at 0°C.

Power Source: Non replaceable battery

Sensor: Electronic sensor or irreversible phase change indicator.

Mode of operation: The product to be triggered by exposure to be a temperature of –0.5°C. +_0.5°C. for 60 minutes +_5 minutes maximum. It must not be possible for the end user to re-set the device after freezing event.

Calibration: Measurement standards and instrument standards used during calibration traceable to an ISO/ IEC 17025 accredited laboratory.

Casing:

- **Electronic devices**: The sensor and other working parts are to be housed in a non-corrodible water-resistant casing.
- **Passive devices**: The device must stay unaffected by overall wetting.

IP rating: For Electronic Devices Protection of the product not less than IEC 60529:IP64

Battery Life: Minimum acceptable battery life for electronic products, with the product switched on, measured at any point in the operating temperature range, is to be 3 years.

Shelf Life: Minimum 3 years from the date of manufacture, inclusive of operational life.

Electromagnetic compatibility: Must remain unaffected in the normal electromagnetic environment compatibility in which it is intended to work.

Environment Requirements: Ambient Temperature during transport and storage: 5°C to 55°C with device inactivated.

Ambient humidity range during transport and use: 0 to 95% RH.

Electrical storm activity: Must remain unaffected by intense electrical storm activity.

Impact resistance: To withstand 5 drops from 1 meter onto a concrete floor, when cooled to a temperature of +3°C, without physical damage or loss of calibration.

Vibration: To withstand 30 minutes on a programmable vibrating table without physical damage or loss of calibration.

Physical Characteristics: Overall Dimensions: Not exceeding 100X50X25 mm

Human Factors:

Activation: The product may be supplied already activated. Alternatively, if the device is to be activated by the user, it should be irreversible.

User interface for phase change products: Triggering should effect irreversible colour change from a light to dark, distinguishable by users with all forms of colour blindness.

User interface for LED indicators only: The indicator must provide the user the following information by unambiguous combinations of steady or flashing lights.

- That the product is activated
- That the battery is functioning
- Whether the temperature of the load has remained above 0°C or

- Whether the temperature of the load fallen below 0^{0}C.

Clear instructions on interpreting the display must be printed on the product in graphical form that is not language dependent.
User Interface for products with LCD displays: The product is to have an LCD display with or without LEDs, capable of showing the following information:

- That the product is activated
- That the battery is functioning.
- Whether the temperature of the load has remained above 0°C or
- Whether the temperature of the load fallen below 0°C

The status of the load must be clearly and permanently indicated on LCD. Indicator symbols must not be language dependent and must be easily understood by untrained users. Acceptable indicators include, but not confined to the following:
'Tick' or **'OK'** symbol for temperature above 0°C
OR
'Cross' or **'Crossed OK'** symbol for exposure to 0°C or less
Legibility: It must be possible for a person with normal visual acuity (With or without glasses) to read the indicator both in bright sunlight and in tungsten/fluorescent lighting at 100 lux on the working lane, both before and after exposure to the triggered temperature.
Mounting device: For attaching it to vaccine, load- a-self-adhesive strip or an eyelet.
Materials: During manufacture of the product, ozone depleting substances included in Montreal Protocol should not be used neither the components should contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls or polybrominated biphenyl ethers.
Warranty: one year replacement warranty
Packaging: Material used for packaging should be free from ozone depleting chemicals as per Montreal Protocol.

Reference: WHO/PQS/F06/INO3.1 dated 30 November2006

Temperature Monitoring Devices

Table1: Specifications of the electronic devices for all national and international shipments

Storage temperature Range	-20^{0}C to +70^{0}C
Operating temperature Range	-20C to +55^{0}C
Display Visibility Range	-10^{0}C to +55^{0}C
Temperature measuring accuracy	±0.5^{0}C or better
Time measuring accuracy	±10 seconds per day, or better
Initial delay (see point 2 below)	1 hour
Recording period	10 days
Storage before START	Minimum of 18 months
Data retention after STOP	Minimum of 6 months

A. For specific devices with these features, refer to the WHO web site:
http://www.who.int/vaccines-access/vacman/pis/pqs.htmlhe

The electronic devices should, at a minimum, meet the specifications outlined in Table 1 (above) and have the functions outlined below:

1) A "start" function to activate the device at the time the carton is being loaded with vaccine.
2) A "stop" function to allow the recipient to stop the recording when the vaccine arrives at its destination.
3) A one hour "initial delay" function so the device can acclimatize to the temperature inside the shipping carton before it starts recording.
4) A "history" function to provide details of violations of the temperature limit in terms of time, range and duration. This function is primarily to provide information for the use of the procurement agency.
5) A liquid crystal display (LCD) screen to provide a visual display of the information and also to show the symbol that indicates whether the device is functional or not. This symbol, and also the alarm indicator, should be static (i.e. should not flash or blink) so as to be visible when the screen is scanned or photocopied for documentation purposes.
6) An alarm set according to WHO's recommended settings (see Tables 2 and 3 below).

Table 2: WHO- recommended alarm settings for national/international shipments of DTP, DT, TT, HepB and combination vaccines

Temperature	Alarm type	Period triggering the alarm
45°C	single event	1 hour
30°C	Cumulative	10 hours
-0.5°C	Single event	1hour

Table 3: WHO-recommended alarm settings for all national and international shipments of OPV and freeze-dried BCG, Measles, MR, MMR vaccines

Temperature	Alarm type	Period triggering the alarm
45°C	single event	1 hour
30°C	cumulative	10 hours
10°C	cumulative	20 hours

Vaccine manufacturers are required to validate their packaging twice for a period of 48 hours:

i) at ambient temperatures under +43°Cand
ii) at ambient temperatures under -5°C

This validation is critical to ensure that the packaging complies with the above requirements and will not set off an alarm.

Batteries for electronic devices do not perform under extremely cold temperatures, such as when vaccines are being transported with dry ice.

Each electronic device should be attached to a backing card that includes the information outlined below, in the appropriate language.

1. **The type of device:**
   Type 1: for DTP, DT, TT, HepB and combination Vaccine
   Type 2: for OPV and freeze-dried BCG, measles, MR, MMR vaccines

2. **For the person packing/sending the shipment:**
   a) Instructions on how to activate the device
   b) A reminder that one device must be placed in each shipping carton;
   c) Space for the following information to be entered:
      - The supplier's name;
      - Date and time of the packing;
      - Vaccine purchase order number;
      - Vaccine type

3. **For the person receiving the shipment:**
   a) Instructions on how to stop the device,
   b) Illustrations to show information on the LCD screen- how it will indicate problems/no problems and the alarm-status display;
   c) Tables 4 and 5 (below) showing what to do

Table 4: Information to be displayed on the backing card of electronic device- Type 1 (for DTP, DT, TT, HepB and combination vaccines)

Alarm temperature	What to do with vaccines
45°C	contact consignee
30°C	contact consignee
-0.5°C	conduct shake test USE vaccine if passes inform consignee of test results

Shake test guidelines can be found on Guidelines on the international packaging and shipping of vaccines WHO 2005; Department of Immunization, Vaccines and Biologicals. WHO/IVB/05.23.

Table 5: Information to be displayed on the backing card of electronic device- Type 2 (for OPV and freeze-dried BCG, measles, MR, MMR, lyophilized Hib, yellow fever and meningitis vaccines)

Alarm temperature	What to do with OPV	What to do with other vaccines
45°C	contact consignee	contact consignee
30°C	contact consignee	contact consignee
10°C	contact consignee	accept

SPECIFICATIONS:

Alarm setting	Type 1: for vaccine: DTP, DT, TT, HepB and combination vaccines		Type 2: for vaccine: OPV, freeze dried BCG, measles and MMR	
	≥ +45°C	1 hour single	≥ +45°C	1 hour single
	≥ +30°C	10 hours cumulative	≥ +30°C	10 hours cumulative
	≥ -0.5°C	1 hour single	≥ +10°C	20 hours cumulative
Initial start delay	1 hour		1 hour	

Annexure III

MODEL INSERT

Rotavirus Vaccine

Description:

Rotavirus vaccine is a live attenuated, human-bovine reassortant, monovalent or multivalent vaccine which is liquid, frozen liquid or suspension for oral use. The vaccine contains appropriate amounts of individual components per human dose as approved by the Drugs Controller General of India, if manufactured in India or as approved by regulatory authority in the country of origin. The vaccine is registered with the Drugs Controller General of India.

The unit of concentration per human dose complies with DCG (I) certification.

DOSAGE SCHEDULE:

Vaccine is to be administered orally in 2 to 3 dose as approved by DCG (I). The age schedule should be as per the requirements of Universal Immmunization Programme.

SIDE EFFECTS:

Most common adverse events included diarrhea, vomiting, irritability, otitis media and nasopharyngitis.
Any adverse event should be reported as per the National AEFI Guidelines.

CONTRAINDICATIONS:

(i) Severe allergic reaction (e.g. anaphylaxis) after a previous dose and severe immunodeficiency including combined immunodeficiency (SCID) and history of intussusception.
(ii) Precautions for their use include intestinal malformations, chronic gastrointestinal disease, and severe acute illness.

STORAGE:

The vaccine should be stored at 2 °C to 8 °C or at -20 °C depending on the type of vaccine. Diluent in oral applicator is to be stored at 2 °C to 8 °C and should be discarded if frozen.

PRESENTATION:

The vaccine comes in single or multi dose vial*.

**As the case maybe, as per the tender and notification of award of tender*

Annexure- IV **VACCINE ARRIVAL REPORT (VAR)**

This report is to be filled in by an authorized staff and forwarded to the Supplier within 3 days of vaccine arrival. Use one report for each vaccine in the shipment.

COUNTRY	INDIA
REPORT No.	

Date of Report

Place, Date and Time of Inspection	Name of Cold Store, Date and Time vaccines entered in Cold Store

PART I- ADVANCE NOTICE

MAIN DOCUMENTS	Date received by Consignee	Copy Airway Bill (AWB)		Copy of Packing List		Copy of Invoice		Copy of Release Certificate	
Pre- advice									
Shipping Notification		Yes	No	Yes	No	Yes	No	Yes	No

List of Other Documents (If required)

PART II- FLIGHT ARRIVAL DETAILS

AWB Number	Airport of Destination	Flight No.	ETA as per notification		Actual Time of Arrival	
			Time	Date	Date	Time

Name of Clearing Agent:	On behalf of:

PART III- DETAILS OF VACCINE SHIPMENT

Purchase Order No.	Consignee	Vaccine Description (type & doses/vial)	Manufacture	Country

VACCINE				DILUENT/DROPPERS			
Lot Number	No. of Boxes	No. of Vials	Expiry Date	Lot Number	No. of Boxes	No. of Vials	Expiry Date

	Yes	No	Comments
Was quantity received as per shipping notification?			
If not, were the details of short-shipment provided prior to vaccine arrival?			

Report No

PART IV-DOCUMENTS ACCOMPANYING THE SHIPMENT

Invoice		Packing List		Release Certificate		Vaccine Arrival Report		Other
Yes	No	Yes	No	Yes	No	Yes	No	
Comments								

PART V – STATUS OF SHIPPING INDICATORS

Total No. of Boxes Inspected		
Coolant Type	Ice packs / Any Other	No coolant

Temperature Monitors Present	VVM	Recorder

PROVIDE BELOW THE DETAILS OF THE STATUS ONLY WHEN PROBLEMS ARE OBSERVED

Box No	Lot No	VVM Stage				Cold Chain Monitor				Freeze Watch Burst		Date/Time of Inspection
		1	2	3	4	A	B	C	D	Yes	No	

Temperature Recorder If applicable, send clear copy of chart (together with this report)	Box Number	Model	Serial no

PART VI – GENERAL CONDITIONS

What was the condition of boxes on arrival?	
Were necessary labels attached to shipping boxes?	
Other Comments (continue in separate sheet if necessary)	

PART VII-NAME AND SIGNATURE

Authorized Inspection Supervisor Date

Officer/In-Charge Date

Dr. A. K. Gadpayle
Addl. DGHS/ Principal Consultant, MoHFW

Mr. Chandrashekhar R
DDCI, CDSCO

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Measles- Rubella (MR) Vaccine Specifications
(For NCB/ICB)

A. Specific requirements

Item:

The manufacturer should have a valid drug manufacturing license. Measles-Rubella (MR) vaccine shall meet the requirements as per the latest Indian Pharmacopoeia (IP) 2014. The vaccine shall meet all the requirements of Drugs & Cosmetic Act if manufactured in India, however, in case of international transactions, the vaccine shall meet all the requirements of the regulatory authority of the country of origin and the vaccine shall be registered with Drugs Controller General (India).

Description:

Measles and Rubella Vaccine (Live) is a freeze-dried preparation of suitable attenuated strains of measles virus and rubella virus grown in suitable cell cultures. The vaccine is reconstituted immediately before use to give a clear liquid that may be coloured owing to the presence of a pH indicator.
a) Measles vaccine (Live) is a freeze dried preparation of a live suitable attenuated strain of measles virus propagated in human diploid calls or cultures of chick embryo dells derived from a chicken flock free from specified pathogen.
The minimum virus concentration stated on the label is not less than 1000 $CCID_{50}$ per human dose.
b) Rubella Vaccine (Live) attenuated is a freeze-dried preparation of suitable attenuated strain of rubella virus. The minimum Rubella virus concentration stated on the label is not less than 1000 $CCID_{50}$ per human dose.

Protocol and testing:

Complete Test Protocol along with samples of all batches should be sent to the Head of the vaccine testing laboratory i.e. Central drugs Laboratory Kasauli-173204.

For local manufacturers:
Complete Test Protocol and samples are taken and sent by the Inspecting Officer duly sealed and signed by him or his authorized representative.

The vaccine should be dispatched to the consignee only on clearance from the Central Drugs Laboratory, Kasauli. The vaccine will be released on the basis of Protocol scrutiny and testing of the vaccine by Central Drugs Laboratory, Kasauli. Each batch should be accompanied with a certificate from the manufacturer that the vaccine meets the latest I.P. 2014 requirements.

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Dosage size:

By subcutaneous injection on outer mid-thigh/upper arm, depending on the age, 0.5 ml of reconstituted vaccine.

Dose package:

Freeze-dried vaccine with sterile diluent in corresponding quantity (specifically prepared for diluting MR vaccine), packed separately, in 05/10 doses vial. Container must protect vaccine from exposure to light.

Filling Volume:

Final reconstituted product should contain one dose in 0.5 ml+ 15% overfill.

Storage temperature:

Between $+2^0$ and $+ 8^0$ C. (vaccine may be frozen for long term storage); diluent should not be frozen.

Shelf-life:

At least 24 months from date of manufacture when stored below $+8^0$ C and at least 20 months must remain after shipment. The supplier will provide manufacturer's stability test data substantiating 24 months shelf life in the proposed vial.

Labelling:

The label on each vial shall conform to the requirements of I.P. 2014 and shall appear in the language of English. All labeling shall be in indelible ink and shall withstand immersion in water and remain intact.

All labels shall state the name of the vaccine, name of the manufacturer, address of manufacturer, lot number, composition, concentration, dose and mode for administration, expiry date, storage temperature, time of reconstitution and any other marking that is appropriate.

All labelling should be conforming to the provisions under the Drug and Cosmetics Act, Rule 96.

VVM:

The label on each vial should include a Vaccine Vial Monitor (VVM) designed to meet the heat stability curve of the vaccine supplied. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond and acceptable level.

The Vaccine Vial Monitor (VVM) shall be of VVM category 14 and shall be as per WHO revised Vaccine Vial Monitor specifications 2006 (please refer to annex I).

Labelling for secondary packaging:
A label must be affixed either to the top and/or front surface of the secondary packages. It should indicate the type of vaccine, the name of the manufacturer, presentation, batch number, and date of manufacture, date of expiry, quantity and storage conditions.

Labelling for tertiary packaging (insulated packaging):
The external surface of insulated packages should be either white or in the natural colour of corrugated carton. Dark colours must be avoided.
All labels on tertiary packaging must be attached to all four sides.

Vaccine Rush: A label must be affixed to all four sides of the vaccine package in English/Hindi.

Numbering of tertiary packaging:
All boxes should be numbered consecutively. Shipping documents should be included in the box labeled number 1, and this box should be clearly labeled with the words
"**Containing vaccine shipping documents**"

Additional Labelling:

All the containers and other outer containers shall be marked with the statement "CGS NOT FOR SALE" in English.
All labels on containers i.e. vials/ ampoules, cartons, tubes etc. as well as outer dropper should be marked with the statement "CGS NOT FOR SALE" in bold red letters in English.

Containers:

IP Type I plain glass amber coloured tamper proof vials for vaccine vials, however, for the diluent plain glass vials or pharmaceutical grade plastic container for parenteral preparations (amber coloured for vaccine and colourless for the diluent).

Closures:

Vaccine vials shall be fitted with closures that conform to the latest IP 2014 requirements for injectable preparations

Printed materials:

Two (2) information sheets, printed in English and Hindi, shall be included in each secondary package and shall include in formation as per Annexure III.

B. Quality assurance
Compliance:

The Supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of the specification and related documents; (b) meet I.P/internationally (WHO) recognized standard for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller (d) are free from defects in

workmanship and in materials and (e) the product has been manufactured cGMP included in Schedule M.

Evidence:

The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned.

The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for shipment.

The Supplier shall provide a copy of **Validation record** with regards to process validation demonstrating batch to batch consistency and to confirm that the packaging complies with WHO requirements. The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment.

The Supplier shall provide to the Purchaser a copy of the approval of each source material, constituent material and component for each lot intended for shipment.

The Supplier shall retain a sample of twenty (20) vials from each lot shipped for two years beyond the printed expiration date. Chemical, physical and biological test date for in-process and finished product testing must be on record for each lot shipped and must be available to Purchaser's representatives when requested.

Inspection:

The Purchaser may inspect and sample, or cause to be sampled, the product at the Supplier's factory and/ or warehouse at a mutually agreeable time prior to the shipment of the product.

Testing:

The Purchaser may cause independent laboratory testing to be performed as deemed necessary to assure that the goods conform to the prescribed requirements: The said laboratory testing shall be of the Purchaser's choice if suitably equipped and qualified to conduct quality assurance tests on biological products.

C. Packing

Prior to and at the time of packing, the vaccines must be kept within the storage temperature limits recommended by the manufacturer.

Storage:

Supplier shall state storage volume occupied per infant dose of vaccine (storage volume includes the vaccine vial, packet containing the vaccine vial and any intermediate packaging).

Inner boxes:

_____ (number) individual glass vials or ampoules shall be contained in sturdy white cardboard boxes (of not less than 300 GSM outfitted with individual segments for protecting and separating each vial. Diluents for freeze-dried vaccines must always

be included with the vaccine shipment in a quantity that matches the quantity of vaccine; however, do not require temperature controlled packaging.

Temperature Monitoring Devices:

To be included in all vaccine shipments to document that the temperature limits (+2°C to +8°C) have not been breached during shipment. One electronic temperature device to be included in each shipping carton (Please refer to Annex II).

Vaccine manufacturer is required to validate their packaging twice for a period of 48 hours that the warmest temperature inside the insulated packing does not rise above + 30° C in the continuous outside ambient temperature of + 43° C.

Over packing:

Box shall be over packed so that the vaccine remains refrigerated below + 8°C. The containers must be suitable for export shipping in accordance with *WHO guidelines on the international packaging and shipping of vaccines* (WHO/IVB/05.23). The containers must have adequate insulation and or sufficient refrigerant to ensure that the warmest storage temperature of the vaccine does not rise above +30° C in continuous outside ambient temperature of +43° C during transit and for a period of at least 48 hours after arrival at the consignee point[1].
Additional cushioning shall be provided, sufficient to protect the vials from breakage during transit and handling.

Exterior shipping carton:

Product and printed materials, packaged as specified above, shall be packed in weather-resistant, triple-wall corrugated fiberboard cartons with a bursting test strength of not less than 1900 kPa. The overall dimensions of the exterior shipping cartons should be such that the product does not become damaged during transportation and storage.

Each international shipping carton should weigh less than 50 kg. It is important that individual boxes are not too heavy during transport as they are frequently loaded and offloaded manually at airports and intermediate stores.

D. Markings

All containers and invoices must bear the name of vaccine, expiry dates of the vaccine and appropriate storage temperature

Inner boxes:

The inner boxes shall be marked with the following information in a clearly legible manner which is acceptable to the Purchaser:

- Generic name and trade name if the vaccine
- Manufacturer's name and registered address

1 When considering "best practices" for transport and storage of vaccines, reference should be made to current recommendations in the appropriate literature.

- Manufacturer's national registration number
- Lot or batch number
- Composition and concentration
- Number of vials contained in the box
- Date of manufacture (month and year)
- Expiration date (month and year)
- Instructions for storage and handling[2*]
- Place of manufacture (Made in _____)

Exterior shipping cartons:

The following information shall be stenciled or labeled on the exterior shipping cartons on two opposing sides in bold letters at least '**Arial Font size 14**' high with waterproof ink in a clearly legible manner which is acceptable to the Purchaser:

- Generic name and trade name of the vaccine
- Lot or batch number
- Date of manufacture (month and year)
- Expiration date (month and year)
- Manufacturer's name and registered address
- Manufacturer's national registration number
- Destination country license or registration number
  Consignee's address and emergency phone number including mobile number
- Destination airport
- Contract number
- Number of vials contained in the carton
- Gross weight of each carton (in kg)
- Carton containing -------- secondary packages
- Instructions for storage and handling[3*]
- Place of manufacture (Made in _____)

E. Documentation

Supplier shall provide to Purchaser a copy of the batch record, including all quality assurance documentation for the vaccine being supplied.

Advance notice of arrival and advance shipping documentation:

Copies of the documentation for the goods to be shipped must be sent at least seven days in advance of arrival of the shipment. In the case of an individual contract for a specific destination that requires a longer period of advance notice, a longer period should apply.

2*Markings on inner boxes should state clearly that the reconstituted vaccine is good for 6 hours only; additional text to be provided by the Purchaser.
3*To be provided by Purchaser.

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The consignee(s) shall be intimated well in advance by registered letter/telegram telephone, so that vaccines are received immediately after arrival. Copy of the communication from the supplying firm shall be endorsed to the Deputy Commissioner (Imm/UIP) and Deputy Director (UIP), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi for information.

The documentation must include the following:

- Pre-advice defined by the Purchaser
- Airway bill (AWB);
- Supplier's invoice;
- Packing list;
- Lot release certificate (LRC) issued by the national regulatory authority (NRA) of the country of manufacture for each lot of vaccine supplied; and
- Any other document, certificate or instruction specified in the individual order.

The documents should be sent by e-mail and fax by the freight forwarder or the manufacturer to the consignees, the Purchaser and any other parties specified in the individual contract.

The pre-advice must contain the following information:

- Purchase order reference
- Consignee requisition reference
- Number of packages, gross weight (in kilograms) and volume (in cubic meters);
- Type of vaccine, total number of vials and number of doses per vial/ampoule/ tube;
- Value of shipment (in Indian Rupees and/or US$);
- AWB and flight number(s);
- Date and time for place of departure, transit (if applicable), and arrival:
- Instructions for collection;
- Any other information specified in the individual contract must also be included for the consignee.

The following information shall be stated on the airway bill:

- Consignee's name, address and telephone number (including mobile no.) and e-mail ID;
- Purchase order reference;
- Consignee's requisition reference;
- Type of vaccine and quantity;
- Instructions to: "Telephone consignee upon arrival (repeat telephone number)",
- Handling information: **"Medicines- Vaccine- For human use – Highly Perishable- Not to be delayed.**
- The following instruction should be stated in the AWB: "Throughout shipment, pending reshipment and prior to collection by the consignee, the vaccine must be stored at + 2^0C to +8^0C.

F. Dispatch

Vaccines should travel by a direct route wherever possible; road transport may be used if accompanied by attendant. Where trans-shipment is unavoidable, the journey should be planned through airports that:

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a) Have cold storage facilities, and
b) Are located in countries with a temperate climate

The maximum transit time from the manufacturer to arrival at the final destination must not exceed 48 hours.

Shipments should be scheduled to arrive outside weekends and/or public holidays at the consignee points and bookings should be made well ahead of the date of departure.

- Vaccines must not be transported with radioactive products, fish or meat;
- Correct cold-chain procedures must be observed during transit, warehousing and shipping (i.e., all vaccines must be kept in temperature-controlled environments at all times throughout the shipment process);
-Reactivation of the refrigeration process of shipments must be performed in accordance with the instructions of the supplier of each shipment whenever deemed necessary.

G. References

1) Indian Pharmacopoeia 2014, Indian Pharmacopoeia Commission, Government of India; Ministry of Health & Family Welfare, Ghaziabad.

2) Guidelines on the international packaging and shipping of vaccines. WHO 2005; Department of Immunization, Vaccines and Biologicals. WHO/IVB/ 05.23.

3) WHO revised VVM specifications 2006.

4) Procurement of vaccines for public-sector programmes- A reference manual. WHO/IVB/03.16.2004.

5) WHO/IVB/05.23

6) WHO/IVB/04.06

7) WHO/UNICEF Product specifications.

Annexure- I:

SPECIFICATION FOR VACCINE VIAL MONTITORS (VVM)

Specification reference:	**E06/IN05.2**
Product verification protocol:	**E06/IN05.VP.2**
Issue date:	**26 July 2011**
Date of last revision:	**30 November 2006**

1. **Scope:**
   This specification describes the performance requirements for a Vaccine Vial Monitor (VVM) suitable for application to a vaccine vial by a vaccine manufacturer. The product is used to indicate the cumulative heat exposure of a vial of vaccine so that health workers know whether the cumulative heat history of the product has exceeded a pre-set limit.

2. **Normative references:**
   EMAS: *European Union Eco-Management and Audit Scheme.*
   ISO 9001: 2000: *Quality Management Systems – Requirements.*
   ISO 14001: 2004: *Environmental management systems - Requirements with guidance for use.*
   ISO 2859-1: 1999: *Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection.*
   ISO 3951:1989 Sampling procedures for inspection by variables of percent nonconforming.
   ISO 5-3:1995 Photography-Density measurements-Part 3: Spectral Conditions

3. **Terms and definitions:**
   AQL: Acceptance Quality Limit

   Active surface: A time-temperature sensitive colour patch whose reaction rate closely matches the stability profile of the vaccine to which the VVM is attached1.

   Spectrodensitometer: The specification for the Start R-I, Indicator OD values, Reference Ring, and OD limits found in E06/IN05.2 are based on measurements with an X-Rite Model 500 series spectrodensitometer. Measurements taken with other instrumentation will require a conversion factor. Due to the small size of the VVM's reference ring and indicator area, it is necessary to modify the target and aperture centring of the spectrodensitometer (as sold by the instrument supplier). The VVM manufacturer will be responsible for providing the service to install the target and centre the aperture. Conversion of spectral data to optical density is defined within ISO 5-3:1995 Photography-Density measurements-Part 3: Spectral Conditions.

   End point: The point at which time-temperature exposure has altered the colour of the active surfaceso that it exactly matches the reference surface. At this point, and thereafter, the vaccine should no longer be used.

   In writing: means communication by letter, fax or email.

   Legal Manufacturer: The natural or legal person with responsibility for the design, manufacture, **packaging** and labelling of a product or device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

[1]It is the vaccine manufacturer's responsibility to match the stability profile of their vaccine to the time-temperature profile of one of the four VVM types described in clause 4.2.8 of this specification

Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer.

OD: Optical Density.

Reference surface: A colour patch against which the colour of the active surface can be directly compared.

Reaction rate: The rate at which the active surface responds to time temperature exposure.

Reseller: A commercial entity, licensed to act on behalf of a Legal Manufacturer, and which carries product liability and warranty responsibilities no less onerous than those carried by the Legal Manufacturer.

Start point: The colour of the active surfaceof the VVM at the time when the VVM is received by the vaccine manufacturer[2].

VVM: Vaccine Vial Monitor comprising, as a minimum, an active surface, a reference surface and the substrate to which these are applied by the VVM manufacturer.

4. Requirements:

4.1 *General:* Vaccine Vial Monitor suitable for application to a vaccine vial by a vaccine manufacturer.

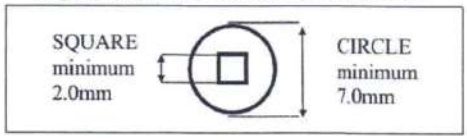
The principal purpose of this product is to warn health workers when the cumulative heat exposure of a vial of vaccine has exceeded a pre-set limit, beyond which the vaccine should not be used. This is defined as the end point.

Before the end point is reached, changes in the appearance of the VVM are used to alert health workers to the fact that heat exposure has occurred. Heat exposed vials can then be used in preference to those that have not been exposed.

4.2 *Performance:*

4.2.1 Format and dimensions: The VVM is a circle of colour, minimum diameter 7.0mm with a square of colour, minimum dimensions 2.0 x 2.0mm positioned in the centre of the circle (See Figure 1). Whatever dimensions are chosen, the ratio of the area of the square to the area of the circle (including the square) is to be at least 0.1:1.

Figure 1. Format and dimensions of VVM



4.2.2 Design: The circle of the VVM comprises a static, reference surface and the square comprises the active surface. The colour change of the active surface is limited to a change of shade, from light to dark. Any colour is permitted for the VVM design, but changes in hue are not permitted.

4.2.3 Colour density change: The colour density change of the indicator is illustrated in the Figure 2 below. At the start point the colour of the square is lighter than the circle. The end point is indicated when the colour of the square matches the circle. The end point is exceeded when the colour of the square is darker than the circle.

[2] It is the vaccine manufacturer's responsibility to store the VVMs correctly to prevent any change in the start OD during the period elapsing between the time of receipt of the VVM to the time of its application to the filled vaccine vial.

The following clauses describe the colour change in more detail:

Figure 2. The colour density change of the indicator

Start point		Square lighter than circle
End point		Square matches the circle
End point exceeded		Square darker than the circle

Note: the central square is the active surface.

4.2.4 Colour at start point and end point:

- At the start point, the colour density of the square as measured by an X-rite Model 500 series spectrodensitometer, must be lighter than the colour shade of the circle by a difference of at least 0.25 OD densitometer units for all VVM except for the VVM2 Dots on Brown Liner where the minimum difference will be 0.23 OD.
- The end point is reached when the difference in the average colour density obtained from readings at least two different points on the circle and the colour density of the square is 0.00 OD, as measured by the densitometer. The end point is exceeded when the colour of the square is darker than the colour of the circle.
- The specifications for the Start R-I and the Indicator OD are shown in Table 1.

Table 1: Start R-I and Indicator OD

Category, Liner	Start R-I	Active Surface Start OD (I)
VVM 30, White and Clear Liner	0.52 ± 0.11	0.09 ± 0.04
VVM 30, Brown Liner	0.49 ± 0.11	0.12 ± 0.04
VVM 14, White and Clear Liner	0.41 ± 0.09	0.10 ± 0.04
VVM 14 Brown Liner	0.38 ± 0.09	0.13 ± 0.04
VVM 7, White Liner	0.41 ± 0.09	0.11 ± 0.04
VVM 7, Brown Liner	0.38 ± 0.09	0.13 ± 0.04
VVM 2, White Liner	0.32 ± 0.07	0.13 ± 0.05
VVM 2, Brown Liner	0.29 ± 0.06	0.16 ± 0.05

4.2.5 Homogeneity of the reference surface: The colour density of one 2mm diameter portion of the circle must be within 0.03 OD of the colour density at any other two 2mm diameter portions of the circle, when measured with a colour densitometer.

4.2.6 Variation of the reference surface within the lot: The colour density of one 2mm diameter portion of the reference circle of one sample must be within 0.03 OD of the colour density of the reference circle of any other sample within the same lot.

4.2.7 Reference surface colours: The colour of the reference area is specified in Table 2.

Table 2: Reference surface colours

Category, Liner	Reference Surface OD (R)
VVM 30, White and Clear Liner	0.61 ± 0.15
VVM 30, Brown Liner	0.61 ± 0.15
VVM 14, White and Clear Liner	0.51 ± 0.13

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VVM 14 Brown Liner	0.51 ± 0.13
VVM 7, White Liner	0.52 ± 0.13
VVM 7, Brown Liner	0.51 ± 0.13
VVM 2, White Liner	0.45 ± 0.12
VVM 2, Brown Liner	0.45 ± 0.11

4.2.8 VVM reaction rates: Reaction rates are specific to four different models of VVM, relating to *four* groups of vaccines according to their heat stability at two specific temperature points (See Table 3).

Table 3: VVM reaction rates by category of heat stability

Category (vaccines)	No. days to end point at +37°C	No. days to end point at +25°C	Time to end point at +5°C
VVM 30: High Stability	30	193	>4 years
VVM 14: Medium Stability	14	90	>3 years
VVM 7: Moderate Stability	7	45	>2 years
VVM 2: Least Stable	2	NA*	225 years

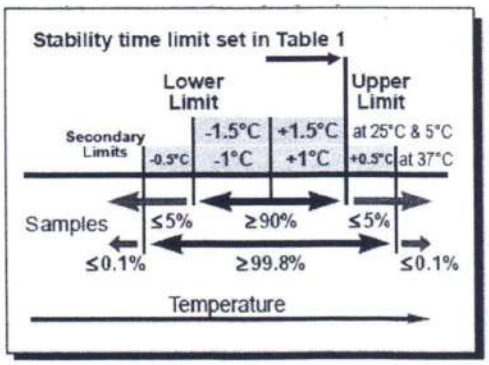
**VVM (Arrhenius) reaction rates determined at two temperature points*

- **At the +37°C specifications, RH 33% +/-5% and RH 75% +/-5%:** At least 90% of VVMs tested should reach the end point at the maximum time in the range of 36 ±1°C. Further, secondary limits are applied to restrict how far beyond the primary specification the TTIs are allowed to be. At least 99.8% of VVMs tested should reach the end point at the maximum time in the range of 36 ±1.5°C.

- **At the 5°C and +25°C specifications (ambient humidity in submerged foil/polythene pouch**): At least 90% of VVMs tested should reach the end point at the maximum time in the range of the specified temperature ±1.5°C.

- **Tolerance:** A tolerance is allowed in the above tests for up to 5% of VVM samples tested to reach the end point at a temperature above the upper limit and 5% at a temperature below the lower limit (See Figure 3).

Figure 3. Stability limit criteria by sample group



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- **Allowable range of end points**: Table 4 defines the allowable range of end points such that 90% of a production lot must reach the end point at the specified time within a range of ±1°C and that 99.8% of the lot must reach end point within a range of ±1.5°C.

Table 4: Allowable range of end points

VVM Type	Primary Limits: ±1°C measured at upper limit (including OD tolerance)		Secondary Limits: ±1.5°C measured at upper limit (including OD tolerance)	
	Lower Limit	Upper Limit	Lower Limit AQL= 0.1%	Upper Limit AQL= 0.1%
VVM 30	-0.19	0.03	-0.23	0.06
VVM 14	-0.15	0.03	-0.18	0.06
VVM 7	-0.11	0.03	-0.13	0.05
VVM 2	-0.09	0.03	-0.10	0.04

4.2.9 Global Measurement Accuracy: The allowable total error for measuring the difference between the colours of the circle and square is ± 0.03 OD when using an X-Rite 500 series spectrodensitometer or later qualified model. The measurement error for a single measurement is ± 0.02 OD. Major sources of error are instrument error, both for the circle and the square, repeatability, and variation in end point caused by an allowed temperature variation of ± 0.2°C. 500 series spectrodensitometers require a smaller target than what is provided by the manufacturer (X-Rite). Installation of the smaller target and centering of the aperture must be performed by the VVM manufacturer.

4.2.10 Water Bath Precision and Control: The VVMs should be tested in water baths controlled to within ± 0.2°C. (Any additional 0.1°C variation in temperature control requires an allowance for additional measurement error.)

4.2.11 Reversion: The indicator must not revert to a lighter colour at any point in its life when exposed to conditions likely to be found during normal use. After the endpoint is reached, the square must remain the same colour as the circle or become darker than the circle.

4.2.12 Integrity and location of VVMs:

Before a vial or ampoule is opened, the VVM should not be removable; it should resist removal from the vaccine vial as much as a label meeting current vaccine labeling requirements. In addition, the performance of the VVM should not be changed by soaking in water for 8 hours. Water-exposed samples should conform to within +/-0.04 OD units. The location of the VVM on the vial depends upon whether the vaccine must be discarded at the end of the immunization session in which it is opened, or whether any remaining contents in an opened vial can be retained for use in subsequent sessions. The following cases apply:

- **For multi-dose vials containing a vaccine that can be used in subsequent sessions:** Regardless of the vaccine presentation (liquid, freeze-dried or two vial combinations of liquid and freeze-dried), the VVM must be permanently attached to the label of the vaccine vial and must remain readily observable before, during, and after use, until the entire contents of the vial have been used.
- **For vaccines that must be discarded at the end of the session or within 6 hours, whichever comes first:** The VVM must be attached to the vaccine vial or ampoule and must remain readily observable until the vial or ampoule is opened, but not observable after opening. In order to achieve this requirement, the VVM must be located on the flip-off top of a vial or on the neck of an ampoule.

On a product by product basis, WHO will advise both the vaccine and the VVM manufacturer where the VVM is to be located. Locating the VVM on the bottom of a vial or ampoule is never acceptable – it must always be in a visible location.

4.2.13 Application Surfaces: VVMs must be designed to be applied to the following substrates:

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- Glass (e.g., glass vials).
- Paperboard (e.g., primary or secondary packaging).
- Plastic containers of a composition for which permeation of adhesive components is not a risk.

For vial *cap* applications, VVM dots are designed to be applied to smooth, flat surfaces with no embossed areas, recessed areas, or ridges. The use of excessive release agents in the manufacture of the vial caps should be avoided.

Note: Each *user* should ensure there is adequate adhesion of the VVM to the vaccine container. Permanent adhesion may not be guaranteed when the VVM is applied to some plastic materials.

4.3Traceability: Each roll of VVMs must be labeled with its product identity (part number) together with its lot number[3].

4.4 Physical characteristics: Overall dimensions: As clause 4.2.1, Figure 1.

4.5 Interface requirements:
None.

4.6 Human factors: The colour change must be monotonic in its response to cumulative heat exposure within the limits of the allowed variation. The observer must be able to distinguish between an unchanged indicator, a 50% colour change and the end point of the indicator.

4.7 Materials: The exposed surface of the VVM must not endanger human health. The materials of the VVM must be non-toxic and non-irritant. The VVM must meet any requirements in force concerning toxicity of labels or packaging in the country of manufacture.

4.8 Reliability: All batches of the product must be warranted to conform to the requirements of this specification.

4.9 Servicing provision: The product is to be maintenance-free.

4.10 Disposal and recycling: The product will be disposed of in conjunction with the vial to which it is attached.

4.11 Instructions: An instruction insert, providing vaccine manufacturers with all necessary storage, handling and application directions and traceability directions (with reference to clause 4.3) is to be supplied with every carton. The insert is to be printed in English. If any vaccine manufacturer requires an instruction insert in an additional language, this will be a matter for independent negotiation between the VVM manufacturer and the vaccine manufacturer.

4.12 Training*:* The VVM manufacturer must provide training for the vaccine manufacturer in order that the manufacturer can correctly handle, apply and test VVMs.

4.13 Verification*:* In accordance with PQS Verification Protocol **E06/IN05.VP.2.**

[3] Vaccine manufacturers must keep records of the lot number of the VVMs affixed to each individual batch of vaccine.

5. **Packaging:**
Materials used for packaging the finished product are to be free of CFC compounds as defined in the Montreal Protocol.

6. **On-site installation:**
VVMs will be applied to vaccine vials by vaccine manufacturers.

7. **Product dossier:**
The legal manufacturer or reseller is to provide WHO with a pre-qualification dossier containing the following:
- Dossier examination fee in US dollars.
- General information about the legal manufacturer, including name and address.
- Unique identification reference for the product type.
- Full specifications of the product being offered, covering all the requirements set out in this document, including details of product marking and traceability.
- Details of the legal manufacturer's internal AQL sampling procedures in respect of ISO 3951:1989.
- Certified photocopies of the legal manufacturer's ISO 9001 quality system certification.
- Where relevant, certified photocopies of the legal manufacturer's ISO 14001 certification, EMAS registration or registration with an equivalent environmental audit scheme. Conformity with an environmental audit scheme is not mandatory; however preference will be given to manufacturers who are able to demonstrate compliance with good environmental practice.
- Where available, laboratory test report(s) proving conformity with the product specifications.
- A minimum of five samples of each of the four types of VVM shipped with frozen icepacks, together with instruction insert in English language.
- Indicative cost of the product per 10,000, per 100,000 units and per 1,000,000 units EXW (Incoterms 2010).

8. **On-site maintenance:**
Not applicable.

9. **Change notification:**
The legal manufacturer or reseller is to advise WHO in writing of any changes which adversely affect the performance of the product, in relation to any of the requirements set out in this specification, after PQS pre-qualification has taken place.

10. **Defect reporting:**
The legal manufacturer or reseller is to advise WHO and the UN purchasing agencies in writing in the event of safety-related product recalls, component defects and other similar events.

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Annex II: Temperature Monitoring Devices

Table1: Specifications of the electronic devices for all national and international shipments

Storage temperature Range	-20°C to +70°C
Operating temperature Range	-20C to +55°C
Display Visibility Range	-10°C to +55°C
Temperature measuring accuracy	±0.5°C or better
Time measuring accuracy	±10 seconds per day, or better
Initial delay (see point 2 below)	1 hour
Recording period	10 days
Storage before START	Minimum of 18 months
Data retention after STOP	Minimum of 6 months

A. For specific devices with these features, refer to the WHO web site:
http://www.who.int/vaccines-access/vacman/pis/pgs.htmthe

The electronic devices should, at a minimum, meet the specifications outlined in Table 1 (above) and have the functions outlined below:

1) A "start" function to activate the device at the time the carton is being loaded with vaccine.
2) A "stop" function to allow the recipient to stop the recording when the vaccine arrives at its destination.
3) A one hour "initial delay" function so the device can acclimatize to the temperature inside the shipping carton before it starts recording.
4) A "history" function to provide details of violations of the temperature limit in terms of time, range and duration. This function is primarily to provide information for the use of the procurement agency.
5) A liquid crystal display (LCD) screen to provide a visual display of the information and also to show the symbol that indicates whether the device is functional or not. This symbol, and also the alarm indicator, should be static (i.e. should not flash or blink) so as to be visible when the screen is scanned or photocopied for documentation purposes.
6) An alarm set according to WHO's recommended settings (see Tables 2 and 3 below).

Table 2: WHO- recommended alarm settings for national/international shipments of DTP, DT, TT, HepB and combination vaccines

Temperature	Alarm type	Period triggering the alarm
45°C	single event	1 hour
30°C	Cumulative	10 hours
-0.5°C	Single event	1hour

Table 3: WHO-recommended alarm settings for all national and international shipments of OPV and freeze-dried BCG, Measles, MR, MMR vaccines

Temperature	Alarm type	Period triggering the alarm
45°C	single event	1 hour
30°C	cumulative	10 hours
10°C	cumulative	20 hours

Vaccine manufacturers are required to validate their packaging twice for a period of 48 hours:

i) at ambient temperatures under +43°Cand
ii) at ambient temperatures under -5°C

This validation is critical to ensure that the packaging complies with the above requirements and will not set off an alarm.

Batteries for electronic devices do not perform under extremely cold temperatures, such as when vaccines are being transported with dry ice.

Each electronic device should be attached to a backing card that includes the information outlined below, in the appropriate language.

1. **The type of device:**
   Type 1: for DTP, DT, TT, HepB and combination Vaccine
   Type 2: for OPV and freeze-dried BCG, measles, MR, MMR vaccines

2. **For the person packing/sending the shipment:**
   a) Instructions on how to activate the device
   b) A reminder that one device must be placed in each shipping carton;
   c) Space for the following information to be entered:
      - The supplier's name;
      - Date and time of the packing;
      - Vaccine purchase order number;
      - Vaccine type

3. **For the person receiving the shipment:**
   a) Instructions on how to stop the device,
   b) Illustrations to show information on the LCD screen- how it will indicate problems/no problems and the alarm-status display;
   c) Tables 4 and 5 (below) showing what to do

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Table 4: Information to be displayed on the backing card of electronic device- Type 1 (for DTP, DT, TT, HepB and combination vaccines)

Alarm temperature	What to do with vaccines
45°C	contact consignee
30°C	contact consignee
-0.5°C	conduct shake test USE vaccine if passes inform consignee of test results

Shake test guidelines can be found on Guidelines on the international packaging and shipping of vaccines WHO 2005; Department of Immunization, Vaccines and Biologicals. WHO/IVB/05.23.

Table 5: Information to be displayed on the backing card of electronic device- Type 2 (for OPV and freeze-dried BCG, measles, MR, MMR, lyophilized Hib, yellow fever and meningitis vaccines)

Alarm temperature	What to do with OPV	What to do with other vaccines
45°C	contact consignee	contact consignee
30°C	contact consignee	contact consignee
10°C	contact consignee	accept

SPECIFICATIONS:

Alarm setting	Type 1: for vaccine: DTP, DT, TT, HepB and combination vaccines		Type 2: for vaccine: OPV, freeze dried BCG, measles and MMR	
	≥ +45°C	1 hour single	≥ +45°C	1 hour single
	≥ +30°C	10 hours cumulative	≥ +30°C	10 hours cumulative
	≥ -0.5°C	1 hour single	≥ +10°C	20 hours cumulative
Initial start delay	1 hour		1 hour	

Annexure III

MODEL INSERT

Measles- Rubella (MR) Vaccine

DESCRIPTION:
Measles and Rubella Vaccine (Live) is a freeze-dried, preparation of suitable attenuated strains of measles virus and rubella virus grown in suitable cell cultures. The minimum virus concentration stated on the label is not less than 1000 CCID50 measles virus and 1000 CCID50 rubella virus per single human dose.

ADMINISTRATION:
It should be injected subcutaneously. The injection site should be outer mid-thigh/upper arm depending on the age. (An injection in to child's buttocks may cause injury to the sciatic nerve and is not recommended). 1 dose is of 0.5 ml.
A sterile needle and sterile syringe should be used for each injection. Once opened multi doses vials should be kept between +2° and +8° C. Reconstituted vials of vaccines should be used within 4 hours. The reconstituted vial must be discarded after 4 hours or at the end of session, whichever is earlier.

IMMUNIZATION SCHEDULE:
As per the national immunization programme.

SIDE EFFECTS:
Malaise, mild fever and rash 5-12 days later. It may result in joint symptoms manifested as arthralgia (25%) and arthritis (12%) among adolescents and adult females usually lasting few days to few weeks. These reactions are very rare in young children.

CONTRAINDICATIONS:
Severe reaction to the previous dose, pregnancy, congenital or acquired immune disorders (not HIV infection). Although it is not recommended to administer the vaccine during pregnancy, there has never been any evidence of damage to the foetus from vaccinating the mother during pregnancy.

STORAGE:
Between +2°C and +8°C.

PRESENTATION:
The vaccine comes in vial of 5/10 doses.

Annexure- IV

VACCINE ARRIVAL REPORT (VAR)

This report is to be filled in by an authorized staff and forwarded to the Supplier within 3 days of vaccine arrival. Use one report for each vaccine in the shipment.

COUNTRY	INDIA
REPORT No.	

Date of Report	

Place, Date and Time of Inspection	Name of Cold Store, Date and Time vaccines entered in Cold Store

PART I- ADVANCE NOTICE

MAIN DOCUMENTS	Date received by Consignee	Copy Airway Bill (AWB)	Copy of Packing List	Copy of Invoice	Copy of Release Certificate
Pre- advice					
Shipping Notification		Yes No	Yes No	Yes No	Yes No

List of Other Documents (If required)

PART II- FLIGHT ARRIVAL DETAILS

AWB Number	Airport of Destination	Flight No.	ETA as per notification		Actual Time of Arrival	
			Time	Date	Date	Time

Name of Clearing Agent:	**On behalf of:**

PART III- DETAILS OF VACCINE SHIPMENT

Purchase Order No.	Consignee	Vaccine Description (type & doses/vial)	Manufacture	Country

VACCINE				DILUENT/DROPPERS			
Lot Number	No. of Boxes	No. of Vials	Expiry Date	Lot Number	No. of Boxes	No. of Vials	Expiry Date

	Yes	No	Comments
Was quantity received as per shipping notification?			
If not, were the details of short-shipment provided prior to vaccine arrival?			

Report No	

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PART IV-DOCUMENTS ACCOMPANYING THE SHIPMENT

Invoice		Packing List		Release Certificate		Vaccine Arrival Report		Other
Yes	No	Yes	No	Yes	No	Yes	No	
Comments								

PART V – STATUS OF SHIPPING INDICATORS

Total No. of Boxes Inspected		
Coolant Type:	Ice packs / Any Other	No coolant
Temperature Monitors Present:	VVM	Recorder

PROVIDE BELOW THE DETAILS OF THE STATUS ONLY WHEN PROBLEMS ARE OBSERVED

Box No.	Lot No.	VVM Stage				Cold Chain Monitor				Freeze Watch Burst		Date/Time of Inspection
		1	2	3	4	A	B	C	D	Yes	No	

Temperature Recorder If applicable, send clear copy of chart (together with this report)	Box Number	Model	Serial no

PART VI – GENERAL CONDITIONS

What was the condition of boxes on arrival?	
Were necessary labels attached to shipping boxes?	
Other Comments: (continue in separate sheet if necessary)	

PART VII-NAME AND SIGNATURE

Authorized Inspection Supervisor **Date** **Officer/In-Charge** **Date**

Ms.Swati Srivastava, CDSCO HQ

Dr. Raj Shankar Ghosh, BMGF

Dr. Nivedita Gupta, ICMR

Dr. Srihari Dutta, UNICEF

Dr. Dipika Sur, THSTI

Dr. Manoj Grover, ITSU

Dr. M.K. Aggarwal, MoHFW

Dr. Yashika Negi, MoHFW-ITSU

Dr. Sourabh Saxena, MoHFW-ITSU

22-07-15

Dr. N.S. Dharmshaktu, Additional DG

Dr. N.S. Dharmshaktu / Dr. N.S. Dharmshaktu
Additional Director General of Health Services (PH) / DGHS
Directorate General of Health Services, Nirman Bhawan, New Delhi

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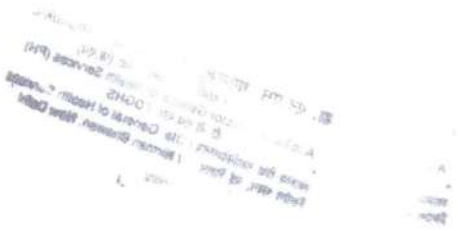


Corrigendum to the Technical specification of MR vaccine:

The following amendment is hereby authorized in the technical specification :

A. In the Vaccine Specifications of MR Vaccine Page No.1, Point A , under "ITEM" details and should be read as below:

For : Measles Rubella(MR) Vaccine shall meet the requirement of latest Indian Pharmacopoeia (IP) 2014.

Read : Measles Rubella(MR) Vaccine shall meet the requirement of latest Indian Pharmacopoeia (IP)

B. under point **"Protocol & testing"**

Each Batch should be accompanied with a certificate from the manufacturer that the vaccine meets the latest I.P"

-----**In the "Model Inserts", Annexure III under Administration, the amendment should be as under :**

For :The reconstituted vial must be discarded after 4 hours or at the end of session, whichever is earlier."

Read :"**Once the vaccine has been reconstituted, it should be used immediately. If the vaccine is not used immediately then it should be stored at 2°C to 8°C for no longer than 6 hour. The reconstituted product should be discarded at the end of immunization session, or within six hours of opening, whichever is earlier."**

3. In the Point B , under **"Evidence",** these lines should be read as below:

For : The supplier shall retain a sample of Twenty (20) vials from each lot shipped for Two years beyond the Printed Expiration Date

Read :"The supplier shall retain a sample of Twenty (20) vials from each lot shipped for **Three Months** beyond the Printed Expiration Date."

4. In the Vaccine Specifications MR under clause **Dose package:**

For

Freeze-dried vaccine with sterile diluent in corresponding quantity (specifically prepared for diluting MR vaccine), packed separately, in 05/10 doses per vial. Container must protect vaccine from exposure to light.

Read

Freeze-dried vaccine with sterile diluent in corresponding quantity (specifically prepared for diluting MR vaccine), packed separately, **in 05 doses per vial.** Container must protect vaccine from exposure to light.

Tetanus toxoid with adult diphtheria (Td) vaccine specifications

(For NCB/ICB)

A. Specific requirements

Item

Td vaccine shall meet the requirements of the Indian Pharmacopeia (IP) and Drugs and Cosmetics Act and Rules thereunder.

The vaccine shall meet all the requirements of Drugs and Cosmetics Act if manufactured in India. However, in the cases of international transactions, the vaccine shall meet all the requirements of the country of origin and the vaccine shall be registered with the Drugs Controller General of India (DCGI).

Description

Tetanus toxoid with adult diphtheria (Td) vaccine is an adsorbed vaccine which is a suspension for intramuscular use. The vaccine shall contain appropriate amount of individual components per human dose as approved by the Drugs Controller General of India, if manufactured in India or as approved by regulatory authority in the country of origin. The vaccine shall be registered with the Drugs Controller General of India.

The unit of concentration per human dose varies with the product and it should comply with DCGI certification.

Protocol and Testing

Complete test protocol along with samples of all batches should be sent to the Head of the vaccine testing laboratory i.e. Central Drugs Laboratory, Kasauli, Himachal Pradesh.

For local manufacturers

Complete test protocol and samples are taken and sent by the inspecting officer and duly sealed and signed by him/her or his/her authorized representative.

Dosage schedule

The Td vaccine dose is 0.5 ml and is administered intramuscularly. TT vaccine will be replaced with Td vaccine in India's immunization programme for adolescents and adults, including pregnant women.

Dose package

The vaccine shall be presented as a suspension containing the requisite amount of individual components as approved by the DCGI or Regulatory Authority of the country of origin. The vaccine should be multi dose with reuse of open vial as per the national guidelines.

Dose size

By intramuscular injection; 0.5ml of liquid vaccine.

Filling volume

Final product should contain sufficient overfill to deliver the required volume and number of doses per vial.

Storage temperature

The vaccine should be stored at a temperature between +2°C to +8°C and should be protected from light. It should be discarded if frozen.

Shelf life

At least 24 months from the date of manufacture when stored at recommended temperatures. The supplier will provide manufacturer's stability test data substantiating 24 months shelf life in the proposed vial. At least four-fifth of shelf life must remain after shipment.

Labelling

The label on each vial shall conform to the requirements of IP and shall appear in English language. All labelling shall be in indelible ink and shall withstand immersion in water and remain intact.

All labels shall state name of the manufacturer, address of manufacturer, date of manufacture, lot number, composition, concentration, dose and mode of administration, expiry date, storage temperature and any other marking that is appropriate.

All labelling should be conforming to the provisions under the Drug and Cosmetics Act, Rule 96.

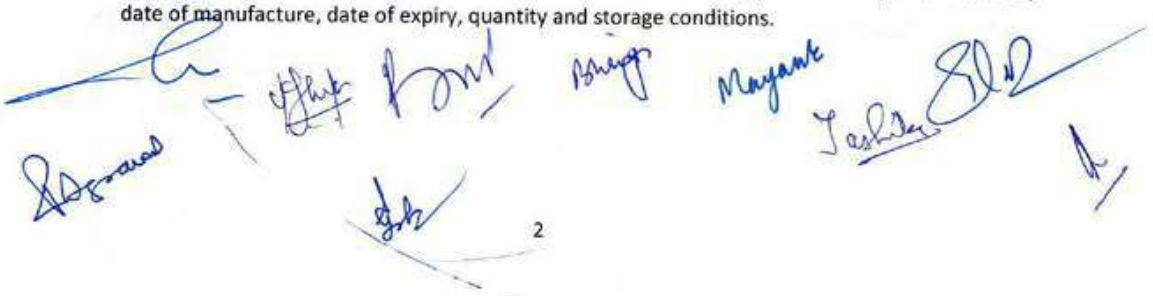
Vaccine Vial Monitor

Each vaccine vial has to have a VVM. The Vaccine Vial Monitor (VVM) shall be as per WHO Vaccine Vial Monitor Specifications 2011 (Refer to Annexure I).

The label on each vial should include a Vaccine Vial Monitor (VVM) designed to meet the heat stability curve of the vaccine supplied. This is a time temperature dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond acceptable level. Each vaccine vial has to have a VVM.

Labelling for secondary packaging

A label must be affixed either to the top and/ or front surface of the secondary packages. It should indicate the type of vaccine, the name of manufacturer, presentation, batch number, date of manufacture, date of expiry, quantity and storage conditions.



Labelling for tertiary packaging

The external surface of insulated packages should be either white or in the natural colour of corrugated carton. Dark colours must be avoided. All labels on tertiary packaging must be attached to all four sides.

Vaccine rush

A label of must be affixed to all four sides of the vaccine package in English/ Hindi ("Vaccine Rush").

Do not freeze

"Do not freeze" sticker should be attached to all four sides of the vaccine package.

Numbering of tertiary packaging

All boxes should be numbered consecutively. Shipping documents should be included in the box labelled number 1, and this box should clearly be labelled with following words-
"Containing vaccine shipping documents"

Additional labelling

The vaccine container and other outer containers shall be marked with the statement "CGS NOT FOR SALE" in English.

All the labels on the containers i.e. vials, cartons etc. should be marked with the statement "CGS NOT FOR SALE" in bold red letters in English.

Containers

IP type I glass tamper proof vials as approved by DCGI.

Closures

Vaccine vial shall be fitted with closures that conform to IP 2014 requirements for injectable preparations.

Printed materials

Two (2) information sheets, printed in at least English and Hindi, shall be included in each secondary package.

B. <u>Quality Assurance</u>

Compliance

The 'supplier' shall guarantee that the products as packed for shipment

a. Comply with all provisions of the specifications and related documentation
b. Meet IP/ international (WHO recognized) standards for safety, efficacy and quality
c. Are fit for the purposes made known to the Seller
d. Are free from defects in workmanship and in material
e. Product has been manufactured under cGMP included in Schedule M.

Evidence

The 'supplier' shall provide evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned. The 'supplier' shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for shipment. The 'supplier' shall provide a copy of the **Validation Record** with regards to process validation demonstrating batch to batch consistency and to confirm that the packaging complies with WHO requirements. The 'supplier' shall provide a copy of the Certificate of Analysis for each lot intended for shipment. The 'supplier' shall provide to the Purchaser a copy of the approval of each source material, constituent material and component for each lot intended for shipment. The 'supplier' shall retain a sample of twenty (20) vials from each lot shipped for two years beyond printed expiration date. Chemical, physical and biological test data for in-process and finished product testing must be on record for each lot shipped and must be available to Purchaser's representatives when requested.

Inspection

The Purchaser may inspect and sample, or cause to be sampled, the product at the 'supplier's' factory and/ or warehouse at a mutually agreeable time prior to the shipment of the product.

Testing

The Purchaser may cause independent laboratory testing to be performed as deemed necessary to assure that goods conform to the prescribed requirements. The said laboratory testing shall be of the Purchaser's choice if suitably equipped and qualified to conduct quality assurance tests on biological products.

VVM testing:

Maintain not less than 3 containers of the final lot at an elevated temperature for a defined time period using conditions found suitable for the particular product as approved by the local National Regulatory Authority, as per IP 2014, which should be submitted by the manufacturers to DCGI.

C. <u>Packing</u>

Prior to and at the time of packing, the vaccines must be kept within the storage temperature limits recommended by the manufacturer.

Storage

Supplier shall state storage volume occupied per infant dose of vaccine (storage volume includes the vaccine vial, packet containing the vaccine vial and any intermediate packaging).

Inner boxes

_____ (number) individual glass vials or ampoules shall be contained in sturdy white cardboard boxes (of not less than 300 GSM) outfitted with individual segments for protecting and separating each vial.

Freeze indicator devices

To be included in all vaccine shipments to document that the temperature limits have not been breached during shipment. One electronic temperature device to be included in each shipping carton (Refer to Annexure II).

For vaccine requiring storage at +2°C to +8°C:

Vaccine manufacturer is required to validate their packaging twice for a period of 48 hours (i) that the warmest temperature inside the insulated packing does not rise above + 30°C in the continuous outside ambient temperature of + 43°C and (ii) that the coolest storage temperature does not fall below + 2°C in the continuous outside temperature of -5°C.

Over packing

Box shall be over packed so that the vaccine remains refrigerated at the recommended temperature for specific vaccine as per CDSCO license. The containers must be suitable for export shipping in accordance with *WHO guidelines on the international packaging and shipping of vaccines* (WHO/IVB/05.23). The containers must have adequate insulation and or sufficient refrigerant to ensure that the warmest storage temperature of the vaccine does not rise above + 30°C in continuous outside ambient temperature of + 43°C during transit and for a period of at least 48 hours after arrival at the consignee point.[1]

Additional cushioning shall be provided, sufficient to protect the vials from breakage during transit and handling.

Exterior shipping carton

Product and printed materials, packaged as specified above, shall be packed in weather-resistant, triple-wall corrugated fiberboard cartons with a bursting test strength of not less than 1900 kPa.

The overall dimensions of the exterior shipping cartons should be such that the product does not become damaged during transportation and storage.

Each shipping carton should weigh less than 50 kg. It is important that individual boxes are not too heavy during transport as they are frequently loaded and offloaded manually at airports and intermediate stores.

D. <u>Markings</u>

All containers and invoices must bear the name of vaccine, batch number, manufacturing date, expiry dates of the vaccine and appropriate storage temperature.

Inner boxes:

The inner boxes shall be marked with the following information which is acceptable to the Purchaser:

- Generic name and trade name of the vaccine

[1] When considering "best practices" for transport and storage of vaccines, reference should be made to current recommended Good Distribution Practices for Biological Products by CDSCO.

- Manufacturer's name and registered address
- Manufacturer's national registration number
- Lot or batch number
- Composition and concentration
- Number of vials contained in box
- Date of manufacture (month and year)
- Expiration date (month and year)
- Instructions for storage and handling[2]
- Place of manufacture (Made in_____)

Exterior shipping cartons:

The following information shall be stenciled or labeled on the exterior shipping cartons on opposing sides in bold letters, at least 'Arial Font size 14', high with waterproof ink in a clearly legible manner which is acceptable to the Purchaser:

- Generic name and trade name of the vaccine
- Lot or batch number
- Date of manufacture (month and year)
- Expiration date (month and year)
- Manufacturer's name and registered address
- Manufacturer's national registration number
- Destination country license or registration number
- Consignees address and emergency phone number
- Destination airport
- Contract number
- Number of vials contained in the carton
- Gross weight of each carton (in kg)
- Carton containing -- secondary packages
- Instructions for storage and handling[2]
- Place of manufacture (Made in _____)

E. Documentation

Supplier shall provide to Purchaser a copy of the batch record, including all quality assurance documentation for the vaccine being supplied.

Advance notice of arrival and advance shipping documentation:

Copies of the documentation for the goods to be shipped must be sent at least days in advance of arrival of the shipment. In the case of an individual contract for a specific destination that requires a longer period of advance notice, a longer period should apply.

The consignee(s) shall be intimated well in advance by registered letter/fax, email and telephone, so that vaccines are received immediately after arrival. Copy of the communication from the supplying firm shall be endorsed to the Deputy Commissioner (Imm/UIP) and Deputy

[2] To be provided by Supplier

Director (UIP), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi for information.

The documentation must include the following:

- Pre-advice defined by the Purchaser
- Airway bill (AWB)
- Supplier's invoice
- Packing list
- Lot release certificate (LRC) issued by the national regulatory authority (NRA) of the country of manufacture for each lot of vaccine supplied; and
- Any other document, certificate or instruction specified in the individual order

The documents should be sent by e-mail and fax by the freight forwarder or the manufacturer to the consignees, the Purchaser, and any other parties specified in the individual contract.

The pre-advice must contain the following information:

- Purchase order reference
- Consignee requisition reference
- Number of packages, gross weight (in kilograms) and volume (in cubic meters)
- Type of vaccine, total number of vials and number of doses per vial/ampoule/ tube
- Date and time for place of departure, transit (if applicable), and arrival:
- Instructions for collection
- Any other information specified in the individual contract must also be included for the consignee.

The following information shall be stated on the airway bill:

- Consignee's name, address and telephone number (including mobile no.) and email ID
- Purchase order reference
- Consignee's requisition reference
- Type of vaccine and quantity
- Instructions to; "Telephone consignee upon arrival (repeat telephone number)",
- Handling information: "**Medicines- Vaccine- For human use - Highly Perishable- Not to be delayed**".

The following instruction should be stated in the AWB: "Throughout shipment, pending reshipment and prior to collection by the consignee, the vaccine must be stored at + 2°C to +8°C.

F. Dispatch

Vaccines should travel by a direct route wherever possible; road transport may be used if accompanied by attendant. Where trans-shipment is unavoidable, the journey should be planned through airports that:

a. Have cold storage facilities, and
b. Are located in countries with a temperate climate

The maximum transit time from the manufacturer to arrival at the final destination must not exceed 48 hours.

Shipments should be scheduled to arrive outside weekends and/or public holidays at the consignee points and bookings should be made well ahead of the date of departure.

- Vaccines must not be transported with radioactive products, fish or meat
- Correct cold-chain procedures must be observed during transit, warehousing and shipping (i.e., all vaccines must be kept in temperature controlled environments at all times throughout the shipment process)
- Reactivation of the refrigeration process of shipments must be performed in accordance with the instructions of the supplier of each shipment whenever deemed necessary

G. References

1. Indian Pharmacopoeia 2014, Indian Pharmacopoeia Commission, Government of India; Ministry of Health & Family Welfare, Ghaziabad
2. Guidelines on the international packaging and shipping of vaccines, WHO 2005; Department of Immunization, Vaccines and Biologicals. WHO/IVB/ 05.23.
3. WHO revised VVM specifications 2011, WHO/PQS/EO6/INO5.2
4. Procurement of vaccines for public-sector programmes- A reference manual. WHO/IVB/03.16; 2004.
5. WHO/IVB/05.23
6. WHO/IVB/04.06
7. WHO/O/UNICEF Product specifications
8. WHO Technical Requirement Specifications (TRS) 941, Annex 3
9. Guidelines on Good Distribution Practices for Biological Products, 2012, CDSCO (CDSCO/GDP/BP ver:00)

Annexure- I:

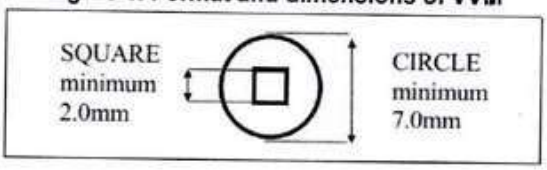
SPECIFICATION FOR VACCINE VIAL MONTITORS (VVM)

Specification reference: **E06/IN05.2**
Product verification protocol: **E06/IN05.VP.2**

1. **Scope:**
   This specification describes the performance requirements for a Vaccine Vial Monitor (VVM) suitable for application to a vaccine vial by a vaccine manufacturer. The product is used to indicate the cumulative heat exposure of a vial of vaccine so that health workers know whether the cumulative heat history of the product has exceeded a pre-set limit.

2. **Requirements:**
   2.1 General: Vaccine Vial Monitor suitable for application to a vaccine vial by a vaccine manufacturer.
   The principal purpose of this product is to warn health workers when the cumulative heat exposure of a vial of vaccine has exceeded a pre-set limit, beyond which the vaccine should not be used. This is defined as the end point.
   Before the end point is reached, changes in the appearance of the VVM are used to alert health workers to the fact that heat exposure has occurred. Heatexposed vials can then be used in preference to those that have not been exposed.
   2.2 *Performance:*
   2.2.1 Format and dimensions: The VVM is a circle of colour, minimum diameter 7.0mm with a square of colour, minimum dimensions 2.0 x 2.0mm positioned in the centre of the circle (See Figure 1). Whatever dimensions are chosen, the ratio of the area of the square to the area of the circle (including the square) is to be at least 0.1:1.

Figure 1. Format and dimensions of VVM



2.2.2 Design: The circle of the VVM comprises a static, reference surface and the square comprises the active surface. The colour change of the active surface is limited to a change of shade, from light to dark. Any colour is permitted for the VVM design, but changes in hue are not permitted.

2.2.3 Colour density change: The colour density change of the indicator is illustrated in the Figure 2 below. At the start point the colour of the square is lighter than the circle. The end point is indicated when the colour of the square matches the circle. The end point is exceeded when the colour of the square is darker than the circle. The following clauses describe the colour change in more detail.

Figure 2. The colour density change of the indicator

Start point		Square lighter than circle
End point		Square matches the circle
End point exceeded		Square darker than the circle

Note: the central square is the active surface.

2.2.4 Colour at start point and end point:

- At the start point, the colour density of the square as measured by an X-rite Model 500 series spectrodensitometer, must be lighter than the colour shade of the circle by a difference of at least 0.25 OD densitometer units for all VVM except for the VVM2 Dots on Brown Liner where the minimum difference will be 0.23 OD.
- The end point is reached when the difference in the average colour density obtained from readings at least two different points on the circle and the colour density of the square is 0.00 OD, as measured by the densitometer. The end point is exceeded when the colour of the square is darker than the colour of the circle.
- The specifications for the Start R-I and the Indicator OD are shown in Table 1.

Table 1: Start R-I and Indicator OD

Category, Liner	Start R-I	Active Surface Start OD (I)
VVM 30, White and Clear Liner	0.52 ± 0.11	0.09 ± 0.04
VVM 30, Brown Liner	0.49 ± 0.11	0.12 ± 0.04
VVM 14, White and Clear Liner	0.41 ± 0.09	0.10 ± 0.04
VVM 14 Brown Liner	0.38 ± 0.09	0.13 ± 0.04
VVM 7, White Liner	0.41 ± 0.09	0.11 ± 0.04
VVM 7, Brown Liner	0.38 ± 0.09	0.13 ± 0.04
VVM 2, White Liner	0.32 ± 0.07	0.13 ± 0.05
VVM 2, Brown Liner	0.29 ± 0.06	0.16 ± 0.05

2.2.5 Homogeneity of the reference surface: The colour density of one 2mm diameter portion of the circle must be within 0.03 OD of the colour density at any other two 2mm diameter portions of the circle, when measured with a colour densitometer.

2.2.6 Variation of the reference surface within the lot: The colour density of one 2mm diameter portion of the reference circle of one sample must be within 0.03 OD of the colour density of the reference circle of any other sample within the same lot.

2.2.7 Reference surface colours: The colour of the reference area is specified in Table 2.

Table 2: Reference surface colours

Category, Liner	Reference Surface OD (R)
VVM 30, White and Clear Liner	0.61 ± 0.15
VVM 30, Brown Liner	0.61 ± 0.15
VVM 14, White and Clear Liner	0.51 ± 0.13
VVM 14 Brown Liner	0.51 ± 0.13
VVM 7, White Liner	0.52 ± 0.13
VVM 7, Brown Liner	0.51 ± 0.13
VVM 2, White Liner	0.45 ± 0.12
VVM 2, Brown Liner	0.45 ± 0.11

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2.2.8 *VVM reaction rates:* Reaction rates are specific to four different models of VVM, relating to four groups of vaccines according to their heat stability at two specific temperature points (See Table 3).

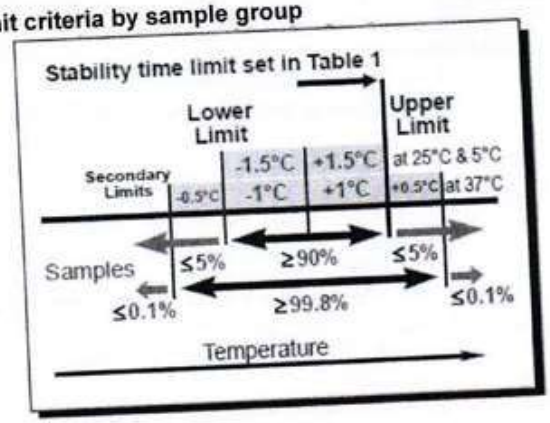
Table 3: VVM reaction rates by category of heat stability

Category (vaccines)	No. days to end point at +37°C	No. days to end point at +25°C	Time to end point at +5°C
VVM 30: High Stability	30	193	>4 years
VVM 14: Medium Stability	14	90	>3 years
VVM 7: Moderate Stability	7	45	>2 years
VVM 2: Least Stable	2	NA*	225 years

**VVM (Arrhenius) reaction rates determined at two temperature points*

- **At the +37°C specifications, RH 33% +/-5% and RH 75% +/-5%:** At least 90% of VVMs tested should reach the end point at the maximum time in the range of 36 ±1°C. Further, secondary limits are applied to restrict how far beyond the primary specification the TTIs are allowed to be. At least 99.8% of VVMs tested should reach the end point at the maximum time in the range of 36 ±1.5°C.
- **At the 5°C and +25°C specifications (ambient humidity in submerged foil/polythene pouch**): At least 90% of VVMs tested should reach the end point at the maximum time in the range of the specified temperature ±1.5°C.
- **Tolerance:** A tolerance is allowed in the above tests for up to 5% of VVM samples tested to reach the end point at a temperature above the upper limit and 5% at a temperature below the lower limit (See Figure 3).

Figure 3. Stability limit criteria by sample group



Allowable range of end points: Table 4 defines the allowable range of end points such that 90% of a production lot must reach the end point at the specified time within a range of ±1°C and that 99.8% of the lot must reach end point within a range of ±1.5°C.

Table 4: Allowable range of end points

VVM Type	Primary Limits: ±1°C measured at upper limit (including OD tolerance)		Secondary Limits: ±1.5°C measured at upper limit (including OD tolerance)	
	Lower Limit	Upper Limit	Lower Limit AQL= 0.1%	Upper Limit AQL= 0.1%
VVM 30	-0.19	0.03	-0.23	0.06
VVM 14	-0.15	0.03	-0.18	0.06
VVM 7	-0.11	0.03	-0.13	0.05
VVM 2	-0.09	0.03	-0.10	0.04

2.2.9 Global Measurement Accuracy: The allowable total error for measuring the difference between the colours of the circle and square is ± 0.03 OD when using an X-Rite 500 series spectrodensitometer or later qualified model. The measurement error for a single measurement is ± 0.02 OD. Major sources of error are instrument error, both for the circle and the square, repeatability, and variation in end point caused by an allowed temperature variation of ± 0.2°C. 500 series spectrodensitometers require a smaller target than what is provided by the manufacturer (X-Rite). Installation of the smaller target and centering of the aperture must be performed by the VVM manufacturer.

2.2.10 Water Bath Precision and Control: The VVMs should be tested in water baths controlled to within ± 0.2°C. (Any additional 0.1°C variation in temperature control requires an allowance for additional measurement error.)

2.2.11 Reversion: The indicator must not revert to a lighter colour at any point in its life when exposed to conditions likely to be found during normal use. After the endpoint is reached, the square must remain the same colour as the circle or become darker than the circle.

2.2.12 Integrity and location of VVMs:

Before a vial or ampoule is opened, the VVM should not be removable; it should resist removal from the vaccine vial as much as a label meeting current vaccine labeling requirements. In addition, the performance of the VVM should not be changed by soaking in water for 8 hours. Water-exposed samples should conform to within +/-0.04 OD units. The location of the VVM on the vial depends upon whether the vaccine must be discarded at the end of the immunization session in which it is opened, or whether any remaining contents in an opened vial can be retained for use in subsequent sessions. The following cases apply:

For multi-dose vials containing a vaccine that can be used in subsequent sessions: Regardless of the vaccine presentation (liquid, freeze-dried or two vial combinations of liquid and freeze-dried), the VVM must be permanently attached to the label of the vaccine vial and must remain readily observable before, during, and after use, until the entire contents of the vial have been used.

- **For vaccines that must be discarded at the end of the session or within 6 hours, whichever comes first:** The VVM must be attached to the vaccine vial or ampoule and must remain readily observable until the vial or ampoule is opened, but not observable after opening. In order to achieve this requirement, the VVM must be located on the flip-off top of a vial or on the neck of an ampoule. On a product by product basis, WHO will advise both the vaccine and the VVM manufacturer where the VVM is to be located. Locating the VVM on the bottom of a vial or ampoule is never acceptable – it must always be in a visible location.

2.2.13 Application Surfaces: VVMs must be designed to be applied to the following substrates:

- Glass (e.g., glass vials).
- Paperboard (e.g., primary or secondary packaging).

• Plastic containers of a composition for which permeation of adhesive components is not a risk.

For vial cap applications, VVM dots are designed to be applied to smooth, flat surfaces with no embossed areas, recessed areas, or ridges. The use of excessive release agents in the manufacture of the vial caps should be avoided.

Note: Each user should ensure there is adequate adhesion of the VVM to the vaccine container. Permanent adhesion may not be guaranteed when the VVM is applied to some plastic materials.

2.3 *Traceability:* Each roll of VVMs must be labeled with its product identity (part number) together with its lot number 3.

2.4 *Physical characteristics:* Overall dimensions: As clause 4.2.1, Figure 1.

2.5 *Interface requirements:*

None.

2.6 *Human factors:* The colour change must be monotonic in its response to cumulative heat exposure within the limits of the allowed variation. The observer must be able to distinguish between an unchanged indicator, a 50% colour change and the end point of the indicator.

2.7 *Materials:* The exposed surface of the VVM must not endanger human health. The materials of the VVM must be non-toxic and non-irritant. The VVM must meet any requirements in force concerning toxicity of labels or packaging in the country of manufacture.

2.8 *Reliability:* All batches of the product must be warranted to conform to the requirements of this specification.

2.9 *Servicing provision:* The product is to be maintenance-free.

2.10 *Disposal and recycling:* The product will be disposed of in conjunction with the vial to which it is attached.

2.11 *Instructions:* An instruction insert, providing vaccine manufacturers with all necessary storage, handling and application directions and traceability directions (with reference to clause 4.3) is to be supplied with every carton. The insert is to be printed in English. If any vaccine manufacturer requires an instruction insert in an additional language, this will be a matter for independent negotiation between the VVM manufacturer and the vaccine manufacturer.

2.12 *Training:* The VVM manufacturer must provide training for the vaccine manufacturer in order that the manufacturer can correctly handle, apply and test VVMs.

2.13 *Verification:* In accordance with PQS Verification Protocol **E06/IN05.VP.2.**

3. **Packaging:**

Materials used for packaging the finished product are to be free of CFC compounds as defined in the Montreal Protocol.

4. **On-site installation:**

VVMs will be applied to vaccine vials by vaccine manufacturers.

3 Vaccine manufacturers must keep records of the lot number of the VVMs affixed to each individual batch of vaccine.

5. **Product dossier:**

The legal manufacturer or reseller is to provide WHO with a pre-qualification dossier containing the following:

• Dossier examination fee in US dollars.
• General information about the legal manufacturer, including name and address.
• Unique identification reference for the product type.
• Full specifications of the product being offered, covering all the requirements set out in this document, including details of product marking and traceability.

• Details of the legal manufacturer's internal AQL sampling procedures in respect of ISO 3951:1989.
• Certified photocopies of the legal manufacturer's ISO 9001 quality system certification.
• Where relevant, certified photocopies of the legal manufacturer's ISO 14001 certification, EMAS registration or registration with an equivalent environmental audit scheme. Conformity with an environmental audit scheme is not mandatory; however preference will be given to manufacturers who are able to demonstrate compliance with good environmental practice.
• Where available, laboratory test report(s) proving conformity with the product specifications.
• A minimum of five samples of each of the four types of VVM shipped with frozen icepacks, together with instruction insert in English language.
• Indicative cost of the product per 10,000, per 100,000 units and per 1,000,000 units EXW (Incoterms 2010).

6. **On-site maintenance:**
   Not applicable.
7. **Change notification:**
   The legal manufacturer or reseller is to advise WHO in writing of any changes which adversely affect the performance of the product, in relation to any of the requirements set out in this specification, after PQS pre-qualification has taken place.
8. **Defect reporting:**
   The legal manufacturer or reseller is to advise WHO and the UN purchasing agencies in writing in the event of safety-related product recalls, component defects and other similar events.

Annexure II: Freeze Indicator Devices

The product will be packed with freezes sensitive vaccines during transport, during storage in fixed locations in a shipping carton, and will be used to warn of exposure to temperature below -5°C.

Performance:

Upper Limit	Lower Limit (without triggering alarm)	Lower Limit (without device failure)
+43°C	-0.5°C	-20°C

Accuracy: +_0.5°C or below at 0°C.
Power Source: Non replaceable battery
Sensor: Electronic sensor or irreversible phase change indicator.
Mode of operation: The product to be triggered by exposure to be a temperature of –0.5°C, +_0.5°C, for 60 minutes +_5 minutes maximum. It must not be possible for the end user to re-set the device after freezing event.
Calibration: Measurement standards and instrument standards used during calibration traceable to an ISO/ IEC 17025 accredited laboratory.
Casing:

- **Electronic devices**: The sensor and other working parts are to be housed in a non-corrodible water-resistant casing.
- **Passive devices**: The device must stay unaffected by overall wetting.

IP rating: For Electronic Devices Protection of the product not less than IEC 60529:IP64
Battery Life: Minimum acceptable battery life for electronic products, with the product switched on, measured at any point in the operating temperature range, is to be 3 years.
Shelf Life: Minimum 3 years from the date of manufacture, inclusive of operational life.
Electromagnetic compatibility: Must remain unaffected in the normal electromagnetic environment compatibility in which it is intended to work.
Environment Requirements: Ambient Temperature during transport and storage: 5°C to 55°C with device inactivated.
Ambient humidity range during transport and use: 0 to 95% RH.
Electrical storm activity: Must remain unaffected by intense electrical storm activity.
Impact resistance: To withstand 5 drops from 1 meter onto a concrete floor, when cooled to a temperature of +3°C, without physical damage or loss of calibration.
Vibration: To withstand 30 minutes on a programmable vibrating table without physical damage or loss of calibration.
Physical Characteristics: Overall Dimensions: Not exceeding 100X50X25 mm
Human Factors:
Activation: The product may be supplied already activated. Alternatively, if the device is to be activated by the user, it should be irreversible.
User interface for phase change products: Triggering should effect irreversible colour change from a light to dark, distinguishable by users with all forms of colour blindness.
User interface for LED indicators only: The indicator must provide the user the following information by unambiguous combinations of steady or flashing lights.

- That the product is activated
- That the battery is functioning
- Whether the temperature of the load has remained above 0°C or
- Whether the temperature of the load fallen below 0°C.

Clear instructions on interpreting the display must be printed on the product in graphical form that is not language dependent.
User Interface for products with LCD displays: The product is to have an LCD display with or without LEDs, capable of showing the following information:

- That the product is activated
- That the battery is functioning.
- Whether the temperature of the load has remained above 0°C or
- Whether the temperature of the load fallen below 0°C

The status of the load must be clearly and permanently indicated on LCD. Indicator symbols must not be language dependent and must be easily understood by untrained users. Acceptable indicators include, but not confined to the following:
'Tick' or **'OK'** symbol for temperature above 0°C

OR

'Cross' or **'Crossed OK'** symbol for exposure to 0°C or less
Legibility: It must be possible for a person with normal visual acuity (With or without glasses) to read the indicator both in bright sunlight and in tungsten/fluorescent lighting at 100 lux on the working lane, both before and after exposure to the triggered temperature.
Mounting device: For attaching it to vaccine, load- a-self-adhesive strip or an eyelet.
Materials: During manufacture of the product, ozone depleting substances included in Montreal Protocol should not be used neither the components should contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls or polybrominated biphenyl ethers.
Warranty: one year replacement warranty
Packaging: Material used for packaging should be free from ozone depleting chemicals as per Montreal Protocol.

Reference: WHO/PQS/F06/INO3.1 dated 30 November 2006

Annexure III: Model Insert

Model insert to be provided by the manufacturer as per the DCGI guidelines.

Annexure- IV

VACCINE ARRIVAL REPORT (VAR)

This report is to be filled in by an authorized staff and forwarded to the Supplier within 3 days of vaccine arrival. Use one report for each vaccine in the shipment.

COUNTRY	**INDIA**
REPORT No.	

Date of Report	

Place, Date and Time of Inspection	Name of Cold Store, Date and Time vaccines entered in Cold Store

PART I- ADVANCE NOTICE

MAIN DOCUMENTS	Date received by Consignee	Copy Airway Bill (AWB)	Copy of Packing List	Copy of Invoice	Copy of Release Certificate
Pre- advice					
Shipping Notification		Yes No	Yes No	Yes No	Yes No

List of Other Documents (If required)

PART II- FLIGHT ARRIVAL DETAILS

AWB Number	Airport of Destination	Flight No.	ETA as per notification		Actual Time of Arrival	
			Time	Date	Date	Time

Name of Clearing Agent:	**On behalf of:**

PART III- DETAILS OF VACCINE SHIPMENT

Purchase Order No.	Consignee	Vaccine Description (type & doses/vial)	Manufacture	Country

VACCINE				**DILUENT/DROPPERS**			
Lot Number	No. of Boxes	No. of Vials	Expiry Date	Lot Number	No. of Boxes	No. of Vials	Expiry Date

	Yes	No	Comments
Was quantity received as per shipping notification?			
If not, were the details of short-shipment provided prior to vaccine arrival?			

Report No	

PART IV-DOCUMENTS ACCOMPANYING THE SHIPMENT

Invoice	Packing List	Release Certificate	Vaccine Arrival Report	Other
Yes No	Yes No	Yes No	Yes No	
Comments				

PART V – STATUS OF SHIPPING INDICATORS

Total No. of Boxes Inspected		
Coolant Type:	Ice packs / Any Other	No coolant
Temperature Monitors Present:	VVM	Recorder

PROVIDE BELOW THE DETAILS OF THE STATUS ONLY WHEN PROBLEMS ARE OBSERVED

Box No.	Lot No.	VVM Stage				Cold Chain Monitor				Freeze Watch Burst		Date/Time of Inspection
		1	2	3	4	A	B	C	D	Yes	No	

Temperature Recorder	Box Number	Model	Serial no
If applicable, send clear copy of chart (together with this report)			

PART VI – GENERAL CONDITIONS

What was the condition of boxes on arrival?	
Were necessary labels attached to shipping boxes?	
Other Comments: (continue in separate sheet if necessary)	

PART VII-NAME AND SIGNATURE

Authorized Inspection Supervisor **Date** **Officer/In-Charge** **Date**

* * * * * * * * *

Dr. Yogesh Sheler, CDSCO HQ

Dr. Balwinder Singh, WHO

Dr. Bhrigu Kapuria, UNICEF

Dr. Pritu Dhalaria, ITSU

Dr. Pradeep Haldar, MoHFW

Dr. Veena Dhawan, MoHFW

Dr. Mayank Shersiya, ITSU

Dr. Yashika Negi, Imm Div., MoHFW

Dr. Pankaj Agrawal, Imm Div., MoHFW

Dr. A K Gadpayle, Additional DGHS, MoHFW

Inactivated poliovirus vaccine (IPV) Liquid Formulation Specifications

(For NCB/ICB)

A. Specific requirements

The manufacturer should have a valid drug manufacturing license. The vaccine shall meet all the requirements of Drugs & Cosmetic Act and conform to Indian Pharmacopeia(IP) 2014 and the amendments thereof or WHO pre-qualified as applicable. The vaccine shouldalso be registered with Drugs Controller General of India(DCGI). DCGI is the National RegulatoryAuthority (NRA).

Description: Poliomyelitisvaccine (Inactivated) is a liquid preparation of suitable strains of human polioviruses 1, 2 and 3 grown in suitable cell cultures and inactivated by a validated method.

Protocol and testing:

Complete Test Protocol along with samples of all batches should be sent to the Head of the vaccine testing laboratory - Central Drugs Laboratory Kasauli-173204.

Production and testing:

The vaccines shall be produced and tested in conformity with the requirements of Drugs and Cosmetics Act, 1940 and Rules, amended in the year 2014.

For local manufacturers:

Complete Test Protocol and samples are taken and sent duly sealed and signed by the Inspecting Officer or by his authorized representative to the vaccine testing laboratory.

The vaccine should be dispatched to the consigneeonly on clearance from the Central Drugs Laboratory, Kasauli. The vaccine will be released on the basis of protocol scrutiny and testing of the vaccine by Central Drugs Laboratory,Kasauli. Each batch should be accompanied with a certificate from the manufacturer that vaccine meets the I.P 2014 requirements.

Vaccines:

Vaccines should meet the requirements or recommendations to assure the quality, safety and efficacy of poliomyelitis vaccine (inactivated)according to *WHO Technical Requirement Specification (TRS) 933,Annex 3, 2015.Replacement of: TRS 910, Annex 2*

http://www.who.int/biologicals/areas/vaccines/IPV_Recommendations_to_assure_the_quality_safety_and_efficacy_IPV_ECBS_adopted_2014.pdf?ua=1

The general manufacturing requirements contained in Good manufacturing practices for pharmaceutical products: main principles (42) and Good manufacturing practices for biological products (43) should apply to establishments manufacturing IPV.

In general, wIPV that have been formulated to contain 40, 8 and 32 D-antigen units or more per dose for types 1, 2 and 3 respectively are effective. Vaccines with lower D-antigen contents may be acceptable if supported by clinical data.

2-Phenoxyethanol has been the only preservative used by IPV manufacturers during the past 50 years as the use of thiomersal can result in loss of D-antigen content.

IPV should not contain more than 10µg of protein per human dose. If animal serum is used for the growth of cell cultures, the serum concentration (bovine serum albumin) in the final lot should be no more than 50ng per human dose. The test for bovine serum may be omitted if performed on the trivalent or final bulk, subject to approval by the DCGI/NRA.

Changes in formulation, methods or processes:

Change introduced in formulation, manufacturing process or in any other aspects which have potential impact on the identity, safety, efficacy and quality of the vaccine, requires DCGI/NRA approval in accordance with CDSCO guidance for industry for post approval changes.

National regulatory licensure requirements in India:

Only vaccines which are licensed by DCGI/NRAat the time of delivery shall be considered for an award. In the Qualitative proposal sheet attached as **Annexure-I,** Proposers are requested to provide information on status and timelines for registering their product(s) in India.

Dosage and administration:

0.5 ml vaccine administered as intramuscular injection on the anterolateral aspect of mid-thigh.

Presentation and dosage form: A stand-alone IPV in 5 and 10 dose presentations registered by DCGI/NRA.

Storage temperature:

The vaccineshould be stable when stored between $+2^0$C to $+8^0$ C for 24 months and ensure it is notfrozen.

Shelf-life:

Vaccine shall be supplied with the maximum shelf life possible consistent with current vaccine production technology and stability data. Unless specified otherwise by Ministry of Health and Family Welfare-Government of India (MoHFW-GoI), the remaining shelf life at the time of dispatch shall not be less than **18 months.**

Labelling:

The label on each vial shall conform to the requirements of Drugs and Cosmetic act, and I.P.2014. All labelling shall appear in English text, in indelible ink and shall withstand immersion in water and remain intact.

All labels shall state the name of the vaccine, name of the manufacturer, address of manufacturer, lot number, composition, concentration, dose and mode for administration, manufacturing and expiry date, storage temperature and number of doses per primary container.

Storage temperature and any other marking that is appropriate:

If the vaccine is formulated, filled and packaged from trivalent inactivated bulk antigen supplied by a pre-qualified IPV vaccine manufacturer and/or approved by NRA/DCGI in countryof manufacture, the source of bulk supply shall be indicated either on the label affixed on the primary container or on the packaging box.

Inserts shall be printedin English and approved by NRA/DCGI.

All labeling should be conforming to the provisions under the Drugs and Cosmetics Act, Rule 96.

Over labelling

Over labeling will only be accepted if the following criteria are met:

B. The over labeling of the vaccine has been approved by NRA/DCGI.
C. Government of India is consulted prior to delivery.

VVM:

The label on each vial should have an appropriate Vaccine Vial Monitor (VVM) complying with WHO specifications designed to meet the heat stability curve of the vaccine to be supplied. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level. The firm should furnish all detailed information to the procurement division.

The WHO specifications can be referred at: "WHO PQS performance Specification (WHO/PQS/E06/IN05.2 issued on 26 July 2011) and meets these as per the PQS independent type-testing protocol performance specification (WHO/PQS/E06/IN05.VP.2 issued on 9th May 2011) – **(Annexure-II).**

Labelling for secondary packaging:

A label must be affixed either to the top and/or front surface of the secondary packages. It should indicate the type of vaccine, the name of the manufacturer, presentation, batch number, date of manufacture, date of expiry, quantity and storage conditions.

Labelling for tertiary packaging (insulated packaging):

The external surface of insulated packages should be either white or in the natural color of corrugated carton. Dark colors must be avoided.

Labels reading "vaccine-rush" must be affixed to all four sides of tertiary packaging.

Numbering of tertiary packaging:

All boxes should be numbered consecutively. Shipping documents should be included in the box labeled number 1, and this box should be clearly labeled with the words**: "Containing vaccine shipping documents".**

Additional Labelling:

All the containers and other outer containers shall be marked with the statement "CGS NOT FOR SALE" in English.

All labels on containers i.e. vials, cartons should be marked with the statement "CGS NOT FOR SALE" in bold red letters in English.

Containers:

IP Type I plain glass tamperproof vials.

Closures:

Vaccine vials shall be fitted with closures that conform to IP 2014requirements for injectable preparations.

The container/closure system must be the same as submitted for DCGI/NRA registration. Any change should be approved by DCGI/NRA.

Printed materials (Vaccine or package inserts):

Two Information sheetsprinted in Englishshall be included in each secondary package and shall include information as per **Annexure-III.**

Release certification:

Final acceptance of vaccines shall be subject to lot release by NRA.

Lot release certificates and Production and Control Summary Lot Protocols shall be provided upon request to consignees.

B. Quality assurance

Compliance:

The Supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of the specification and related documents; (b) meet Drugs and Cosmetic act and I.P recognized standard for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller; (d) are free from defects in workmanship and in materials; and (e) that the product has been manufactured according to cGMP included in Schedule M.

Evidence:

The Supplier shall provide objective evidence acceptable to MoHFW, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned. The Supplier shall provide a copy of the manufacturing record and procedures to the MoHFW for each lot intended for shipment. The Supplier shall provide a copy of Validation record with regards to process validation demonstrating batch to batch consistency and to confirm that the packaging complies with Drugs and Cosmetic act. The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment. The Supplier shall provide to MoHFW a copy of the approval of each source material, constituent material and component for each lot intended for shipment. The Supplier shall retain a sample of twenty (20) vials from each lot shipped for a period of at least two years beyond the printed expiration date. Chemical, physical and biological test date for in-process and finished product testing must be on record for each lot shipped and must be available to MoHFWrepresentatives when requested.

Inspection:

MoHFWmay inspect any sample, or cause to be sampled, the product at the Supplier‟s factory and/or warehouse at a mutually agreeable time prior to the shipment of the product.

Testing:

The MoHFWmay cause independent laboratory testing to be performed as deemed necessary to assure that the goods conform to the prescribed requirements.

C. Packing

Prior to and at the time of packing, the vaccines must be kept within the storage temperature limits recommended.

Retention of samples and testing:

Samples of each batch of vaccine supplied under any resulting arrangement shall be retained by the supplier for twoyears beyond expiry date. A total of **20 vials of IPV as samples**have to be retained for each presentation of vaccine. These samples shall be provided, upon request, to NRA for testing.

Inspection of facilities:

The Supplier shall permit MOHFW and NRA, or their representatives as may be designated under notice to the Supplier, to have access to their manufacturing and warehouse facilities at all reasonable times to assess (or periodically reassess) the production and capacity, testing, packaging and storage of the goods, and shall provide reasonable assistance for such assessment including the provision of copies of manufacturing protocols, lot production records, test results or quality control reports.

The frequency, scope and need for assessment/reassessment will be based on quality risk management principles. Reassessments will as a general rule include a site audit.

Packing and Shipping:

The cost of packaging, packing and all temperature monitoring devices must be included in the offered price. Manufacturer is required to specify the price implications of temperature monitoring devices on the packing details sheet.

All containers, invoices and shipping documents are to bear the expiry dates of the vaccine and appropriate storage temperatures.

Temperature monitoring during packaging and shipment:

Vaccine manufacturer is required to validate their packaging twice for a period of 48 hours with the objective to show i) that the warmest temperature inside the insulated packing does not rise above $+30^0$ C in the continuous outside ambient temperature of $+43^0$ C and ii) that the coolest storage temperature does not fall below $+2^0$ C in the continuous outside temperature of -5^0C.

In order to monitor the cold-chain during transit to consignee points, manufacturer is required to include Electronic shipping Indicator meeting the specifications laid down in WHO PQS E06/TR07.1 issued on 5 December 2006 and as applicable to IPV.

Electronic shipping Indicator:

One electronic temperature device should be included in each shipping carton to document that the temperature limits ($+2^0$C and $+8^0$C) have not been breached during shipment. The specifications for electronic shipping indicator can be seen in **Annexure-IV.**

Storage:

Supplier shall state storage volume occupied per dose of vaccine (storage volume includes the vaccine vial, packet containing the vaccine vial and any intermediate packaging).

Inner boxes:

_____ (number) individual glass vials shall be contained in sturdy white cardboard boxes (of not less than 300 GSM outfitted with individual segments for protecting and separating each vial.

Over packing:

Box shall be over packed so that the vaccine remains refrigerated below $+8^0$C. The containers must be suitable for export shipping in accordance with WHO guidelines on the international packaging and shipping of vaccines (WHO/IVB/05.23). The containers must have adequate insulation and or sufficient refrigerant to ensure that the warmest storage temperature of the vaccine does not rise above $+30^0$ C in continuous outside ambient temperature of $+43^0$ C during transit and for a period of at least 48 hours after arrival at consignee point.

Additional cushioning shall be provided, sufficient to protect the vials from breakage during transit and handling*[1].

1.* When considering "best practices" for transport and storage of vaccines, reference should be made to current recommendations in the appropriate literature.

Exterior shipping carton:

Product and printed materials, packaged as specified above, shall be packed in weather-resistant, triple-wall corrugated fiberboard cartons with a bursting test strength of not less than 1900 kPa.

The overall dimensions of the exterior shipping cartons should be such that the product does not become damaged during transportation and storage.

Each shipping carton should weigh less than 50 kg. It is important that individual boxes are not too heavy during transport as they are frequently loaded and offloaded manually at airports and intermediate stores.

D.Markings:

All containers and invoices must bear the name of vaccine, date of expiry and appropriate storage temperature.

Inner boxes:

The inner boxes shall be marked with the following information in a clearly legibleand generic manner which is acceptable to MoHFW-GoI.

C. Manufacturer‟s name and registered address
D. Manufacturer‟s national registration number
E. Lot or batch number
F. Composition and contained in box
G. Date of manufacture (month and year)
H. Expiration date (month and year)
I. Instructions for storage and handling*[2]
J. Place of manufacture

Exterior shipping cartons:

The following information shall be stenciled or labeled on the exterior shipping cartons on two opposing sides in bold letters at least „**Arial Font size 14'** high with waterproof ink in a clearly legible manner which is acceptable to MoHFW:

-----Generic name and trade name of the vaccine
-----Lot or batch number
-----Date of manufacture (month and year)
-----Expiration date (month and year)
-----Manufacturer‟s name and registered address
-----Manufacturer‟s national registration number

Consignee‟s address and emergency phone number including mobile number.

D. Destination Office name
E. Contact number
F. Number of vials contained in the carton
G. Gross weight of each carton (in kg)
H. Carton containing ----------secondary packages
I. Instructions for storage and handling[2]*
J. Place of manufacture
K. Vaccine Rush

*2: to be provided by MoHFW.

E. Documentation

Supplier shall provide to MoHFW a copy of the batch record, including all quality assurance documentation for the vaccine being supplied.

Advance notice of arrival and advance shipping documentation:

Copies of the documentation for the goods to be shipped must be sent **at least seven days (7) in advance** of arrival of the shipment. In case of an individual contract for a specific destination that requires alonger period should apply. The consignees(s) shall be intimated well in advance by registered letter/telegram,email, telephone,and fax so that vaccines are received immediately after arrival. Copy of the communication from the supplying firm shall be endorsed to the Deputy Commissioner (Immunization/UIP) and Deputy Director(UIP),Ministry of Health and Family Welfare, NirmanBhawan, New Delhi for information.

The documentation must include the following:

1 Pre-advice defined by MoHFW
2 Airway bill (AWB);
3 Supplier‟s invoice;
4 Packing list;
5 Lot release certificate (LRC) issued by NRAfor each lot of vaccine supplied; and
6 Any other document, certificate or instruction specified in the individual order.

The documents should be sent by e-mail and fax by the manufacturer to the consignees, MoHFW and any other parties specified in the individual contract.

The pre-advice must contain the following information:

- Purchase order reference;
- Consignee requisition reference;
- Number of packages, gross weight;
- Type of vaccine, total number of vials and number of doses per vial;
- Date and time for place of departure, transit (if applicable), and arrival:
- Instructions for collection;
- Any other information specified in the individual contract must also be included for the consignee;

The following information shall be stated on the airway bill;

D. Consignee‟s name, address and telephone number (including mobile no.) and e-mail ID;
E. Purchase order reference;
F. Consignee‟s requisition reference;
G. Type of vaccine and quantity;
H. Instructions to: “Telephone consignee upon arrival (repeat telephone number)”,
I. Handling information:
J. **“Medicines – Vaccines - For human use – Highly Perishable- Not to be delayed”**.

The following instruction should be stated in the AWB:

“Throughout shipment, pending reshipment and prior to collection by the consignee, the vaccine must be stored at +2^{0}C to +8^{0}C”

F. Dispatch

Vaccines should be sent by a direct route wherever possible; road transport may be used if accompanied by attendant. Where trans-shipment is unavoidable, the Journey should be planned through airports thathave cold storage facilities.

The maximum transit time from the manufacturer to arrival at the airport of final destination must not exceed **4 days (96 hours).**

Shipments should be scheduled to arrive outside weekends and/or public holidays at the consignee point andbookings should be made well ahead of the date of departure.

Vaccines must not be transported with radioactive products, fish or meat;

Correct cold-chain procedures must be observed during transit, warehousing and shipping (i.e., all vaccines must be kept in temperature-controlled environments at all times throughout the shipment process);

Reactivation of the refrigeration process of shipments must be performed in accordance with the instructions of the supplier of each shipment whenever deemed necessary;

Interruptions in production and release processes:

Any issues arising which may result in problems with production, quality control and/or release of vaccine should be communicated in a timely manner to MoHFWand NRA/DCGI.

Adverse events and recalls:

The Supplier shall comply with all applicable laws, regulations and requirements regarding vaccine safety. The terms used surrounding adverse experiences shall have the meanings set forth in the International Conference on Harmonization (ICH) of Technical Requirements of Pharmaceuticals for Human Use E2A.

The Supplier shall be solely responsible for global pharmaco-vigilance activities regarding the Vaccine including but not limited to: adverse events following immunization(AEFI), experience (AE) or adverse drug reaction (ADR) reporting including literature review and associated reporting; AE/ADR follow-up reporting; preparation and submission of all safety reports to applicable regulatory agencies, as required; periodic submissions; labeling modifications; risk management; safety monitoring and detection and coordinating and implementing safety measures.

The Supplier shall promptly inform the DCGI/NRA and MoHFW of serious issues (actual or alleged) regarding vaccine safety and shall provide them with information sufficient to consider such issues. The DCGI/NRA shall promptly notify the Supplier of serious adverse events involving the Supplier‟s vaccine of which they become aware.

If any circumstance or event may require or make reasonably appropriate any recall or withdrawal of Vaccine or any field alert regarding the vaccine, Supplier shall immediately notify the DCGI/NRAand other MoHFW. When a recall, withdrawal or field alert is required or appropriate, the Supplier shall take all appropriate actions and shall bear all associated expenses.

Vaccine arrival report:

Manufacturer is required to include a Vaccine Arrival Report (VAR) together with the other shipping documentation in shipping box number one of each shipment. The current VAR will be provided by MoHFWupon award. An example VAR is included in the Guidelines on the International Packaging and Shipping of Vaccines, WHO/IVB/05.23**(Annex V)**

Temporary storage:

The supplier agrees to properly store, from time to time and at no cost to MoHFW,finished products of vaccines for delivery at a later date. Storage of vaccines shall be under controlled environmental conditions to facilitate the conservation of the vaccines. The storage facilities shall comply with all national regulations for the storage of vaccines in force in the country.

3 References

Indian Pharmacopoeia 2014; Indian Pharmacopoeia Commission, Government of India; Ministry of Health & Family Welfare, Ghaziabad. Indian Pharmacopoeia.

Vaccine Vial Monitor. Specification references E06/IN05.2

Guidelines on the international packaging and shipping of vaccines. WHO 2005; Department of Immunization, Vaccines and Biological. WHO/IVB/ 05.23.

Procurement of vaccines for public-sector programmes-A reference manual. WHO/IVB/03.16; 2004.

WHO/IVB/05.23

WHO/IVB/04.06

WHO/O/UNICEF Product specifications.

Recommendations to assure the quality, safety and efficacy ofpoliomyelitis vaccine (inactivated).Replacement of: TRS 910, Annex2http://www.who.int/biologicals/areas/vaccines/IPV_Recommendations_to_assure_the_quality_safety_and_efficacy_IPV_ECBS_adopted_2014.pdf?ua=1

Annexure- I

Qualitative proposal sheet

- Please provide responses to the following in your proposal together with any other information deemed relevant.
- Provide names of two persons primarily responsible for Government of India in all matters related to IPV.
- Provide either the original date of registration/licensure with the National Regulatory body or planned date for registration/licensure for IPV.
- If applicable, please explain the rationale for any difference in price between IPV products.
- Provide information on the following points related to IPV production:

  Annual production capacity for finished IPV product

  Any plans that may affect production capacity and availability during the period covered by the tender.

  If the vaccine bulk is not produced by the proposer, please advise source of bulk, evidence of contractual access to bulk and delivery schedules supporting the offer.
- In the past, how has your company been able to maintain the quality level for vaccines? If your company has faced quality problem, please provide frequency and explanations as well as measures taken for improvement.
- Please indicate if your company would be able to maintain the timelines, as indicated and notified as per the tender document awarded to you.
- Please indicate the capacity and willing to store vaccines on the need basis and maintain a buffer stock, indicating the any condition that may apply.
- Please indicate the availability to respond to emergency request for supply of IPV.

Annexure- II

SPECIFICATION FOR VACCINE VIAL MONITORS (VVM)

PQS performance specification

WHO/PQS/E06/TR07.1
Original: English
Distribution: General

TITLE: Electronic shipping indicators:

Specification reference:	E06/TR07.1
Product verification protocol:	E06/TR07.VP.1
Date of origin:	05 December 2006
Date of last revision:	New specification

Contents:

1. Scope:

This specification describes the performance requirements for a *Vaccine Vial Monitor (VVM)* suitable for application to a vaccine vial by a vaccine manufacturer. The product is used to indicate the cumulative heat exposure of a vial of vaccine so that health workers know whether the cumulative heat history of the product has exceeded a pre-set limit.

2. Normative references:

EMAS: *European Union Eco-Management and Audit Scheme.*
ISO 9001: 2000: *Quality Management Systems – Requirements.*
ISO 14001: 2004: *Environmental management systems - Requirements with guidance for use.*
ISO 2859-1: 1999: *Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection.*
ISO 3951:1989 Sampling procedures for inspection by variables of percent nonconforming.
ISO 5-3:1995 Photography-Density measurements-Part 3: Spectral Conditions.

3. Terms and definitions:

AQL: Acceptance Quality Limit
Active surface: A time-temperature sensitive colour patch whose reaction rate closely matches the stability profile of the vaccine to which the VVM is attached[1].
Spectrodensitometer: The specification for the Start R-I, Indicator OD values, Reference Ring, and OD limits found in **E06/IN05.2** are based on measurements with an X-Rite Model 500 series spectrodensitometer. Measurements taken with other instrumentation will require a conversion factor. Due to the small size of the VVM's reference ring and indicator area, it is necessary to modify the target and aperture centring of the spectrodensitometer (as sold by the instrument supplier). The VVM manufacturer will be responsible for providing the service to install the target and centre the aperture. Conversion of spectral data to optical density is defined within ISO 5-3:1995 Photography-Density measurements-Part 3: Spectral Conditions.
End point: The point at which time-temperature exposure has altered the colour of the active surface so that it exactly matches the reference surface. At this point, and thereafter, the vaccine should no longer be used.
In writing: means communication by letter, fax or email.
Legal Manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a product or device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.
Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer.

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[1] It is the vaccine manufacturer's responsibility to match the stability profile of their vaccine to the time-temperature profile of one of the four VVM types described in clause 4.2.8 of this specification.

OD: Optical Density.
Reference surface: A colour patch against which the colour of the active surface can be directly compared.
Reaction rate: The rate at which the active surface responds to time-temperature exposure.
Reseller: A commercial entity, licensed to act on behalf of a Legal Manufacturer, and which carries product liability and warranty responsibilities no less onerous than those carried by the Legal Manufacturer.
Start point: The colour of the active surface of the VVM at the time when the VVM is received by the vaccine manufacturer[2].
VVM: Vaccine Vial Monitor comprising, as a minimum, an active surface, a reference surface and the substrate to which these are applied by the VVM manufacturer.

4. Requirements:

4.1 *General:* Vaccine Vial Monitor suitable for application to a vaccine vial by a vaccine manufacturer.

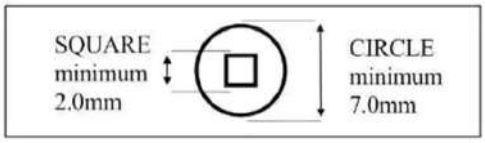
The principal purpose of this product is to warn health workers when the cumulative heat exposure of a vial of vaccine has exceeded a pre-set limit, beyond which the vaccine should not be used. This is defined as the end point.

Before the end point is reached, changes in the appearance of the VVM are used to alert health workers to the fact that heat exposure has occurred. Heat-exposed vials can then be used in preference to those that have not been exposed.

4.2 *Performance:*

4.2.1 *Format and dimensions:* The VVM is a circle of colour, minimum diameter 7.0mm with a square of colour, minimum dimensions 2.0 x 2.0mm positioned in the centre of the circle (See Figure 1). Whatever dimensions are chosen, the ratio of the area of the square to the area of the circle (including the square) is to be at least 0.1:1.

Figure 1. Format and dimensions of VVM



4.2.2 *Design:* The circle of the VVM comprises a static, reference surface and the square comprises the active surface. The colour change of the active surface is limited to a change of shade, from light to dark. Any colour is permitted for the VVM design, but changes in hue are not permitted.

[2] It is the vaccine manufacturer's responsibility to store the VVMs correctly to prevent any change in the start OD during the period elapsing between the time of receipt of the VVM to the time of its application to the filled vaccine vial.

4.2.3 *Colour density change:* The colour density change of the indicator is illustrated in the Figure 2 below. At the start point the colour of the square is lighter than the circle. The end point is indicated when the colour of the square matches the circle. The end point is exceeded when the colour of the square is darker than the circle. The following clauses describe the colour change in more detail.

Figure 2. The colour density change of the indicator

Start point		Square lighter than circle
End point		Square matches the circle
End point exceeded		Square darker than the circle

Note: the central square is the active surface.

4.2.4 *Colour at start point and end point:*

- At the start point, the colour density of the square as measured by an X-rite Model 500 series spectrodensitometer, must be lighter than the colour shade of the circle by a difference of at least 0.25 OD densitometer units for all VVM except for the VVM2 Dots on Brown Liner where the minimum difference will be 0.23 OD.
- The end point is reached when the difference in the average colour density obtained from readings at least two different points on the circle and the colour density of the square is 0.00 OD, as measured by the densitometer. The end point is exceeded when the colour of the square is darker than the colour of the circle.
- The specifications for the Start R-I and the Indicator OD are shown in Table 1.

Table 1: Start R-I and Indicator OD

Category, Liner	Start R-I	Active Surface Start OD (I)
VVM30, White and Clear Liner	0.52 ± 0.11	0.09 ± 0.04
VVM30, Brown Liner	0.49 ± 0.11	0.12 ± 0.04
VVM14, White and Clear Liner	0.41 ± 0.09	0.10 ± 0.04
VVM14, Brown Liner	0.38 ± 0.09	0.13 ± 0.04
VVM7, White Liner	0.41 ± 0.09	0.11 ± 0.04
VVM7, Brown Liner	0.38 ± 0.09	0.13 ± 0.04
VVM2, White Liner	0.32 ± 0.07	0.13 ± 0.05
VVM2, Brown Liner	0.29 ± 0.06	0.16 ± 0.05

4.2.5 *Homogeneity of the reference surface:* The colour density of one 2mm diameter portion of the circle must be within 0.03 OD of the colour density at any other two 2mm diameter portions of the circle, when measured with a colour densitometer.

4.2.6 *Variation of the reference surface within the lot:* The colour density of one 2mm diameter portion of the reference circle of one sample must be within 0.03 OD of the colour density of the reference circle of any other sample within the same lot.

4.2.7 *Reference surface colours:* The colour of the reference area is specified in Table 2.

Table 2: Reference surface colours

Category, Liner	Reference Surface OD (R)
VVM30, White and Clear Liner	0.61 ± 0.15
VVM30, Brown Liner	0.61 ± 0.15
VVM14, White and Clear Liner	0.51 ± 0.13
VVM14, Brown Liner	0.51 ± 0.13
VVM7, White Liner	0.52 ± 0.13
VVM7, Brown Liner	0.51 ± 0.13
VVM2, White Liner	0.45 ± 0.12
VVM2, Brown Liner	0.45 ± 0.11

4.2.8 *VVM reaction rates:* Reaction rates are specific to four different models of VVM, relating to four groups of vaccines according to their heat stability at two specific temperature points (See Table 3).

Table 3: VVM reaction rates by category of heat stability

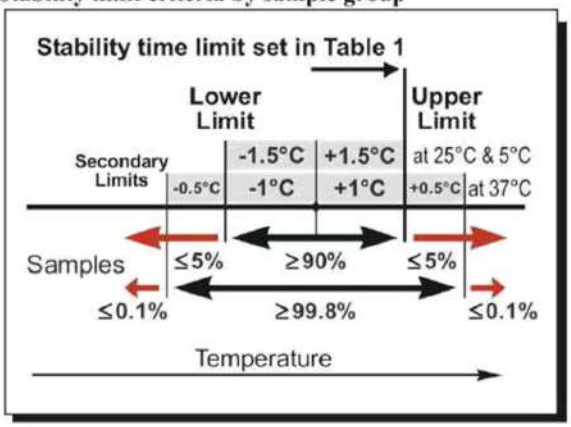
Category (Vaccines)	No. of days to end point at +37°C	No. of days to end point at +25°C	Time to end point at +5°C
VVM 30: High Stability	30	193	> 4 years
VVM 14: Medium Stability	14	90	> 3 years
VVM 7: Moderate Stability	7	45	> 2 years
VVM 2: Least Stable	2	N/A*	225 days

**VVM (Arrhenius) reaction rates determined at two temperature points*

- **At the +37°C specifications, RH 33% +/-5% and RH 75% +/-5%:** At least 90% of VVMs tested should reach the end point at the maximum time in the range of 36 ±1°C. Further, secondary limits are applied to restrict how far beyond the primary specification the TTIs are allowed to be. At least 99.8% of VVMs tested should reach the end point at the maximum time in the range of 36 ±1.5°C.

- **At the 5°C and +25°C specifications (ambient humidity in submerged foil/polythene pouch)**: At least 90% of VVMs tested should reach the end point at the maximum time in the range of the specified temperature ±1.5°C.
- **Tolerance:** A tolerance is allowed in the above tests for up to 5% of VVM samples tested to reach the end point at a temperature above the upper limit and 5% at a temperature below the lower limit (See Figure 3).

Figure 3. Stability limit criteria by sample group



- **Allowable range of end points:** Table 4 defines the allowable range of end points such that 90% of a production lot must reach the end point at the specified time within a range of ±1°C and that 99.8% of the lot must reach end point within a range of ±1.5°C.

Table 4: Allowable range of end points

VVM Type	Primary Limits: ±1°C measured at upper limit (including OD tolerance)		Secondary Limits: ±1.5°C measured at upper limit (including OD tolerance)	
	Lower Limit	Upper Limit	Lower Limit AQL=0.1%	Upper Limit AQL=0.1%
VVM30	-0.19	0.03	-0.23	0.06
VVM14	-0.15	0.03	-0.18	0.06
VVM7	-0.11	0.03	-0.13	0.05
VVM2	-0.09	0.03	-0.10	0.04

4.2.9 *Global Measurement Accuracy:* The allowable total error for measuring the difference between the colours of the circle and square is ± 0.03 OD when using an X-Rite 500 series spectrodensitometer or later qualified model. The measurement error for a single measurement is ± 0.02 OD. Major sources of error are instrument error, both for the circle and the square, repeatability, and variation in end point caused by an allowed temperature variation of ± 0.2°C.

500 series spectrodensitometers require a smaller target than what is provided by the manufacturer (X-Rite). Installation of the smaller target and centering of the aperture must be performed by the VVM manufacturer.

4.2.10 *Water Bath Precision and Control:* The VVMs should be tested in water baths controlled to within ± 0.2°C. (Any additional 0.1°C variation in temperature control requires an allowance for additional measurement error.)

4.2.11 *Reversion:* The indicator must not revert to a lighter colour at any point in its life when exposed to conditions likely to be found during normal use. After the endpoint is reached, the square must remain the same colour as the circle or become darker than the circle.

4.2.12 *Integrity and location of VVMs:*

Before a vial or ampoule is opened, the VVM should not be removable; it should resist removal from the vaccine vial as much as a label meeting current vaccine labeling requirements. In addition, the performance of the VVM should not be changed by soaking in water for 8 hours. Water-exposed samples should conform to within +/-0.04 OD units.

The location of the VVM on the vial depends upon whether the vaccine must be discarded at the end of the immunization session in which it is opened, or whether any remaining contents in an opened vial can be retained for use in subsequent sessions. The following cases apply:

- **For multi-dose vials containing a vaccine that can be used in subsequent sessions:** Regardless of the vaccine presentation (liquid, freeze-dried or two vial combinations of liquid and freeze-dried), the VVM must be permanently attached to the label of the vaccine vial and must remain readily observable before, during, and after use, until the entire contents of the vial have been used.
- **For vaccines that must be discarded at the end of the session or within 6 hours, whichever comes first:** The VVM must be attached to the vaccine vial or ampoule and must remain readily observable until the vial or ampoule is opened, but not observable after opening. In order to achieve this requirement, the VVM must be located on the flip-off top of a vial or on the neck of an ampoule.

On a product by product basis, WHO will advise both the vaccine and the VVM manufacturer where the VVM is to be located. Locating the VVM on the bottom of a vial or ampoule is never acceptable – it must always be in a visible location.

4.2.13 *Application Surfaces:* VVMs must be designed to be applied to the following substrates:

- Glass (e.g., glass vials).
- Paperboard (e.g., primary or secondary packaging).
- Plastic containers of a composition for which permeation of adhesive components is not a risk.

For vial cap applications, VVM dots are designed to be applied to smooth, flat surfaces with no embossed areas, recessed areas, or ridges. The use of excessive release agents in the manufacture of the vial caps should be avoided.

Note: Each user should ensure there is adequate adhesion of the VVM to the vaccine container. Permanent adhesion may not be guaranteed when the VVM is applied to some plastic materials.

4.3 *Traceability:* Each roll of VVMs must be labeled with its product identity (part number) together with its lot number[3].

4.4 *Physical characteristics:* Overall dimensions: As clause 4.2.1, Figure 1.

4.5 *Interface requirements:*
None.

4.6 *Human factors:* The colour change must be monotonic in its response to cumulative heat exposure within the limits of the allowed variation. The observer must be able to distinguish between an unchanged indicator, a 50% colour change and the end point of the indicator.

4.7 *Materials:* The exposed surface of the VVM must not endanger human health. The materials of the VVM must be non-toxic and non-irritant. The VVM must meet any requirements in force concerning toxicity of labels or packaging in the country of manufacture.

4.8 *Reliability:* All batches of the product must be warranted to conform to the requirements of this specification.

4.9 *Servicing provision:* The product is to be maintenance-free.

4.10 *Disposal and recycling:* The product will be disposed of in conjunction with the vial to which it is attached.

4.11 *Instructions:* An instruction insert, providing vaccine manufacturers with all necessary storage, handling and application directions and traceability directions (with reference to clause 4.3) is to be supplied with every carton. The insert is to be printed in English. If any vaccine manufacturer requires an instruction insert in an additional language, this will be a matter for independent negotiation between the VVM manufacturer and the vaccine manufacturer.

4.12 *Training:* The VVM manufacturer must provide training for the vaccine manufacturer in order that the manufacturer can correctly handle, apply and test VVMs.

4.13 *Verification:* In accordance with PQS Verification Protocol **E06/IN05.VP.2.**

5. Packaging:
Materials used for packaging the finished product are to be free of CFC compounds as defined in the Montreal Protocol.

6. On-site installation:
VVMs will be applied to vaccine vials by vaccine manufacturers.

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[3] Vaccine manufacturers must keep records of the lot number of the VVMs affixed to each individual batch of vaccine.

7. **Product dossier:**
The legal manufacturer or reseller is to provide WHO with a pre-qualification dossier containing the following:

- Dossier examination fee in US dollars.
- General information about the legal manufacturer, including name and address.
- Unique identification reference for the product type.
- Full specifications of the product being offered, covering all the requirements set out in this document, including details of product marking and traceability.
- Details of the legal manufacturer's internal AQL sampling procedures in respect of ISO 3951:1989.
- Certified photocopies of the legal manufacturer's ISO 9001 quality system certification.
- Where relevant, certified photocopies of the legal manufacturer's ISO 14001 certification, EMAS registration or registration with an equivalent environmental audit scheme. Conformity with an environmental audit scheme is not mandatory; however preference will be given to manufacturers who are able to demonstrate compliance with good environmental practice.
- Where available, laboratory test report(s) proving conformity with the product specifications.
- A minimum of five samples of each of the four types of VVM shipped with frozen icepacks, together with instruction insert in English language.
- Indicative cost of the product per 10,000, per 100,000 units and per 1,000,000 units EXW (Incoterms 2010).

8. **On-site maintenance:**
Not applicable.

9. **Change notification:**
The legal manufacturer or reseller is to advise WHO in writing of any changes which adversely affect the performance of the product, in relation to any of the requirements set out in this specification, after PQS pre-qualification has taken place.

10. **Defect reporting:**
The legal manufacturer or reseller is to advise WHO and the UN purchasing agencies in writing in the event of safety-related product recalls, component defects and other similar events.

Revision history:

Date	Change summary	Reason for change	Approved
14 Mar 2006	Test procedure redrafted with general amendments to the form of wording but not to the content. Normative references, definitions	To achieve conformity with PQS documentation standards.	UK

	and additional clauses added.		
29 Nov 2006	General revisions	Following consultation with industry.	UK (30 November 2006 - PQS secretariat)
7 Apr 2011	2: ISO 3951 and 5-3 added. 3: Spectrodensitometer definition added. 4.2.4: Spectrodensitometer specification changed. VVM2 brown liner OD exception added. 4.2.4: Table 1 changed. 4.2.7: Table 2 changed. 4.2.9: Spectrodensitometer change. 4.2.12: Clause renamed. Text amended. 4.2.13: New clause added. 4.12: Training requirement added. 7. ISO 9001 date removed. 7. Incoterms date amended.	Consultation with industry. Consultation with industry. Previous model no longer manufactured. Plus manufacturer's suggestion. Spectrodensitometer model change. Spectrodensitometer model change. Spectrodensitometer model change. To accommodate reconstituted vaccines that can be kept for subsequent immunization sessions. Consultation with industry. Consultation with industry. Consistency with other PQS documents. Current edition.	UK (9 May 2011)
18 July 2011	4.2.12: Text amended	Consistency with suggested VVM location	UK (15 July 2011)

Revision history:			
Date	Change summary	Reason for change	Approved
12 Jul 06	4.1: type descriptions. 4.2.2: temperature. 4.2.8: minor change. 4.2.12: type descriptions. 4.2.16 added. 4.6.3: minor changes and addition. 4.6.4: minor change. 4.6.5: re-drafted with card illustration in Annex 1. New clause 4.7.2. 4.7.3 and 4.7.4 deleted. 5: 'CFC' changed to 'ozone-depleting'.	In response to final review comments. EU RoHS Directive material restrictions incorporated.	Yes (UK)
29 Nov 06	Annex 1: Notes added. French and Spanish versions added. "What to do" section on the back face of the shipment information card changed to "contact procurement agency"	Initial information was to contact only UNICEF, whereas other procurement agencies may also be using the same device.	Yes (30 November 2006, UK - PQS secretariat)
01 Dec 06	Annex 1 French and Spanish versions added	French and Spanish language versions added	Yes (01 December 2006 - UK PQS secretariat)
05 Dec 06	"Assembled and distributed by [company name and web address]" information is added to backing cards.	Add missing information on assembly and distribution to backing cards.	Yes (05 December 2006 - UK PQS secretariat)

Annexure - III

MODEL INSERT

Inactivated polio vaccine(IPV)

DESCRIPTION: Poliomyelitisvaccine(Inactivated) is a liquid preparation of suitable strains of human polioviruses 1,2 and 3 grown in suitable cell cultures and inactivated by a validated method.

ADMINISTRATION:

It should be injected intramuscularly. Theinjection site should be on the anterolateral aspect of mid-thigh. One dose is of 0.5ml.

A fresh auto-disable (AD) syringe and needle should be used for each injection.

IMMUNIZATION SCHEDULE: Single dose of IPV at 14 weeks of age concomitantly with OPV-3,DPT-3 and/or Penta-3.

SIDE EFFECTS:

If serious reaction does occur, health worker should report to the supervisor and all serious reactions should be reported as AEFI. Children who have serious AEFI should not receive additional doses of the vaccine.

CONTRAINDICATIONS:

IPV should not be administered to children with a documented/known allergy to any of the components of the vaccine, or with a history of a previous allergic reaction after IPV injection.

SPECIAL GROUPS: IPV can be administered to premature infants (born before 37 weeks gestation) at the recommended chronologic age concurrent with other routine vaccinations. IPV can be safely administered to people with immune deficiencies (e.g. HIV/AIDS, congenital or acquired immunodeficiency, sickle cell disease), as they are at high risk of contracting Vaccine Associated Paralytic Poliomyelitis (VAPP) in case of contact with OPV.

STORAGE: Once opened multi-dose vials should be kept between $+2^0$ and $+8^0$C.

PRESENTATION: DCGI registered stand-alone IPV in 5and 10dose vial presentations.

Annex IV –

SPECIFICATION FOR ELECTRONIC INDICATORS

TITLE: Electronic shipping indicators:

Specification reference:	E06/TR07.1
Product verification protocol:	E06/TR07.VP.1
Date of origin:	05 December 2006
Date of last revision:	New specification

Contents:

1. Scope:

This specification describes the performance requirements for *electronic shipping indicators* to be used to monitor time-temperature exposure inside vaccine shipping containers during transport from the vaccine manufacturer's warehouse to the receiving country's primary vaccine store.

2. Normative references:

EMAS: *European Union Eco-Management and Audit Scheme.*
EN 12830:1999: *Temperature recorders for the transport, storage and distribution of chilled, frozen, deep-frozen/quick-frozen food and ice cream. Tests, performance and suitability.*
European Union Directive 2002/96/EC: *Waste Electrical and Electronic Equipment.*
IEC 60529: Consolidated Edition 2.1 (incl. am1): *Degrees of protection provided by enclosures (IP Code).*
ISO 14001: 2004: *Environmental management systems - Requirements with guidance for use.*
ISO 9001: 2000: *Quality Management Systems – Requirements.*
ISO/IEC 17025: 2005: *General requirements for the competence of testing and calibration laboratories.*
WHO/IVB/05.23. *Guidelines on the international packaging and shipping of vaccines.*

3. Terms and definitions:

Data retention period: The period following the de-activation of the device using the 'stop' function during which it must be possible to recover the data recorded during the recording period.
EPROM: Electrically erasable, programmable, read-only memory.
In writing: means communication by letter, fax or email.
LCD: Liquid Crystal Display.
LED: Light-Emitting Diode.
Legal Manufacturer: The natural or legal person with responsibility for the design, manufacture, packaging and labeling of a product or device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.
Montreal Protocol: Montreal Protocol on Substances that Deplete the Ozone Layer.
NIST: United States National Institute of Standards and Technology.
Primary vaccine store: store which receives vaccine directly from the vaccine manufacturer
Receiver: The person or organization responsible for receiving the vaccine shipment.
Recording period: The period between the activation of the device using the 'start' button or switch and the de-activation of the device using the 'stop' button or switch.
Reseller: A commercial entity, licensed to act on behalf of a Legal Manufacturer, and which carries product liability and warranty responsibilities no less onerous than those carried by the Legal Manufacturer.
Sender: The manufacturer responsible for packing and shipping the vaccine.
Shipping container: Insulated packaging used for shipping vaccines, as described in the WHO document: *Guidelines on the international packaging and shipping of vaccines*. WHO/IVB/05.23.
Storage life: In relation to non-replaceable batteries is the period measured from the date of delivery of the device to the Sender to the time at which the 'start' function is activated.

4. Requirements:

4.1 *General:* Single use pre-programmed electronic time-temperature data logger with non-replaceable battery to accompany vaccine shipments from the vaccine manufacturer's warehouse to the receiving country's primary vaccine store. The logger must be able to display the shipment's time-temperature exposure without need for downloading to a PC and without need for a separate reading device. Devices that have an additional download function will be acceptable, but a download function is unnecessary, will not routinely be used, and does not form part of this specification.

The device must be supplied in two versions:

- **Type 1:** Programmed with alarm settings suitable for the international shipment of DTP, DT, TT, Td, HepB, IPV, liquid Hib and combination vaccines.

- **Type 2:** Programmed with alarm settings suitable for the international shipment of BCG, lyophilized Hib, measles, MR, MMR, meningitis, OPV and yellow fever vaccines shipped with frozen water-ice packs.

It must be possible to photocopy the logger display as a permanent record of the shipment's arrival status. A legible copy must be produced using a photocopier, scanner or all-in-one printer.

4.2 *Performance:*

4.2.1 Operating temperature range:
Upper limit: +55°C.
Lower limit: -30°C.

4.2.2 Accuracy:
- **Temperature:** ±0.5°C or better within the range -5°C to +25°C; ±1°C within the ranges -20°C to -5°C and +25°C to +55°C.
- **Time:** ± 10 seconds per day or better.

4.2.3 Resolution: ±0.2°C or better within the range -20°C to +55°C

4.2.4 Power source: Non-replaceable battery.

4.2.5 Sensor: Electronic.

4.2.6 Memory: EPROM or equivalent non-volatile solid-state memory device.

4.2.7 Product response time: T90 10 minutes maximum in accordance with **EN12830:1999**.

4.2.8 Unit of measurement: Temperatures must be recorded and displayed in degrees Centigrade.

4.2.9 Calibration: Each product is to be covered by a Certificate of Traceability and Calibration. The traceability declaration is to confirm that the measurement standards and instruments used during calibration of the product are traceable to an ISO/IEC 17025 accredited testing laboratory, to NIST, or to another internationally recognized standards agency.

4.2.10 Logging interval: The device must measure the storage temperature at intervals not exceeding 10 minutes. As a minimum the device must log the first instance of a time-temperature-violation for each alarm type equaling or exceeding the threshold parameters set out in clause 4.2.12. Devices that can log more than one instance of each type of time-temperature violation will not be excluded.

4.2.11 Logging start delay: 60 minute start delay function after user activation to allow the device to equilibrate with the temperature inside the shipping container before it starts to record temperatures.

4.2.12 Alarm settings: The device must be pre-programmed with the following alarm settings:

- **Type 1:**

Alarm type	*Time-temperature alarm threshold*	*Period of exposure*
High threshold	>= 45°C single event	1 hour
Medium threshold	>= 30°C cumulative exposure	10 hours
Low threshold	<= -0.5°C single exposure	1 hour

- **Type 2:**

Alarm type	*Time-temperature alarm threshold*	*Period of exposure*
High threshold	>= 45°C single event	1 hour
Medium threshold	>= 30°C cumulative exposure	10 hours
Low threshold	>= 10°C cumulative exposure	20 hours

4.2.13 *Casing:* Non-corrodible plastics or metal case.

4.2.14 *IP rating:* Protection of the product not less than IEC 60529: IP64.

4.2.15 *Battery:* Non-replaceable battery capable of powering the device in accordance with the following criteria:

- Minimum storage life of 18 months before 'start'.
- Minimum recording period: 10 days.
- Minimum data retention period after 'stop': 6 months.

4.2.16 *Electromagnetic compatibility:* Operation of the device must be unaffected in the normal electromagnetic compatibility environment in which it is intended to work, taking into account disturbance generated by adjacent apparatus which is compliant with relevant ISO, EN, or other internationally recognized standards. Information required to ensure uninterrupted use of the device must be contained in the user instructions.

4.3 *Environmental requirements:*

4.3.1 *Ambient temperature range during transport and storage:* -30°C to +55°C with device inactivated.

4.3.2 *Ambient humidity range during transport, storage and use:* 0 to 95% RH.

4.3.3 *Resistance to electrical storms:* The functionality of the device must not be affected by intense electrical storm activity.

4.3.4 *Impact resistance:* Product to withstand 5 drops from 1 metre onto a concrete floor, with battery in place, without physical damage or loss of calibration.

4.3.5 *Vibration:* Product to withstand 30 minutes on a programmable vibrating table without physical damage or loss of calibration.

4.4 *Physical characteristics:*

4.4.1 *Overall dimensions:* Not critical provided volume of the device does not exceed 150 cubic centimeters when detached from shipment information card.

4.4.2 *Weight:* Not critical.

4.5 *Interface requirements:*

4.5.1 *Software compatibility* (for devices with additional download function):

- If the software requires an interface with a proprietary spreadsheet program, the list of compatible programs must include all releases of Microsoft Excel currently supported by Microsoft.
- The software must be compatible with all Microsoft PC operating systems currently supported by Microsoft.

4.6 *Human factors:*

4.6.1 *Activation:* The device is to be activated by the sender at the beginning of the recording period by means of a 'start' button or switch mounted on the unit.

4.6.2 *De-activation:* The device is to be de-activated by the receiver at the end of the recording period by means of a 'stop' button or switch mounted on the unit. If the 'stop' button or switch is not de-activated, the device should automatically default to the de-activated state at the end of the 10 day maximum recording period. The 'stop' button or switch should be designed to prevent inadvertent de-activation - for example by contact with a shifting load.

4.6.3 *User interface:*

The device is to have an LCD display screen, with or without LEDs, capable of showing the following information:

- Activation status.
- Post activation battery status, or clearly marked expiry date in the format mm/yyyy.
- Overall alarm status: whether or not an alarm condition of any kind has occurred since the device was activated.
- Time-temperature alarm status: the status of each of the three time-temperature alarm thresholds specified in clause 4.2.12 at the time when the 'stop' button is activated.
- Total elapsed transport time in days and hours or in hours measured from device activation to device de-activation.
- Shipment history: A history of the shipment capable of showing details of at least one time-temperature limit violation for each alarm type including the first time-temperature-violation of each alarm type.
- The LCD must either show all this information together on a single display screen or the user must be able to access the information on sequential screens by means of a button mounted on the product. In the latter case, the overall status of the indicator ('OK', or 'Alarm') must be permanently displayed on every screen. Flashing displays are not acceptable because they cannot be photocopied.
- The display must be capable of being photocopied in order to provide a hardcopy record of the status of the device upon arrival. For this reason the display must not incorporate any flashing or blinking symbols or lights.
- Alarm symbols must not be language-dependent and must be easily understood by untrained users. Acceptable symbols include, but are not confined to, the following:
  Tick' or 'OK' symbol for shipments where no temperature violation has occurred, as graphic below:

☑ or

OK

'Cross' or 'Crossed OK' symbol for shipments where any type of temperature violation has occurred, as graphic below:

☒ or

- As a battery saving measure, the display may switch off automatically when not required, provided it can be activated by the user by means of a push button.

4.6.4 *Type identification:* Type 1 and Type 2 devices are to be clearly identified in a manner which avoids the risk that the wrong type of device will be packed by the sender. Acceptable identification includes, but is not confined to, the following:

- Printed identification.
- Different coloured casings.

4.6.5 *Shipment information card:* Mount the device on a moisture resistant backing card, using moisture resistant adhesive. The card material must accept indelible markings in ball point pen. The width of the card must be at least the same as the length of the device, subject to a minimum width of 7.5cm. The length of the card must not exceed 14cm. The card design must follow the generic format and colours set out in **Annex 1** (yellow for Type 1 and blue for Type 2). User instructions are to be available either in English, French or Spanish language, as requested by the customer. Text is to be in a high legibility font – minimum 8 point, colour black.

4.7 *Materials:*

4.7.1 *Ozone depleting chemicals:* During manufacture and assembly of the printed circuit boards and final assembly of the product do not use any substance included in Annex A, B or C of the Montreal Protocol.

4.7.2 *Other restricted materials:* The product and its constituent components, including batteries, must not contain lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated biphenyl ethers (PBDE).

4.8 *Warranty:* The product is to be covered by a warranty covering the designed lifetime of the device in the event of any component failure not caused by mechanical damage.

4.9 *Servicing provision:* The product is to be maintenance-free.

4.10 *Disposal and recycling:* The manufacturer is to provide information to the buyer on the hazardous materials contained within the system and suggestions for resource recovery/recycling and/or environmentally safe disposal. For the European Union WEEE compliance in accordance with European Union Directive 2002/96/EC is mandatory.

4.11 *Instructions:* User instructions in Arabic, English, French, Mandarin Chinese, Russian and Spanish. Where relevant the software manual may be in hard copy format or supplied with the software on CD.

4.12 *Training:* No requirement.

4.13 *Verification:* In accordance with PQS Verification Protocol **E06/TR06.VP.1**

5. Packaging:
Materials used for packaging the finished product are to be free of ozone-depleting compounds as defined in the Montreal Protocol.

6. On-site installation:
Not applicable.

7. Product dossier:
The legal manufacturer or reseller is to provide WHO with a pre-qualification dossier containing the following:

- Dossier examination fee in US dollars.
- General information about the legal manufacturer, including name and address.
- Unique identification reference for the product.
- Full specifications of the product being offered, covering all the requirements set out in this document, including details of product marking and traceability and documentary evidence of claimed battery life.
- Certified photocopy of Certificate of Traceability and Calibration traceable to an ISO/IEC 17025 accredited testing laboratory, to NIST, or to another internationally recognized standards agency.
- Certified photocopies of all type-approvals obtained for the product, including CE marking and the like.
- Certified photocopies of the legal manufacturer's ISO 9001 2000 quality system certification.
- Where relevant, certified photocopies of the legal manufacturer's ISO 14001 certification, EMAS registration or registration with an equivalent environmental audit scheme. Conformity with an environmental audit scheme is not mandatory; however preference will be given to manufacturers who are able to demonstrate compliance with good environmental practice.
- Where available, laboratory test report(s) proving conformity with the product specifications.
- One sample of the product, complete with data connection lead and software, where offered.
- Indicative cost of the product per unit, per 10 units and per 100 units EXW (Incoterms 2000).

8. On-site maintenance:
Not applicable.

9. Change notification: The legal manufacturer or reseller is required to advise WHO in writing of any changes which adversely affect the performance of the product after PQS pre-qualification has taken place.

10. Defect reporting:

The legal manufacturer or reseller is to required to advise WHO and the UN purchasing agencies in writing in the event of safety-related product recalls, component defects and other similar events.

Annex 1 – Shipment information card

Notes:

1. Card colour is to match as closely as possible the Microsoft® colours shown here: 'light yellow' for Type 1 and 'pale blue' for Type 2.
2. English, French and Spanish language versions are shown. With the exception of text in <arrow brackets>, manufacturers must use the exact wording shown in this annex.
3. The text enclosed in <arrow brackets> must be replaced with the appropriate product-specific name or description. Manufacturers are responsible for the correct translation of these passages.

FRONT FACE (English)

Type 1 – on light yellow card

Front face

Mount device here
and this way up

Use only for DTP, TT, DT, Td, HepB, IPV, liquid Hib and combination vaccines.

SENDER

1. Prepare the shipping container.
2. Break off the twin label with bar code and stick it onto the shipping documents.
3. Activate <DEVICE NAME> by <describe activation procedure for device> with a start delay of 1 hour.
4. Complete the card below in ball point pen.
5. Insert this card, with the activated device attached, into the shipping container.
6. Seal the shipping container.

Supplier name:

_____

Date: _____ Time: _____
dd.mm.yyyy hh:mm

Vaccine PO number: _____

Vaccine:

_____

RECEIVER: please turn the card!

⇨⇨

Type 2 – on pale blue card

Front face

Mount device here
and this way up

Use only for OPV, freeze-dried BCG, measles, MR, MMR, Hib, yellow fever and meningitis vaccines.

SENDER

1. Prepare the shipping container.
2. Break off the twin label with bar code and stick it onto the shipping documents.
3. Activate <DEVICE NAME> by <describe activation procedure for device> with a start delay of 1 hour.
4. Complete the card below in ball point pen.
5. Insert this card, with the activated device attached, into the shipping container.
6. Seal the shipping container.

Supplier name:

_____

Date: _____ Time: _____
dd.mm.yyyy hh:mm

Vaccine PO number: _____

Vaccine:

_____

RECEIVER: please turn the card!

⇨⇨

BACK FACE (English)

Type 1 - Back face

RECEIVER

1. On arrival, remove <DEVICE NAME> from the shipping container immediately.
2. <Describe stop procedure for device>.
3. Read the LCD display and follow the instructions as described below.

OK DISPLAY

<clearly illustrate OK screen display>

If OK, use vaccines normally.

ALARM DISPLAY

<clearly illustrate alarm screen display

If <DEVICE NAME> displays an alarm please proceed according to the decision table below:

Alarm temperature	What to do with vaccines:
>= 45° C	Contact procurement agency
>= 30° C	Contact procurement agency
<= -0.5° C	Conduct Shake Test. Use vaccines if passes. Inform procurement agency of test result.

Assembled and distributed by [company name and web address]

Type 2 - Back face

RECEIVER

1. On arrival, remove <DEVICE NAME> from the shipping container immediately.
2. <Describe stop procedure for device>.
3. Read the LCD display and follow the instructions as described below.

OK DISPLAY

<clearly illustrate OK screen display>

If OK, use vaccines normally.

ALARM DISPLAY

<clearly illustrate alarm screen display

If <DEVICE NAME> displays an alarm please proceed according to the decision table below:

Alarm temperature	What to do with vaccines:	
	OPV only	Other vaccines
>= 45° C	Contact procurement agency	Contact procurement agency
>= 30° C	Contact procurement agency	Contact procurement agency
>= 10° C	Contact procurement agency	Accept

Assembled and distributed by [company name and web address]

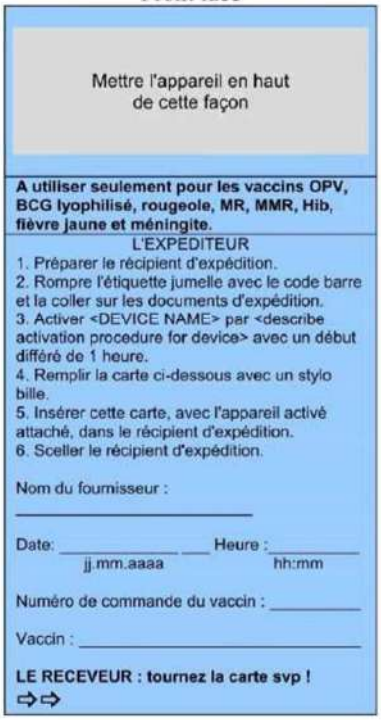
FRONT FACE (French)

Type 1 – on light yellow card

Front face

Type 2 – on pale blue card

Front face



BACK FACE (French)

Type 1 - Back face

RECEVEUR

1. A l'arrivée, enlever immédiatement <DEVICE NAME> du récipient d'expédition.
2. <Describe stop procedure for device>.
3. Lire l'affichage du LCD et suivre les instructions comme décrites ci-dessous.

SIGNAL OK

<clearly illustrate OK screen display>

Si OK, utiliser les vaccins normalement.

SIGNAL D'ALARME

<clearly illustrate alarm screen display

Si <DEVICE NAME> affiche une alarme s'il vous plaît procéder selon la table de décision ci-dessous

Température d'alarme	**Que faire avec les vaccins :**
>= 45° C	Contacter l'agence d'approvisionement
>= 30° C	Contacter l'agence d'approvisionement
<= -0.5° C	Faire un Test d'Agitation. Utiliser les vaccins si le test est conforme. Informer l'agence d'approvisionement du résultat du test.

Assemblé et distribué par [company name and web address]

Type 2 - Back face

RECEVEUR

1. A l'arrivée, enlever immédiatement <DEVICE NAME> du récipient d'expédition.
2. <Describe stop procedure for device>.
3. Lire l'affichage du LCD et suivre les instructions comme décrites ci-dessous.

SIGNAL OK

<clearly illustrate OK screen display>

Si OK, utiliser les vaccins normalement.

SIGNAL D'ALARME

<clearly illustrate alarm screen display

Si <DEVICE NAME> affiche une alarme s'il vous plaît procéder selon la table de décision ci-dessous

Température d'alarme	**Que faire avec les vaccins :**	
	Seulement OPV	Autres vaccins
>= 45° C	Contacter l'agence d'approvision-ement	Contacter l'agence d'approvision-ement
>= 30° C	Contacter l'agence d'approvision-ement	Contacter l'agence d'approvision-ement
>= 10° C	Contacter l'agence d'approvision-ement	Accepter

Assemblé et distribué par [company name and web address]

FRONT FACE (Spanish)

Tipo 1 – en tarjeta amarillo claro
Cara frontal

Coloque el dispositivo aquí, en la posición correcta

Para ser solo utilizado en vacunas de DTP, TT, DT, Td, HepB, IPV, Hib liquida y vacunas combinadas.

REMITENTE

1. Prepare el contenedor de embarque.
2. Rompa la etiqueta con el código de barras por la marca identificada y colóquela en los documentos de embarque.
3. Active <DEVICE NAME> por <describe activation procedure for device> con comienzo demorado de 1 hora.
4. Complete la tarjeta amarilla que aparece debajo utilizando un bolígrafo.
5. Inserte esta tarjeta, con el dispositivo activado, dentro del contenedor de embarque.
6. Selle el contenedor de embarque.

Nombre del suministrador:
_____

Fecha: _____ Tiempo:_____
dd.mm.yyyy hh:mm

Numero OP de la vacuna: _____

Vacuna: _____

RECEPTOR: Por favor voltee la tarjeta!
⇨⇨

Tipo 2 – en tarjeta azul pálido
Cara frontal

Coloque el dispositivo aquí, en la posición correcta

Para ser solo utilizado en vacunas de OPV, BCG liofilizada, sarampión, MR, MMR, Hib, fiebre amarilla y vacunas antimeningococcicas.

SENDER

1. Prepare el contenedor de embarque.
2. Rompa la etiqueta con el código de barras por la marca identificada y colóquela en los documentos de embarque.
3. Active <DEVICE NAME> por <describe activation procedure for device> con comienzo demorado de 1 hora.
4. Complete la tarjeta amarilla que aparece debajo utilizando un bolígrafo.
5. Inserte esta tarjeta, con el dispositivo activado, dentro del contenedor de embarque.
6. Selle el contenedor de embarque.

Nombre del suministrador:
_____

Fecha:: _____ Tiempo:_____
dd.mm.yyyy hh:mm

Numero OP de la vacuna _____

Vacuna: _____

RECEPTOR: Por favor voltee la tarjeta!
⇨⇨

BACK FACE (Spanish)

Type 1 - Cara posterior

RECEPTOR

1. A la llegada, remueva inmediatamente <DEVICE NAME> del contenedor de embarque.
2. <Describe stop procedure for device>.
3. Lea la pantalla de cristal líquido del dispositivo y siga las instrucciones que se detallan a continuación.

PANTALLA

<clearly illustrate OK screen display>

Si OK, use la vacuna normalmente.

PANTALLA DE ALARMA

<clearly illustrate alarm screen display>

Si <DEVICE NAME> ilustra alarma, por favor proceda de acuerdo con lo indicado en la tabla de decisión que aparece a continuación:

Temperatura alarma	Qué hacer con la vacuna:
>= 45° C	Contactar con el proveedor
>= 30° C	Contactar con el proveedor
<= -0.5° C	Realizar el ensayo de agitación o Shake Test. Use la vacuna si esta pasa el ensayo. Informe al proveedor de los resultados del ensayo.

Ensamblado y distribuido por [company name and web address]

Type 2 - Back face

RECEPTOR

1. A la llegada, remueva inmediatamente <DEVICE NAME> del contenedor de embarque.
2. <Describe stop procedure for device>.
3. Lea la pantalla de cristal líquido del dispositivo y siga las instrucciones que se detallan a continuación.

PANTALLA

<clearly illustrate OK screen display>

Si OK, use la vacuna normalmente.

PANTALLA DE ALARMA

<clearly illustrate alarm screen display>

Si <DEVICE NAME> ilustra alarma, por favor proceda de acuerdo con lo indicado en la tabla de decisión que aparece a continuación:

Temperatura alarma	Qué hacer con la vacuna:	
	Solo OPV	Otras vacunas
>= 45° C	Contactar con el proveedor	Contactar con el proveedor
>= 30° C	Contactar con el proveedor	Contactar con el proveedor
>= 10° C	Contactar con el proveedor	Aceptado

Assembled and distributed by [company name and web address]

Annexure- V

VACCINE ARRIVAL REPORT (VAR)

This report is to be filled in by an authorized staff and forwarded to the Supplier within 3 days of vaccine arrival. Use one report for each vaccine in the shipment.

Date of Report	

COUNTRY	**INDIA**
REPORT No.	

Place, Date and Time of Inspection	Name of Cold Store, Date and Time vaccines entered in Cold Store

PART I- ADVANCE NOTICE

MAIN DOCUMENTS	Date received by Consignee	Copy Airway Bill (AWB)	Copy of Packing List	Copy of Invoice	Copy of Release Certificate
Pre- advice					
Shipping Notification		Yes No	Yes No	Yes No	Yes No

List of Other Documents (If required)

PART II- FLIGHT ARRIVAL DETAILS

AWB Number	Airport of Destination	Flight No.	ETA as per notification		Actual Time of Arrival	
			Time	Date	Date	Time

Name of Clearing Agent:	**On behalf of:**

PART III- DETAILS OF VACCINE SHIPMENT

Purchase Order No.	Consignee	Vaccine Description (type & doses/vial)	Manufacture	Country

VACCINE				**DILUENT/DROPPERS**			
Lot Number	No. of Boxes	No. of Vials	Expiry Date	Lot Number	No. of Boxes	No. of Vials	Expiry Date

	Yes	No	Comments
Was quantity received as per shipping notification?			
If not, were the details of short-shipment provided prior to vaccine arrival?			

Report No	

PART IV-DOCUMENTS ACCOMPANYING THE SHIPMENT

Invoice	Packing List	Release Certificate	Vaccine Arrival Report	Other
Yes No	Yes No	Yes No	Yes No	
Comments				

PART V – STATUS OF SHIPPING INDICATORS

Total No. of Boxes Inspected		
Coolant Type:	Ice packs / Any Other	No coolant
Temperature Monitors Present:	VVM	Recorder

PROVIDE BELOW THE DETAILS OF THE STATUS ONLY WHEN PROBLEMS ARE OBSERVED

Box	**Lot**	**VVM Stage**	**Cold Chain Monitor**	**Freeze Watch**	**Date/Time of**

No.	No.									Burst		Inspection
		1	2	3	4	A	B	C	D	Yes	No	

Temperature Recorder	Box Number	Model	Serial no
If applicable, send clear copy of chart (together with this report)			

PART VI – GENERAL CONDITIONS

What was the condition of boxes on arrival?	
Were necessary labels attached to shipping boxes?	
Other Comments: (continue in separate sheet if necessary)	

SECTION VII: GENERAL CONDITIONS OF CONTRACT (GCC)

1. General	**1.1 Tenets of Interpretation** Unless where the context requires otherwise, throughout the contract: 1) The heading of these conditions shall not affect the interpretation or construction thereof. 2) Writing or written includes matter either whole or in part, in digital communications, manuscript, typewritten, lithographed, cyclostyled, photographed, or printed under or over signature or seal or digitally acceptable authentication, as the case may be. 3) Words in the singular include the plural and vice-versa. 4) Words importing the masculine gender shall be taken to include other genders, and words importing persons shall include any company or association or body of individuals, whether incorporated or not. 5) Terms and expression not herein defined shall have the meanings assigned to them in the contract Act, 1872 (as amended) or the Sale of Goods Act, 1930 (as amended) or the General Clauses Act, 1897 (as amended) or of INCOTERMS, (current edition published by the International Chamber of Commerce, Paris) as the case may be. 6) Any reference to 'Goods' shall be deemed to include the incidental Works/ Services also. 7) Any generic reference to GCC shall also imply a reference to SCC as well. 8) In case of conflict, provisions of SCC shall prevail over those in GCC. 9) Any reference to 'Contract' shall be deemed to include all other documents (inter-alia GCC, SCC) as described in GCC-clause 2.5. 10) Any reference to any legal Act, Government Policies or orders shall be deemed to include all amendments to such instruments, from time to time, till date. 11) Deleted. **1.2 Definitions** In the contract, unless the context otherwise requires: 1) "Agent" is a person employed to do any act for another or represent another in dealings with a third person. In the context

	of public procurement, an Agent is a representative participating in the Tender Process or Execution of a Contract for and on behalf of its principals. 2) "Allied Firm" are all business entities that are within the 'controlling ownership interest' (ownership of or entitlement to more than twenty-five percent of the company's shares or capital or profits) or 'control'(including the right to appoint a majority of the directors or to control the management or policy decisions including by virtue of their shareholding or management rights or shareholder agreements or voting agreements) of the principal firm acting alone or together or through one or more juridical persons. All successor firms or assigns of the principal firm shall be considered allied firms. 3) "bid" (including the term 'tender', 'offer', 'quotation' or 'proposal' in specific contexts) means an offer to supply goods, services or execution of works made as per the terms and conditions set out in a document inviting such offers. 4) "Bidder" (including the term 'Bidder', 'consultant' or 'service provider' in specific contexts) means any person or firm or company, including any member of a consortium or joint venture (that is an association of several persons, or firms or companies), every artificial juridical person not falling in any of the descriptions of bidders stated hereinbefore, including any agency branch or office controlled by such person, participating in a Tender Process. 5) "Bill of Quantities" (including the term Price Schedule or BOQ) means the priced and completed Bill of Quantities forming part of the bid. 6) "Commercial Bank" means a bank, defined as a scheduled bank under section 2(e) of the Reserve Bank of India Act, 1934. 7) "Consignee" means the person to whom the goods are required to be delivered as stipulated in the contract. A contract may provide the goods to be delivered to an interim consignee for further dispatch to the ultimate consignee. 8) "Contract" (including the terms 'Purchase Order' or 'Supply Order' or 'Withdrawal Order' or 'Work Order' or 'Consultancy Contract' or 'Contract for Services', 'rate contract' or 'framework contract' or 'Letter of Award – LoA' (letter or memorandum communicating to the contractor the acceptance of his bid) or 'Agreement' or a 'repeat order' accepted/ acted upon by the contractor or a 'formal agreement', under specific contexts), means a formal legal agreement in writing relating to the subject matter of procurement, entered into between the

	Procuring Entity and the contractor on mutually acceptable terms and conditions and which are in compliance with all the relevant provisions of the laws of the country; 9) "Contractor" (including the terms 'Supplier' or 'Service Provider' or 'Consultant' or 'Firm' or 'Vendor' or 'Manufacturer' or 'Successful Bidder' under specific contexts) means the person, firm, company, or a Joint Venture with whom the contract is entered into and shall be deemed to include the contractor's successors (approved by the Procuring Entity), agents, subcontractor, representatives, heirs, executors, and administrators as the case may be unless excluded by the terms of the contract.; 10) "Day", "Month", "Year" shall mean calendar day/ month or year (unless reference to financial year is clear from the context). 11) "Drawing" means the drawing or drawings stipulated in or annexed to the Specifications or the Tender Document/ Contract; 12) "General Conditions" means the General Conditions of Contract, also referred to as GCC. 13) "Goods" (including the terms 'Stores', 'Material(s)' in specific contexts) includes all articles, material, commodity, livestock, medicines, furniture, fixtures, raw material, consumables, spare parts, instruments, machinery, equipment, industrial plant, vehicles, aircrafts, ships, railway rolling stock assemblies, sub-assemblies, accessories, a group of machines comprising an integrated production process or such other categories of goods or intangible, products like technology transfer, licenses, patents or other intellectual properties (but excludes books, publications, periodicals, etc., for a library) under specific context), procured or otherwise acquired by a Procuring Entity. Any reference to Goods shall be deemed to include specific small work or some services that are incidental or consequential to the supply of such goods; 14) "Government" means the Central Government or a State Government as the case may be and includes agencies and Public Sector Enterprises under it, in specific contexts; 15) "Inspection" means activities such as measuring, examining, testing, analysing, gauging one or more characteristics of the goods or services or works, and comparing the same with the specified requirement to determine conformity. 16) "Inspecting Officer" means the person or organisation stipulated in the contract for inspection under the contract and includes his/ their authorised representative;

	17) "Intellectual Property Rights" (IPR) means the rights of the intellectual property owner concerning a tangible or intangible possession/ exploitation of such property by others. It includes rights to Patents, Copyrights, Trademarks, Industrial Designs, Geographical indications (GI). 18) **"**Parties": The parties to the contract are the "Contractor" and the Procuring Entity, as defined in this clause; 19) "Performance Security" (includes the terms 'Security Deposit' or 'Performance Bond' or 'Performance Bank Guarantee' or other specified financial instruments in specific contexts) means a monetary guarantee to be furnished by the successful Bidder or Contractor in the form prescribed for the due performance of the contract; 20) "Place of Delivery" the delivery of the Goods shall be deemed to take place on delivery of the Goods, at consignees' premises, unless otherwise stipulated in the contract. 21) "Procurement" or "public procurement" (or 'Purchase', or 'Government Procurement/ Purchase' including an award of Public-Private Partnership projects, in specific contexts) means the acquisition of Goods/ Services/ works by way of purchase, lease, license or otherwise, either using public funds or any other source of funds (e.g. grant, loans, gifts, private investment etc.) of goods, works or services or any combination thereof, by a Procuring Entity, whether directly or through an agency with which a contract for procurement services is entered into, but does not include any acquisition without consideration. The term "procure"/ "procured" or "purchase"/ "purchased" shall be construed accordingly; 22) "The Procuring Entity" means the entity in The Procuring Organization procuring Goods or Works or Services; 23) "Procurement Officer" means the officer signing the Letter of Award (LoA) and/or the contract on behalf of the Procuring Entity; 24) "Service(s)" (including the term 'Non-consultancy services' or 'Outsourcing of Services' in specific contexts) are defined by exclusion as services that cannot be classified as Consultancy Services. Services (Non-consultancy) involve routine, repetitive physical, procedural, and non-intellectual outcomes for which quantum and performance standards can be tangibly identified and consistently applied and are bid and contracted on such basis but does not include the appointment of an individual made under any law, rules, regulations, or order issued in this behalf. Any reference to Services shall be deemed to include the supply

	of goods or performance of consultancy service or small works, which are incidental or consequential to such services; 25) "Special Conditions" means Special Conditions of Contract, which override the General Conditions, also referred to as SCC. 26) "Specification" or "Technical Specification" means the drawing/ document/ standard or any other details governing the construction, manufacture or supply of goods or performance of services that prescribes the requirement to which goods or services have to conform as per the contract. 27) "Signed" means ink signed or digitally signed with a valid Digital Signature as per IT Act 2000 (as amended from time to time). It also includes stamped, except in the case of Letter of Award or amendment thereof.; 28) "Tender"; "Tender Document"; "Tender Enquiry" or "Tender Process": 'Tender Process' is the whole process from the publishing of the Tender Document till the resultant award of the contract. 'Tender Document' means the document (including all its sections, appendices, forms, formats, etc.) published by the Procuring Entity to invite bids in a Tender Process. The Tender Document and Tender Process may be generically referred to as "Tender" or "Tender Enquiry", which would be clear from context without ambiguity. 29) "Test" means such test as is prescribed by the particulars governing the construction, manufacture or supply of Goods as may be prescribed by the contract or considered necessary by the Inspecting Officer whether performed or made by the Inspecting Officer or any agency acting under the direction of the Inspecting Officer; 30) "Works" refer to any activity involving construction, fabrication, repair, overhaul, renovation, decoration, installation, erection, excavation, dredging, and so on, which make use of a combination of one or more of engineering design, architectural design, material and technology, labour, machinery, and equipment. **1.3 Document Conventions** All words and phrases defined in GCC-clause 1.2 are written as 'Capitalized word' and shall have the defined meaning. The rest of the words shall be as per grammar, inter-alia 'Goods' shall indicate definition as given in the GCC while 'goods' shall have usual dictionary meaning. **1.4 Abbreviations:**

Abbreviation	Definition
BOQ	Bill of Quantities (Excel sheet of Price Schedule)
BSD	Bid Securing Declaration
CGST	Central Goods and Services Tax
CPPP	Central Public Procurement Portal
DoE	Department of Expenditure
DP	Delivery Period
DPIIT	Department for Promotion of Industry and Internal Trade
DSC	Digital Signature Certificate
EFT/ NEFT	(National) Electronic Funds Transfer
GCC	General Conditions of Contract
GeM	Government e-Marketplace
GRIR	Goods Receipt and Inspection Report
GST	Goods and Services Tax
GTE	Global Tender Enquiry (International Competitive Bidding)
HSN	Harmonized System of Nomenclature
IEM	Independent External Monitor
IPR	Intellectual Property Rights
INR	Indian Rupee
ITB	Instructions To Bidders
ITC (HS)	Indian Tariff Classification (Harmonised System)
LoA	Letter of Award (Acceptance)
MII	Make in India
MSE	Micro and Small Enterprises
MSME	Micro, Small and Medium Enterprises
MSMED	MSME Development (Act)
NIT	Notice Inviting Tender

		OEM	Original Equipment Manufacturer
		PAN	Permanent Account Number
		PC	(Indian) Penal Code
		PPD	Procurement Policy Division
		PQB	Pre-Qualification Bidding
		RCM	Reverse Charge Mechanism
		SC	Scheduled Caste
		SCC	Special Conditions of Contract
		ST	Scheduled Tribe
		TCS	Tax Collected at Source
		TDS	Tax Deducted at Source
		TIA	Tender Inviting Authority
		TIS	Tender Information Summary
2. The	**2. The Contract** **2.1 Language of Contract** The contract shall be written in the English Language. All correspondence and other contract documents, which the parties exchange, shall also be written accordingly in English language. **2.2 The Entire Agreement** This Contract and its documents (referred to in GCC-clause 2.5 below) constitutes the entire agreement between the Procuring Entity and the contractor and supersedes all other communications, negotiations, and agreements (whether written or oral) of the Parties made before the date of this Contract. No agent or representative of either Party has the authority to make, and the Parties shall not be bound by or be liable for, any statement, representation, promise or agreement not outlined in this Contract. **2.3 Severability** If any provision or condition of this Contract is prohibited or rendered invalid or unenforceable, such prohibition, invalidity or unenforceability shall not affect the validity or enforceability of any other provisions and conditions of this Contract. **2.4 Parties** The parties to the contract are the contractor and the Procuring Entity,		

	as defined in GCC-clause 1.2 above and nominated in the contract. **2.5 Contract Documents and their Precedence** The following conditions and documents in indicated order of precedence (higher to lower) shall be considered an integral part of the contract, irrespective of whether these are not appended/ referred to in it. Any generic reference to 'Contract' shall imply reference to all these documents as well: 1) Valid and authorized Amendments issued to the contract. 2) the Agreement consisting of the initial paragraphs, recitals and other clauses set forth immediately before the GCC and including the formats annexed to it and signatures of Procuring Entity; 3) the Letter of Award (LoA) 4) Final written submissions made by the contractor during negotiations, if any; 5) the SCC 6) the GCC 7) the contractor's bid; 8) any other document listed in the SCC as forming part of this Contract. 9) Integrity Pact, if any **2.6 Modifications/ Amendments, Waivers and Forbearances** **2.6.1 Modifications/ Amendments of Contract** 1) If any of the contract provisions must be modified after the contract documents have been signed, the modifications shall be made in writing and signed by the Procuring Entity, and no modified provisions shall be applicable unless such modifications have been done. No variation in or modification of the contract terms shall be made except by a written amendment signed by the Procuring Entity. Requests for changes and modifications may be submitted in writing by the contractor to the Procuring Entity. At any time during the currency of the contract, the Procuring Entity may suo-moto or, on request from the contractor, by written order, amend the contract by making alterations and modifications within the general scope of the Contract. 2) If the contractor does not agree to the suo-moto modifications/ amendments made by the Procuring Entity, he shall convey his views within 03 working days from the date of amendment/

	modification. Otherwise, it shall be assumed that the contractor has consented to the amendment. 3) Any verbal or written arrangement abandoning, modifying, extending, reducing, or supplementing the contract or any of the terms thereof shall be deemed conditional and shall not be binding on the Procuring Entity unless and until the same is incorporated in a formal instrument and signed by the Procuring Entity, and till then the Procuring Entity shall have the right to repudiate such arrangements. **2.6.2 Waivers and Forbearances** The following shall apply concerning any waivers, forbearance, or similar action taken under this Contract: 1) Any waiver of a Procuring Entity's rights, powers, or remedies under this Contract must be in writing, dated, and signed by an authorized representative of the Procuring Entity granting such waiver and must specify the terms under which the waiver is being granted. 2) No relaxation, forbearance, delay, or indulgence by Procuring Entity in enforcing any of the terms and conditions of this Contract or granting of an extension of time by Procuring Entity to the contractor shall, in any way whatsoever, prejudice, affect, or restrict the rights of Procuring Entity under this Contract, neither shall any waiver by Procuring Entity of any breach of Contract operate as a waiver of any subsequent or continuing breach of Contract.
3. Governing Laws and Jurisdiction	**3.1 Governing Laws and Jurisdiction** 1) This Contract, its meaning and interpretation, and the relation between the Parties shall be governed by the Laws of India for the time being in force. 2) Irrespective of the place of delivery, or the place of performance or the place of payments under the contract, the contract shall be deemed to have been made at the place from which the Letter of Award (LoA or the contract Agreement, in the absence of LoA) has been issued. The courts of such a place shall alone have jurisdiction to decide any dispute arising out or in respect of the contract. **3.2 Changes in Laws and Regulations** Unless otherwise stipulated in the contract, if after the last deadline for the bid submission (Techno-commercial), any law, regulation,

	ordinance, order or bye-law having the force of law is enacted, promulgated, abrogated, or changed in India (which shall be deemed to include any change in interpretation or application by the competent authorities) that subsequently affects the Delivery Date and/ or the contract Price, then such Delivery Date and/ or Contract Price shall be correspondingly increased or decreased, to the extent that the contractor has thereby been affected in the performance of any of its obligations under the contract. Notwithstanding the foregoing, such additional or reduced cost shall not be separately paid or credited if the same has already been accounted for in the price adjustment provisions where applicable.
4. Communications	**4.1 Communications** 1) All communications under the contract shall be served by the parties on each other in writing, in the contract's language, and served in a manner customary and acceptable in business and commercial transactions. 2) The effective date of such communications shall be either the date when delivered to the recipient or the effective date mentioned explicitly in the communication, whichever is later. 3) No communication shall amount to an amendment of the terms and conditions of the contract, except a formal letter of amendment of the contract, so designated. 4) Such communications would be an instruction or a notification or an acceptance or a certificate from the Procuring Entity, or it would be a submission or a notification from the contractor. A notification or certificate which the contract requires must be communicated separately from other communications. **4.2 The person signing the Communications** For all purposes of the contract, including arbitration, thereunder all communications to the other party shall be signed by: 1) The person who has signed the contract on behalf of the contractor shall sign all correspondences. A person signing communication in respect of the contract or purported to be on behalf of the contractor, without disclosing his authority to do so, shall be deemed to warrant that he has authority to bind the contractor. If it is discovered at any time that the person, so signing has no authority to do so, the Procuring Entity reserves its right to, without prejudice to any other right or remedy, to terminate the contract for default in terms of the contract and avail any or all the remedies thereunder and hold such person

	personally and/ or the contractor liable to the Procuring Entity for all costs and damages arising from such remedies. 2) Unless otherwise stipulated in the contract, the Procurement Officer signing the contract shall administer the contract and sign communications on behalf of the Procuring Entity. Interim or ultimate consignees; Inspecting Agency/ officers and the paying authorities mentioned in the contract shall also administer respective functions during Contract Execution. **4.3 Address of the parties for sending communications by the other party.** 1) For all purposes of the contract, including arbitration, thereunder the address of parties to which the other party shall address all communications and notices shall be: a) The address of the contractor as mentioned in the contract unless the contractor has notified the change of address by a separate communication containing no other topic to the Procuring Entity. The Contractor shall be solely responsible for the consequence of an omission to notify a change of address in the manner aforesaid, and b) The address of the Procuring Entity shall be the address mentioned in the contract. The contractor shall also send additional copies to officers of the Procuring Entity presently dealing with the contract. c) In case of the communications from the contractor, copies of communications shall be marked to the Procurement Officer signing the contract, and as relevant also to Inspecting Agency/ Officer; interim/ ultimate consignee and paying authorities mentioned in the contract. Unless already stipulated in the contract before the contract's start, the Procuring Entity and the contractor shall notify each other if additional copies of communications are to be addressed to additional addresses.
5. Contractor's Obligations and restrictions on its Rights	**5.1 Changes in Constitution/ financial stakes/ responsibilities of a Contract's Business** The Contractor must proactively keep the Procuring Entity informed of any changes in its constitution/ financial stakes/ responsibilities during the execution of the contract. Where the contractor is a partnership firm, the following restrictions shall apply to changes in the constitution during the execution of the contract:

1) A new partner shall not be introduced in the firm except with the previous consent in writing of the Procuring Entity, which shall be granted only upon execution of a written undertaking by the new partner to perform the contract and accept all liabilities incurred by the firm under the contract before the date of such undertaking.

2) On the death or retirement of any partner of the contractor firm before the complete performance of the contract, the Procuring Entity may, at his option, terminate the contract for default as per the Contract and avail any or all remedies thereunder.

3) If the contract is not terminated as provided in Sub-clause (2) above notwithstanding the retirement of a partner from the firm, that partner shall continue to be liable under the contract for acts of the firm until a copy of the public notice given by him under Section 32 of the Partnership Act, has been sent by him to the Procuring Entity in writing or electronically.

5.2 Obligation to Maintain Eligibility and Qualifications

1) The contract has been awarded to the contractor based on specific eligibility and qualification criteria. The Contractor is contractually bound to maintain such eligibility and qualifications during the execution of the contract. Any change which would vitiate the basis on which the contract was awarded to the contractor should be pro-actively brought to the notice of the Procuring Entity within 7 days of it coming to the Contractor's knowledge. These changes include but are not restricted to:

   a) Change regarding declarations made by it in its bid in Form 1.2: Eligibility Declaration
   b) Change in its qualification criteria submitted in its bid in Form 4: Qualification Criteria - Compliance and its sub-form(s).

5.3 Restriction on Potential Conflict of Interests

Neither the contractor nor its Subcontractors nor the Personnel shall engage, either directly or indirectly, in any of the following activities:

1) during the term of this Contract, any business or professional activities in India that would conflict with the activities assigned to them under this Contract.

2) after the termination of this Contract, such other activities as may be stipulated in the contract.

5.4 Consequences of a breach of Obligations

Should the contractor or any of its partners or its Subcontractors or the

	Personnel commit a default or breach of GCC-clause 5.1 to 5.7, the Contractor shall remedy such breaches within 21 days, keeping the Procuring Entity informed. However, at its discretion, the Procuring Entity shall be entitled, and it shall be lawful on his part, to treat it as a breach of contract and avail any or all remedies thereunder. The decision of the Procuring Entity as to any matter or thing concerning or arising out of GCC-clause 5.1 to 5.7 or on any question whether the contractor or any partner of the contractor firm has committed a default or breach of any of the conditions shall be final and binding on the contractor. **5.5 Assignment and Sub-contracting** 1) the contractor shall not, save with the previous consent in writing of the Procuring Entity, sublet, transfer, or assign the contract or any part thereof or interest therein or benefit or advantage thereof in any manner whatsoever. 2) the contractor shall notify the Procuring Entity in writing all subcontracts awarded under the contract if not already stipulated in the contract. In its original bid or later, such notification shall not relieve the contractor from any of its liability or obligation under the terms and conditions of the contract. Subcontract shall be only for bought out items and incidental Works/ Services. Subcontracts must comply with and should not circumvent Contractor's compliance with its obligations under GCC-clause 5.1 to 5.7, based on which the contract was awarded to him. 3) If the Contractor sublets or assigns this contract or any part thereof without such permission, the Procuring Entity shall be entitled, and it shall be lawful on his part, to treat it as a breach of contract and avail any or all remedies thereunder. **5.6 Indemnities for breach of IPR Rights** 1) the contractor shall indemnify and hold harmless, free of costs, the Procuring Entity and its employees and officers from and against all suits, actions or administrative proceedings, claims, demands, losses, damages, costs, and expenses of any nature, including attorney's fees and expenses, which may arise in respect of the Goods provided by the contractor under this Contract, as a result of any infringement or alleged infringement of any patent, utility model, registered design, copyright, or other Intellectual Proprietary Rights (IPR) or trademarks, registered or otherwise existing on the date of the contract arising out of or in connection with:

a) any design, data, drawing, specification, or other documents or Goods provided or designed by the contractor for or on behalf of the Procuring Entity, and
b) The installation of the Goods by the contractor or the use of the Goods at the Procuring Entity's Site

2) Such indemnity shall not cover any use of the Goods or any part thereof or any products produced thereby:

a) other than for the purpose indicated by or to be reasonably inferred from the contract
b) in association or combination with any other equipment, plant, or materials not supplied by the contractor.

3) If any proceedings are brought, or any claim is made against the Procuring Entity arising out of the matters referred above, the Procuring Entity shall promptly give the contractor a notice thereof. At its own expense and in the Procuring Entity's name, the contractor may conduct such proceedings and negotiations to settle any such proceedings or claim, keeping the Procuring Entity informed.

4) If the contractor fails to notify the Procuring Entity within twenty-eight (28) days after receiving such notice that it intends to conduct any such proceedings or claim, then the Procuring Entity shall be free to conduct the same on its behalf at the risk and cost to the contractor.

5) At the contractor's request, the Procuring Entity shall afford all available assistance to the contractor in conducting such proceedings or claim and shall be reimbursed by the contractor for all reasonable expenses incurred in so doing.

5.7 Confidentiality, Secrecy and IPR Rights

5.7.1 IPR Rights

All deliverables, outputs, plans, drawings, specifications, designs, reports, and other documents and software submitted by the contractor under this Contract shall become and remain the property of the Procuring Entity and subject to laws of copyright and must not be shared with third parties or reproduced, whether in whole or part, without the Procuring Entity's prior written consent. The contractor shall, not later than upon termination or expiration of this Contract, deliver all such documents and software to the Procuring Entity, together with a detailed inventory thereof. The contractor may retain a copy of such documents and software but shall not use it for any commercial purpose**.**

5.7.2 Confidentiality

All documents, drawings, samples, data, associated correspondence or other information furnished by or on behalf of the Procuring Entity to the contractor, in connection with the contract, whether such information has been furnished before, during or following completion or termination of the contract, are confidential and shall remain the property of the Procuring Entity and shall not, without the prior written consent of Procuring Entity neither be divulged by the contractor to any third party, nor be used by him for any purpose other than the design, procurement, or other services and work required for the performance of this Contract. If advised by the Procuring Entity, all copies of all such information in original shall be returned on completion of the contractor's performance and obligations under this contract.

5.7.3 Secrecy

If the Contract declares the subject matter of this Contract as coming under the Official Secrets Act, 1923 or if the contract is marked as "Secret", the contractor shall take all reasonable steps necessary to ensure that all persons employed in any connection with the contract, have acknowledged their responsibilities and penalties for violations under the Official Secrets Act and any regulations framed thereunder.

5.7.4 Obligations of the contractor

1) Without the Procuring Entity's prior written consent, the contractor shall not use the information mentioned above except for the sole purpose of performing this contract.

2) The contractor shall treat and mark all information as confidential (or secret – as the case may) and shall not, without the written consent of the Procuring Entity, divulge to any person other than the person(s) employed by the contractor in the performance of the contract. Further, any such disclosure to any such employed person shall be made in confidence and only so far as necessary for such performance for this contract.

3) Notwithstanding the above, the contractor may furnish to its holding company or its Subcontractor(s) such documents, data, and other information it receives from the Procuring Entity to the extent required for performing the contract. In this event, the contractor shall obtain from such holding company/ Subcontractor(s) an undertaking of confidentiality (or secrecy – as the case may be) similar to that imposed on the contractor under the above clauses.

4) The obligation of the contractor under sub-clauses above, however, shall not apply to information that:

   a) the contractor needs to share with the institution(s) participating in the financing of the contract;
   b) now or hereafter is or enters the public domain through no fault of Contractor;
   c) can be proven to have been possessed by the contractor at the time of disclosure and which was not previously obtained, directly or indirectly, from the Procuring Entity; or
   d) Otherwise lawfully becomes available to the contractor from a third party that has no obligation of confidentiality.

5) The above provisions shall not in any way modify any undertaking of confidentiality (or Secrecy – as the case may be) given by the contractor before the date of the contract in respect of the contract/ the Tender Document or any part thereof.

6) The provisions of this clause shall survive completion or termination for whatever reason of the contract.

5.8 Performance Security

1) Unless stipulated otherwise in SCC, within fourteen days after the issue of Letter of Award (LoA or the contract, if LoA is skipped) by the Procuring Entity, the contractor shall furnish to the Procuring Entity, performance security, as per details given in SCC.

2) The Performance security shall be denominated in Indian Rupees or the currency of the contract and shall be in one of the following forms:

   a) Unless otherwise stipulated in Tender Document or Contract, Account Payee Demand Draft or Fixed Deposit Receipt or Banker's Cheque drawn on any commercial bank in India, favoring Central Medical Services Society payable at New Delhi.
   b) Bank Guarantee issued by a commercial bank in India, in the prescribed form provided in Format 1.1.

3) If the contractor, having been called upon by the Procuring Entity to furnish Performance Security, fails to do so within the specified period, it shall be lawful for the Procuring Entity at its discretion to annul the award and forfeit the EMD/ enforce Bid Securing Declaration, as the case may be.

	4) If the contractor during the currency of the Contract fails to maintain the requisite Performance Security, it shall be lawful for the Procuring Entity at its discretion a) to terminate the Contract for Default besides availing any or all contractual remedies provided for breaches/ default, or b) without terminating the Contract: 1. Recover from the contractor the amount of such security deposit by deducting the amount from the pending bills of the contractor under the contract or any other contract with the Procuring Entity or 2. Treat it as a breach of contract and avail any or all contractual remedies provided for breaches/ default. 5) In the event of any amendment issued to the contract, the contractor shall furnish suitably amended value and validity of the Performance Security in terms of the amended contract within fourteen days of issue of the amendment. 6) The Procuring Entity shall be entitled, and it shall be lawful on his part, a) to deduct from the performance securities or to forfeit the said security in whole or in part in the event of: i. any default, or failure or neglect on the part of the contractor in the fulfilment or performance in all respect of the contract under reference or any other contract with the Procuring Organisation or any part thereof ii. for any loss or damage recoverable from the contractor which the Procuring Entity may suffer or be put to for reasons of or due to above defaults/ failures/ neglect b) and in either of the events aforesaid to call upon the contractor to maintain the said performance security at its original limit by making further deposits, provided further that the Procuring Entity shall be entitled, and it shall be lawful on his part, to recover any such claim from any sum then due or which at any time after that may become due to the contractor for similar reasons. 7) Subject to the sub-clause above, the Procuring Entity shall release the performance security without any interest to the contractor on completing all contractual obligations, including the warranty obligations, if any.

8) No claim shall lie against the Procuring Entity regarding interest on cash deposits or Government Securities or depreciation thereof.

5.9 Permits, Approvals and Licenses

Whenever the supply of Goods and incidental Works/ Services requires that the contractor obtain permits, approvals, and licenses from local public authorities, it shall be the contractor's sole responsibility to obtain these and keep these current and valid. Such requirements may include but not be restricted to export licence or environmental clearance if required. If requested by the contractor, the Procuring Entity shall make its best effort to assist the contractor in complying with such requirements in a timely and expeditious manner, without any dilution of the Contractor's responsibility in this regard.

5.10 Book Examination Clause

The Procuring Entity reserves the right for 'Book Examination' as follows:

1) the contractor shall, whenever called upon and required to produce or cause to be produced, for examination by any Government Officer duly authorised in that behalf, any cost or other book of account, voucher, receipt, letter, memorandum, paper or writing or any copy of or extract from any such document. The Contractor shall also furnish information relating to the execution of this contract or relevant for verifying or ascertaining the cost of executing this contract to such Government Officer in such manner as may be required. The decision of such Government Officer on the question of relevancy of any document, information of return being final and binding on the parties. The obligation imposed by this clause is without prejudice to the contractor's obligations under any other statute, rules or orders which shall be concurrently binding on the contractor.

2) the contractor shall, if the authorised Government Officer so requires (whether before or after the prices have been finally fixed), afford facilities to the Government Officer concerned to visit the contractor's premises to examine the processes of production and estimate or ascertaining the cost of performance of Contract. The authorised Government Officer shall have power, mutadis mutandis, to examine all the relevant books of Contractor's subcontractor, or any subsidiary or allied firm or

	company, If any portion of the contract is entrusted or carried out by such entities. 3) If on such examination, it is established that the contracted price is more than the actual cost-plus reasonable margin of profit, the Procuring Entity shall have the right to reduce the price and determine the amount to a reasonable level. 4) The Contractor or its agency is bound to allow examination of its books within 60 days from the date the notice is received by the contractor or its agencies calling for the production of documents under sub-clause (1) above. In the event of the contractor's or his agency's failure to do so, the contract price would be reduced and determined according to the best judgment of the Procuring Entity, which would be final and binding on the contractor and his agencies. **5.11– Deleted.** **5.12– Deleted**
6. Scope of Supply and Technical Specifications	**6.1 The Scope of Supply** 1) The contract is for supply of goods as stipulated in "Schedule of Requirement" conforming to specification as indicated in the "Technical Specification and Quality Assurance" and as per terms and conditions as indicated in GCC (General Condition of contract) read with SCC (Special Condition of Contract). 2) Incidental Works/ Services: If so stipulated, the contractor shall be required to perform specified incidental Works/ Services as an integral part of the Goods in the contract. **6.2 Technical Specifications and Standards** The Goods & incidental Works/ Services to be provided by the contractor under this contract shall conform to the technical specifications and quality control parameters mentioned in 'Technical Specification and Quality Assurance' under Section VI of the Tender Document and as stipulated in the contract. Wherever references are made in the Contract to codes and standards by which it shall be executed, the edition or the revised version of such codes and standards shall be those specified in the Contract. During Contract execution, any changes in any such codes and standards shall be applied only after approval by the Purchaser. For standards and requirements where no applicable specifications/ Quality Assurance are mentioned, appropriate latest authoritative standards and quality assurance issued by the concerned institution shall be applicable. The

Goods supplied shall be.

1) Entirely brand new, unused, and incorporate all recent improvements in design and materials unless prescribed otherwise by the Procuring Entity in the contract.
2) conform to materials, manufacture and workmanship as stipulated in the contract, free of all defects and faults using specified/ appropriate materials, manufacture, and workmanship throughout and consistent with the established and generally accepted standards for Goods of the type ordered and in full conformity with the contract specification, drawing or sample, if any.
3) No modification can be made in artwork of product unless prior approved from programme division

6.3 Quantity Tolerance

Purchaser reserves the right to treat the supply obligations of contractor complete if goods have been supplied to the extent of 98% of the contracted quantity. Only the supplied quantity shall be paid for as per the terms of the contract.

6.4 Eligible Goods - Country of Origin and Minimum Local Content

The country of origin of 'Goods' and 'incidental Works/ Service' to be supplied under the contract shall have their origin in India and must conform to the declaration made by the contractor in its bid regarding but not limited to i) restrictions on certain countries with land-borders with India; ii) minimum local content and location of value addition (Make in India Policy); iii) Contractor's status as MSE or Start-up. The term "origin" used in this clause means where the goods (including subcontracted components) are mined, grown, produced, or manufactured or from where the incidental Works/ Services are arranged and supplied. For purposes of this Clause, the term 'Goods' shall have the meaning as defined in GCC-clause 1.2.

6.5- Option Quantity Clause

In exceptional situation where the requirement is of an emergent nature and/ or it is necessary to ensure continued supplies from the existing vendors, the purchaser reserves the right to place repeat order up to 50% of the quantity of the goods and/or services contained in the contract till the last scheduled date of supplies OR up to a period of twelve months from the date of Long Term agreement (LTA), whichever is later, at the same rate or a rate negotiated (downwardly) with the existing vendors considering the reasonability of rates based on prevailing market conditions and the impact of reduction in duties and taxes etc. The delivery period for the aforesaid ordered quantity shall be scheduled after the completion of the delivery of

	the original tendered quantity or on mutual consent between the supplier and CMSS. **6.6 - Deleted.** **6.7 Warranty/ Guarantee** The following warranty/ Guarantee clause shall apply: 1) the contractor hereby covenants that it is a condition of the contract that all Goods supplied to the Procuring Entity under this contract shall comply to technical specification, free of all defects and faults arising from design, materials or workmanship or from any act or omission of the contractor, that may develop under the conditions prevailing in India. 2) the contractor also guarantees that the said Goods would continue to conform to the description and quality as aforesaid, throughout the specified shelf life as stipulated in the contract. 3) Obligations of the contractor under the warranty clause shall survive even though: a) The Goods may have been inspected, accepted, and paid for by the Procuring Entity. b) The contract is terminated for any reason whatsoever. 4) The Procuring Entity shall promptly notify in writing to the contractor, if during the period above, the said goods/ stores/ articles are discovered not to conform to the description and quality or have deteriorated. The decision of the Procuring Entity in that behalf being final and conclusive. If the said goods/ stores/ articles are declared not to conform to the description and quality or have deteriorated during its shelf life in any particular batch/different batches at any of the consignee location, such cases shall be treated as localised failure of the goods supplied and the entire quantity of the batch (Consumed as well as not consumed) supplied to that particular location shall stand rejected. However, if the aforesaid deterioration in quality is observed in same/ different batches at more than one locations, such cases shall be treated as widespread failure of the goods supplied and the entire quantity of the batch (Consumed as well as not consumed) supplied under the contract at all the locations shall stand rejected. If any sample is declared as not to conform to the description or "Not of Standard Quality such batch/ batches will be deemed to be rejected goods and notice through Return Orders shall be issued to Contractor.

	5) Upon receipt of such notice, the contractor shall, within 03 working days acknowledge the receipt of such notices and its commitment to expeditiously, but not later within 60 days from the date of receipt of such notice, replace the defective Goods free of cost, at the Consignee destination. The Contractor shall take over the replaced parts/ Goods after providing their replacements, and no claim shall lie on the Procuring Entity for such replaced parts/ Goods after that. 6) If the contractor, having been notified, fails to replace the defect(s) within the aforesaid period of 60 days it shall amount to breach of Contract for default under GCC-clause 12.1, and the Procuring Entity shall avail any or all remedial action(s) thereunder. 7) The warranty shall apply to replacement batches also. **6.8 – Deleted**
7. Inspection and Quality Assurance	**7.1 QUALITY CONTROL** 1) Quality Control is an essential part of the current procurement and it is the responsibility of the supplier to ensure the products conform to the standards as specified in 'Technical Specification and Quality Assurance' under Section VI of the Tender Document during its entire shelf life. 2) The bidder/ supplier understand that the tendered item/items is/are critical health goods and the quality parameters of supplied goods are to be ensured during complete specified shelf life as indicated in technical specification/bid document/ official compendium. Bidder/Supplier also appreciate that failure in quality checks is serious default as it may derail entire programme and can also risk the life of users of supplied health goods. 3) Purchaser will embark on stringent quality checks to ensure that tendered goods meet required standards throughout specified shelf life. For this purpose, Purchaser reserves the right to carry necessary inspections/tests at any of, or any combination of or/ all of following stages: a) Pre-dispatch inspection b) Delivery Stage Inspection c) Post-Delivery Surveillance

	4) The goods supplied under the contract shall be subjected to PDI/ Delivery Stage Inspection/ "Accepted without PDI and Delivery Stage Inspection", as indicated in SCC. This is however without prejudice to the Purchaser's right to alter Inspection at any stage for whole/ part of the supplies. The purchaser's decision in this regard shall be final. **Pre-dispatch inspection** 5) Pre-dispatch inspection (PDI) for passing the quality of the goods, would be done before direct shipment to the consignees from supplier manufacturing premises. If the contract stipulates pre-dispatch inspection, the supplier after completion of manufacturing process, should offer goods for PDI inspection in writing to Quality Assurance Department of the Purchaser at least 10 days before proposed inspection date, which in turn shall inform the contractor in writing of its programme for such inspection and the officials' identity to be deputed for this purpose. The samples of each batch 3 sets (Testing, Control and Reserve) will be collected and Testing sample shall be sent to designated laboratories (Government/ Private Drugs Testing Laboratories) for testing as decided by the Purchaser. Sample quantities will be borne by the supplier. However, handling and testing charges will be borne by the Purchaser. After satisfactory quality report of testing lab, dispatch clearance shall be given to supplier by Quality Assurance Department of Purchaser. Only after getting dispatch clearance, supplier will deliver the items to the consignees as per the schedule mentioned in the Purchase Order. If the supplier delivers/dispatches goods without complying with aforesaid Quality Assurance and dispatch clearance process, The Purchaser shall not accept such supplies and will not process the bills for payments of such goods. The supplier will be solemnly responsible for any of its actions. 6) In the event of the samples of Drugs/goods supplied fails in quality tests/ found "Not of Standard Quality" (NSQ), and the supplier disputes the rejection of goods, the control samples collected during PDI shall be sent to designated laboratories (Government/ Private Drugs Testing Laboratories) for testing as decided by the Purchaser. If, the control samples also fail in quality tests/ found "Not of Standard Quality", purchaser shall take actions against the supplier as per provisions of the contract including cancellation of contract, forfeiture of PBG and

	blacklisting/debarment of the supplier for the quoted product for a specific period. 7) In the event of the samples of Drugs/goods supplied fails in quality tests/ found "Not of Standard Quality" (NSQ), and the supplier does not dispute rejection of samples as detailed in sub para above, the purchaser at its discretion may give one more opportunity to the supplier to offer a fresh batch for pre-dispatch inspection. If, the batch so offered also fails in quality tests/ found "Not of Standard Quality", the purchaser shall take actions against the supplier as per provisions of the contract including cancellation of contract, forfeiture of PBG and blacklisting/debarment of the supplier of the supplier for the quoted product for a specific period. **Delivery Stage Inspection** 8) Delivery stage inspection is done after the goods reach at consignee location. If the contract stipulates inspection at delivery stage, the supplier will deliver/dispatch the manufactured items (as per the technical specifications) to consignee's location. The samples will be collected from the consignee's location and sent to designate Quality Control Labs, as decided by Purchaser. Sample quantities will be borne by Purchaser. Also, handling and testing charges will be borne by Purchaser. The supplies will be deemed to be completed only upon receipt of the quality certificates from the laboratories. "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be deemed to be rejected goods. 9) If the said goods/ stores/ articles are declared not to conform to the description or Not of Standard quality after analysis at CMSS empanelled Lab and the entire quantity of the batch supplied shall stand rejected. Upon receipt of such rejection notice, the contractor shall, within 03 working days acknowledge it and confirm its commitment to expeditiously, but not later within 60 days from the date of receipt of such notice, to replace the defective Goods free of cost, at the ultimate destination, failing which supplier will be liable for punitive actions as per tender terms and conditions. Notwithstanding above, the LD will be applicable as per original scheduled delivery.

	10) In case, a batch is declared 'of standard Quality' from one location and from other location it is declared as 'not of standard quality', then complete batch shall be declared as NSQ for all locations. **Post-Delivery Surveillance** 11) Notwithstanding pre-dispatch/ delivery stage inspection, purchaser shall also carry out Post Delivery Surveillance/ Quality Monitoring Activities to ensure that the supplied Drugs/goods have the active ingredients and all other parameters at the prescribed level as indicated in official compendiums or technical specifications throughout the shelf life period of the drugs/ goods. Samples, which do not meet quality requirement/specifications, shall render the relevant batches liable to be rejected and procedure of handling post surveillance complaint is as per Warranty clause defined above at GCC 6.7. **Consequence of Rejection** 12) In the event of the samples of Drugs/goods supplied fails in quality tests or found to be not as per specifications at any of stage mentioned above, depending upon the type, nature and seriousness of failure, consequences resulting from such default, availability of alternate sources, the Purchaser is at liberty to either: a) Short Close the Purchase Order for entire quantity of batch (localized/ widespread, as the case may be), which failed in quality test and recover the cost of entire batch paid for (whether consumed fully/ partially). or b) Ask the supplier to replace the entire quantity of relevant batches (localized/ widespread, as the case may be), under its warranty obligation. or c) To make alternative purchase of the items of Drugs from other approved suppliers or in the open market or from any other Tenderer who might have quoted higher rates, at the risk and the cost of the supplier. d) In addition to above, action to debar/blacklist the supplier for suitable period, as decided by Purchaser may also be initiated. In addition to forfeiture of Performance Security Deposit.

	e) In addition, the FDA/ Drugs Control Authority of concerned State will be informed for initiating necessary action on the Tenderer in their state. f) The decision of the Purchaser or any officer authorized by Purchaser, as to the quality of the supplied drugs, medicines, vaccines etc., shall be final and binding. 13) In case, supplier is asked to make replacement of rejected batches and if replaced batch is also found "NOT OF STANDARD QUALITY", the supplier shall be blacklisted for the product and no further supplies shall be accepted for the particular product category. In addition, the licensing authority will be informed for initiating necessary action on the supplier in their state. The performance security will also be forfeited. The decision of Purchaser, as to the quality of the supplied goods shall be final and binding. 14) If the product is non-Pharmacopeial then the supplier must provide the in house test method along with the required reference standards if asked for. The Master Formula (BMR) of the products shall be provided whenever asked for. 15) The Purchaser may engage the services of a Quality Control Agent & Quality Control Testing Laboratories for the purpose of Inspection & Quality Control. In case of failure of batches during or at any stage, the testing charges of all samples (testing/control/reserve/field samples) would be claimed from the defaulting vendor. 16) Upon the Goods being rejected by the Testing lab and Inspecting Officer or Interim Consignee or Consignee at a place other than the premises of the contractor, the Procuring Entity shall be at liberty to: a) Demand that such stores shall be removed by the contractor at his cost subject as hereinafter stipulated, within 60 days of the date of intimation of such rejection. Provided that the Inspecting Officer may call upon the contractor to remove dangerous, infected, or perishable stores within 48 hours of the receipt of such communication and the decision of the Inspecting Officer in this regard shall be final in all respects. Provided further that where the price or part thereof has been paid, the consignee is entitled without prejudice to his other rights to retain the rejected stores till the price paid for such stores is refunded by the contractor or dispose off such

rejected Goods as per clause below save that such retention shall not in any circumstances be deemed to be acceptance of the stores or waiver of rejection thereon. The Contractor shall bear all cost of such replacement, including testing, taxes and freight, if any, on replacing and replacing Goods without being entitled to any extra payment on that or any other account.

b) All rejected Goods shall, in any event, and circumstances remain and always be at the contractor's risk immediately on such rejection. If the contractor does not remove such Goods within the periods aforementioned, the Procuring entity /inspecting officer, as the case may be as per the place of rejection, may remove the rejected Goods. The Procuring Entity or Inspecting Officer may either return the same to the contractor at his risk and cost by such mode of transport as it may decide or dispose off such Goods at the contractor's risk and on his account and retain such portion of the proceeds from such disposal, as may be necessary to recover any expense incurred in connection with such disposals (or any price refundable as a consequence of such rejection). The Procuring Entity shall, in addition, be entitled to recover from the contractor ground rent/ demurrage charges on the rejected Goods after the expiry of the time-limit mentioned above.

c) Disposal of rejected goods in an aforesaid manner shall not exonerate contractor but still hold him liable to pay to the procuring entity, the dues as may arise as per the terms of contract besides the cost of goods if already paid to the contractor and any inspection charges. The Purchaser can take action as per contract terms if the contractor fails to pay the amount due to him.

d) Deleted.

7.2 Inspections at the last moment

1) If the contract stipulates pre-dispatch inspection of the ordered Goods at Contractors premises, he shall put up the Goods for inspection well ahead of the delivery period to complete the inspection within that period. After completion of manufacturing process, the supplier should offer goods for PDI inspection in writing to Quality Assurance department of CMSS at least 10 days before proposed inspection date.

2) In cases where only a portion of the Goods ordered is tendered for inspection at the last moments of the delivery period and also in cases where inspection is not completed in respect of the

	portion of the Goods tendered for inspection during the delivery period, the inspector shall carry out the inspection and complete the formality beyond the contractual delivery period at the specific written request by and at the risk and expense of the contractor. The fact that the Goods have been inspected after the contractual delivery period shall not amount to keeping the contract alive, and this shall be without any prejudice to the legal rights and remedies available to the Procuring Entity under the terms & conditions of the contract. 3) If the Goods tendered for inspection during or at the last moments of the delivery period are not found acceptable after carrying out the inspection, the Procuring Entity is entitled to cancel the contract in respect of the same at the risk and expense of the contractor. If the Goods tendered for inspection are found acceptable, the Procuring Entity may grant an extension of the delivery period subject to conditions mentioned in GCC-clause 9.11 below. **7.3 Consignee's right of Rejection of Inspected Goods** 1) Goods accepted by the Procuring Entity and/ or its inspector at the initial inspection and final inspection in terms of the contract shall in no way dilute the Procuring Entity's right to reject the same later if found deficient concerning 'Technical Specifications and Quality Assurance'. 2) Deleted. **7.4 Handling of quality complaints** **1)** In case of quality complaints at any stage during its shelf life, purchaser shall investigate the nature of complaint by collecting field samples and its discretion test the samples so collected at any Govt. Lab/ purchasers approved lab, if considered necessary. On evaluation, if it is established that the samples are not of standard quality, the same may be rejected and supplier shall be asked to give replacement supplies as prescribed in the preceding paragraphs. **2)** In case manufacturer raises objection/disputes purchaser's decision, the control samples collected during PDI/ delivery stage inspection shall be tested at any Govt. Lab/ purchasers approved lab. The findings of the control sample shall be binding on both the parties. **3)** Purchaser at its discretion may also test control sample at any stage of investigation of complaint/ as part of post delivery surveillance.

	4) In case replacement supplies are not completed within the stipulated period, liquidated damages as per GCC-9.12 shall be levied for delayed supplies beyond the stipulated period.
8. Packing, Transportation, Insurance and Receipt	**8.1 Packing Specifications and Quality** 1) The marking of the Goods must comply with the Goods of the laws relating to merchandise marks for the time being in force in India. 2) The packing for the Goods to be provided by the contractor should be strong and durable enough to withstand, without limitation, the entire journey during transit, including transhipment (if any), rough handling, open storage etc., without any damage, deterioration etc. If necessary, the size, weights, and volumes of the packing cases, the remoteness of the goods' final destination, and availability or otherwise of transport and handling facilities at all points during transit up to the final destination shall also be considered. 3) The packaging unit should be strong, able to be stacked to a height of 4 pallets as static storage and 2 pallets during transport, and resistant to puncturing. Special attention of suppliers is invited to ensure the material is of good quality and is free from development of fungus/termites. In case fungus/termites develops within 15 days of delivery at specified locations, suppliers at their own cost would lift the entire batch from various locations and supply fresh replaced batches. For LD purposes the date of receipt of replaced batches would count. In addition, the expenses on pest control to be undertaken by CMSS would be borne by the tenderer. 4) The quality of packing, the manner of marking within & outside the packages, and accompanying documentation shall strictly comply with the `Technical Specification and Quality Assurance' and in the contract. If the packing requirements are amended due to any amendment to the contract, the contractor shall comply accordingly. 5) Unless otherwise provided in the contract, all containers (including packing cases, boxes, tins, drums, and wrappings) in which the contractor supplies the Goods shall be considered non-returnable and their cost included in the contract price. **8.2 Packing instructions** The suppliers are required to supply the product(s) with printed text "GOVERNMENT OF INDIA SUPPLIES – NOT FOR SALE" (Unless otherwise indicated differently in SCC) in red-colour on the

	strips, blisters, vials, ampoules & bottles and also on the external packings. The type/thickness of packing materials used in Blister packs may also be specified. Goods received without this print will not be accepted by Consignee. Affixing of rubber stamp shall not be accepted. However, the approved art work will prevail. Unless otherwise mentioned in the `Technical Specification and Quality Assurance' under Sections VI and SCC under Section VII, the contractor shall make separate packages for each consignee (in case there is more than one consignee mentioned in the contract) and mark each package on three sides with the following with indelible paint of proper quality: 1) An iconic graphical mark to visually identify a particular consignment. 2) Name of the Procuring Entity; contract number and date 3) brief description of Goods including quantity. 4) the gross weight of the package 5) Serial number of this package and the total number of packages in the consignment 6) packing list reference number 7) country of origin of goods 8) consignee's name and full address and 9) Contractor's name and address **8.3 Transfer of Title of Goods** 1) Unless otherwise stated in the contract, notwithstanding any inspection and approval by the Inspecting Officer on the contractor's premises, or any payments made to the contractor, property in the Goods (and resultant rights and liabilities) shall not pass on to the Procuring Entity until the Goods have been received, inspected, and accepted by the consignee. The Goods and every constituent part thereof, whether in the possession or control of the contractor, his agents or servants or a carrier, or the joint possession of the contractor, his agents or servants and the Procuring Entity, his agents, or servants, shall remain in every respect at the risk of the contractor, until their actual delivery to a person stipulated in the contract as the interim consignee for dispatch to the consignee. The Contractor shall be responsible for all loss, destruction, damage, or deterioration of or to the Goods from any cause whatsoever while the Goods after approval by the Inspecting Officer are awaiting dispatch or delivery or are in the

course of transit from the contractor to the consignee. The Contractor shall alone be entitled and responsible for making claims against any carrier in respect of non-delivery, short delivery, mis-delivery, loss, destruction, damage, or deterioration of the Goods entrusted to such carrier by the contractor for transmission to the consignee or the interim consignee as the case may be.

2) Provided that where, under the terms of the contract, the Goods are required to be delivered to an interim consignee for dispatch to the consignee, the Goods shall be at the Procuring Entity's risk after their delivery to the interim consignee.

8.4 Transportation

The contractor shall be responsible for free delivery of consignment at consignees place. Accordingly, the contractor shall arrange transportation, insurance etc. of the ordered Goods as per its procedure.

8.4.1 Distribution of Dispatch Documents for Clearance/ Receipt of Goods

1) Supplier will integrate with e- aushadhi system of CMSS and Supplier Interface Module in which supplier shall be required to enter/upload batch no, qty, mfg & expiry date, tranche no, invoice/challan copy etc. against PO no. Suppliers are requested to submit their Original Invoice along with copies of Lorry Receipt/ Deliver challans and original Consignee Receipt Certificate (CRC) duly signed & stamped with other necessary documents for smooth processing of payment.

2) The contractor shall notify the Procuring Entity, consignee, and others concerned, if mentioned in the contract, the complete details of dispatch and also supply the following documents (as relevant) to them by registered post/ speed post/ courier besides advance intimation by digital means (or as instructed in the contract or SCC):

Required Documents from Supplier for Material Acceptance at Consignee		
S. No.	**Description**	**Remark**
1	LR Copy (Lorry receipt copy)	Transporter's copy (Builty) of delivery of consignment

	2	Invoice copy of material	To be provided by the supplier having the following details: 1. Invoice Number 2. Invoice Date 3. Item Name 4. PO. No. and Date 5. Tranche No. 6. Quantity 7. Batch Number 8. Date of Manufacturing 9. Date of Expiry
	3	Packing list of inward material	To be provided by the supplier having the following details: 1. Total Number of Intact Boxes/ Cartons 2. Quantity per Box 3. No. of Loose Box (if any) 4. Quantity in Loose Box
	4	Certificate of Analysis (COA in case of Drugs)	To be provided by the supplier with the details of Inhouse Quality Test Report with date of Test. The COA contains the following: a) Manufacturer's Name b) Manufacturing Site Address c) Generic name of the product d) Date of Analysis e) Batch No. f)Pharmacopeial Reference and/ or In-house method g) Date of manufacture h) Expiry date i) All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharmacopoeia and/or In-house method. Both the actual results

			and the limits for the individual tests should be given j) Conclusion k) Authorized signatures
	5.	Performance Evaluation Report(In case of Devices)	To be provided by the supplier with the details of Inhouse Quality Test Report with date of Test. The Performance Evaluation Report shall include: a) Manufacturer's Name b) Manufacturing Site Address c) Product name d) Date of Analysis e) Lot/Batch Number f) Date of manufacture g) Date of Expiry h) Testing principle i) Information about reference used j) TESTING PROCEDURE-Sensitivity, Specificity etc k) Results l) report number m)Date of Analysis n) Designation and signature of analyst o) Authorized signatory of lab
	5.	E way Bill	To be provided by the supplier, the copy of the E way Bill
	6.	Any other document(s), as and if mentioned explicitly in the contract.	

3) The contractor shall send all the relevant dispatch documents well in time to the Procuring Entity to enable it to clear or receive (as the case may be) the Goods in terms of the contract. 8.5 – Deleted.

8.6 – Deleted.

	8.7 Receipt of Consignment **8.7.1 Preliminary Acknowledgement** At the time of the delivery at the destination, the consignee shall receive the Goods on a "subject to inspection and acceptance in terms of contract" basis and shall issue the preliminary receipt to acknowledge having received the claimed quantity (not the quality) of consignment. **8.7.2 Goods Receipt Note (GRN)/Consignee Receipt Certificate (CRC)** If the received consignment successfully passes the quantity and quality checks, procuring Entity shall issue a Goods Receipt Note/Consignee Receipt Certificate (GRN/CRC, or a similar voucher by any other name). The contractor may claim payment based on this document inter-alia other specified documents. **8.7.3 Rejection of Consignment by the Consignee** If the received consignment or part thereof fails to pass quantity and quality checks, the Procuring Entity shall issue a GRN/CRC only for the accepted quantity. **8.7.4 Short Receipt Certificate** If the quantity received is less than claimed/ invoiced, GRN/Rejection Note shall be issued only for the received quantity. **8.7.5 Perishable Goods** For Goods with a limited shelf life, the contractor shall ensure that at least $5/6^{th}$ (or any other period/criteria stipulated in the SCC) of shelf-life remains balance on delivery date. The Procuring Entity reserves rights to reject expired or products with less than such specified shelf life.
9. Terms of Delivery and delays	**9.1 Effective Date of Contract** The effective date of the contract shall be the date on which letter of award (LOA) has been issued by the Procuring Entity. The dates of deliveries shall be counted from such date. No notice to commence the contract shall be issued separately. **9.2 Time is the essence of the contract** The time for and the date for delivering the Goods stipulated in the contract or as extended shall be deemed to be of the essence of the contract. Delivery must be completed not later than the date(s) so specified or extended.

9.3 Destination Places

The destination(s) where the Goods are to be delivered shall be as stipulated in the contract or Section V – Schedule of Requirements.

9.4 Terms of Delivery

1) Terms of delivery is DDP Consignee site unless otherwise stipulated differently in Section V – Schedule of Requirements. Accordingly, the contractor shall arrange transportation, insurance etc. of the ordered Goods as per its own procedure.
2) The delivery shall not be complete unless the Goods are inspected and accepted by the Consignee as provided in the contract. No Goods shall be deliverable to the consignee on Sundays and public holidays or outside designated working hours without the written permission of the consignee.
3) the contractor shall not deliver the Goods after the expiry of the delivery period. The Contractor must apply to the Procuring Entity to extend the delivery period and obtain the same before dispatch. If the contractor dispatches the Goods without obtaining an extension, it would be doing so at its own risk, and no claim for payment for such supply and/ or any other expense related to such supply shall lie against the Procuring Entity.

9.5 – Deleted.

9.6 Progressing of Deliveries

The Contractor shall allow reasonable facilities and free access to his Works/ records to the Inspecting Officer or such other Officer as may be nominated by the Procuring Entity to ascertain the progress of the deliveries under the contract. The Contractor shall, from time-to-time, render such reports concerning the progress of the contract and/ or supply of the Goods in such form as may be required by the Procuring Entity. The submission, receipt and acceptance of such reports shall not prejudice the rights of the Procuring Entity under the contract, nor shall operate as an estoppel against the Procuring Entity merely because he has not taken notice of/ or subjected to test any information contained in such report.

9.7 Notification of Delivery.

Notification of delivery or dispatch regarding every installment shall be made to the consignee and to the Procuring Entity immediately on dispatch or delivery. The Contractor shall further supply to the consignee, packing list of the consignment and the contract references. All packages, containers, bundles, and loose materials part of every

	installment shall be fully described in the packing list, and complete details of the contents of the packages and quantity of materials shall be given to enable the consignee to check the Goods on arrival at destination. **9.8 Dispatches at the last moment or after the expiry of the delivery** 1) If the contractor supplies a consignment after the expiry of the contracted delivery date, the Consignee may either refuse to receive it or receive it without prejudice to the rights of the Procuring Entity under the terms and conditions of the contract. Such consignments shall lie at the risk and responsibility of the contractor. Such a receipt by the consignee shall not acquiesce or condone the late delivery and shall not intend or amount to an extension of the delivery period or keeping the contract alive. The Contractor must obtain an extension of the delivery date/period from the Procuring Entity. 2) Deleted. 3) Deleted. **9.9 Delay in the contractor's performance** If the contractor fails to deliver the Goods or any instalment thereof or delays incidental Work/ Services within the period fixed for such delivery in the contract or as extended or at any time repudiates the contract before the expiry of such period, the Procuring Entity may without prejudice to his other rights: 1) recover from the contractor liquidated damages as per clause 9.12 below, or 2) treat the delay as a breach of contract as per clause 12.1 below and avail all the remedies therein. **9.10– Deleted.** **9.11 Extension of Delivery Period:** 1) If at any time during the currency of the contract, the contractor encounters conditions hindering timely delivery of the Goods and performance of incidental Works/ Services, he shall promptly inform the Procuring Entity in writing about the same and its likely duration. He must make a request to the Procuring Entity for an extension of the delivery schedule. On receiving the contractor's communication, the Procuring Entity shall examine the situation and, at its discretion, may agree to extend the delivery schedule, with or without liquidated damages and

with and without denial clause by issuing an amendment to the contract.

2) **Conditions for Extension of Delivery Period:** When the period of delivery is extended due to unexcused delay by the contractor, the amendment extending the delivery period shall, inter alia, be subject to the following conditions:

a) Liquidated Damages: The Procuring Entity shall recover from the contractor, under the provisions of this clause, liquidated damages on the Goods and incidental Works/ Services, which the contractor has failed to deliver within the delivery period stipulated in the contract.

b) Denial Clause:

i. No increases in price on account of any statutory increase in or fresh Imposition of GST, customs duty or on account of any other taxes/ duty/ cess/ levy), leviable in respect of the Goods and incidental Works/ Services stipulated in the said contract which takes place after the original delivery date, shall be admissible on such of the said Goods, as are delivered after the said date; and

ii. Notwithstanding any stipulation in the contract for an increase in price on any other ground, including price variation clause or foreign exchange rate variation, or any other variation clause, no such increase after the original delivery date shall be admissible on such goods delivered after the said date.

iii. Nevertheless, the Procuring Entity shall be entitled to the benefit of any decrease in price on account of reduction in or remission of GST, customs duty or on account of any other Tax or duty or any other ground as stipulated in the price variation clause or foreign exchange rate variation or any other variation clause which takes place after the expiry of the original delivery date.

9.12Liquidated damages

1) Subject to GCC clause 9.11, if the contractor fails to deliver any or all of the Goods or fails to perform the incidental Works/ Services within the time frame(s) incorporated in the contract, the Procuring Entity shall, without prejudice to other rights and remedies available to the Procuring Entity under the contract, deduct from the contract price, as agreed liquidated damages, but not as a penalty, a sum equivalent to the ½ % (half percent) of the delivered price (including elements of GST & freight) of the delayed Goods and/ or incidental Works/ Services for each week of delay to be applied proportionately on per day basis for first four weeks of delay. For

	subsequent delays, a sum equivalent to 2.5% (two and half percent), instead of 0.5%, for each week of delay to be applied proportionately on per day basis of delivered price shall be deducted as liquidated damages. The maximum deduction on account of LD shall not exceed 10% of the delayed goods or incidental works/service contract price(s). Besides liquidated damages during such a delay, the denial clause as per GCC-clause 9.11-2(b) shall also apply. 2) Deleted. **9.13 Force Majeure** 1) On the occurrence of any unforeseen event, beyond the control of either Party, directly interfering with the delivery of Services arising during the currency of the contract, such as war, hostilities, acts of the public enemy, civil commotion, sabotage, fires, floods, explosions, epidemics, quarantine restrictions, strikes, lockouts, or acts of God, the affected Party shall, within a week from the commencement thereof, notify the same in writing to the other Party with reasonable evidence thereof. Unless otherwise directed by the Procuring Entity in writing, the contractor shall continue to perform its obligations under the contract as far as reasonably practicable and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event. If the force majeure condition(s) mentioned above be in force for 90 days or more at any time, either party shall have the option to terminate the contract on expiry of 90 days of commencement of such force majeure by giving 14 days' notice to the other party in writing. In case of such termination, no damages shall be claimed by either party against the other, save and except those which had occurred under any other clause of this contract before such termination. 2) Notwithstanding the remedial provisions contained in GCC-clause 9.12 or 12.1, none of the Party shall seek any such remedies or damages for the delay and/ or failure of the other Party in fulfilling its obligations under the contract if it is the result of an event of Force Majeure.
10 Prices and Payments	**10.1 Prices** **10.1.1Charged Prices** Prices to be charged by the contractor for the supply of Goods and provision of incidental Works/ Services in terms of the contract shall not vary from the corresponding prices quoted by the contractor in its bid or during negotiations, if any, and incorporated in the contract except for

	any price adjustment authorized in the contract. **10.1.2 Controlled Prices** 1) The price charged by the contractor shall not be higher than the controlled price fixed by law for the Goods, or where there is no controlled price, it shall not exceed the minimum of Maximum Retail Price (MRP) at which the same or similar Goods are available in the market in the relevant region, or contravene the norms for fixation of prices laid down by Government, or where the Government has not fixed such prices or norms, it shall not exceed the price appearing in any agreement relating to price regulation by any industry in consultation with the Government. 2) **Penalties for overcharging:** If the sub-clause above is violated, unless the contractor had explicitly mentioned this fact in his bid giving reasons for quoting a higher price (s), or makes any mis-statement, it shall be lawful for the Procuring Entity to: a) annul the award and treat it as a misdemeanour as per the contract and take any or all punitive remedies available thereunder, or b) without annulling the award, take action as per GCC-clause 10.4 to recover the overcharged amount, or c) treat it as a breach of contract as per GCC-Clause 12.1 and avail any or all remedies thereunder. **10.1.3– Deleted.** **10.1.4 Firm Prices** Prices stipulated in the contract shall be fixed and firm. **10.1.5– Deleted.** **10.1.6 Fall Clause** 1) The price charged for the Goods supplied under the contract by the contractor shall in no event exceed the lowest price at which the contractor sells the Goods or offers to sell Goods of identical description, to any persons/ organizations including the Procuring Entity or any Department or Undertaking of the Central Government, as the case may be during the currency of the contract. Contractor shall forthwith notify such reduction or sale or offer of sale to the Procuring Entity and the price payable under the contract for the Goods supplied after the date of coming into force or such reduction or sale or offer of sale shall stand correspondingly reduced. 2) The above stipulation shall, however, not apply to:

a) Exports by the contractor
b) Sale of Goods as original equipment at prices lower than the prices charged for normal replacement
c) Sale of perishable Goods having a limited shelf life, such as drugs that have expiry dates

3) the contractor shall furnish the following certificate to the concerned Accounts Officer with each bill for payment of supplies made against the contract.

"We certify that there has been no reduction in the sale price of the Goods of description identical to the Goods supplied to the Procuring Entity under the contract herein, and such Goods have not been offered/ sold by me/ us to any person/ organisation including any Ministry/ Department/ Attached and Subordinate Office/ Public Sector Undertaking of Central or State Government(s) as the case may be upto the date of bill/ the date of completion of Contract at a price lower than the price charged under this contract except for the quantity of Goods categories under (a), (b) and (c) of sub-clause (2) above, details of which are as follows:-"

10.1.7 Compliance with PPP-MI Order

In accordance with provision of Para 9 (c) of PPPMII order dated 19.07.2024, for all contracts above INR 10 Crores, the contractor shall provide local contract certificate from practicing Chartered / Cost Accountant with last bill of each tranche. In case the contractor/ supplier does not meet the stipulated local content requirement and the category of the supplier changes from Class-I to Class-II / Non local or from Class-II to Non-local, a penalty upto 10% of the contract value shall be imposed. However, contract once awarded shall not be terminated on this account.

10.2 Taxes and Duties

1) the contractor shall be entirely responsible for all taxes, duties, fees, levies etc., incurred until delivery of the Goods to the Procuring Entity.
2) If applicable under relevant tax laws and rules, the Procuring Entity shall deduct from all payments and deposit required taxes

	to respective authorities on account of GST Reverse Charge Mechanism; Tax Deducted at Source (TDS), and Tax Collected at Source (TCS) relating to Income Tax, labour cess, royalty etc. 3) **Payment of GST Tax under the contract:** a) The payment of GST and GST Cess to the contractor shall be made only on the latter submitting a GST compliant Bill/ invoice indicating the appropriate HSN code and applicable GST rate thereon duly supported with documentary evidence as per the provision of relevant GST Act and the Rules made there under. The delivery shall be shown being made in the name, location/ state, and GSTIN of the consignee only; the location of the procurement office of the procuring entity has no bearing on the invoicing. b) The supply of Goods or services or both, if imported into India, shall be considered as supply under inter-state commerce/ trade and shall attract integrated tax (IGST). The IGST rate and GST cess shall be applicable on the 'Custom Assessable Value' plus the 'Basic Customs duty applicable thereon'. c) While claiming reimbursement of duties, taxes etc. (like GST) from the Procuring Entity, as and if permitted under the contract, the contractor shall also certify that in case it gets any refund out of such taxes and duties from the concerned authorities at a later date, it (the contractor) shall refund to the Procuring Entity, the Procuring Entity's share out of such refund received by the contractor. The Contractor shall also refund the appropriate amount to the Procuring Entity immediately on receiving the same from the concerned authorities. d) All necessary adjustment vouchers such as Credit Notes/ Debit Notes for any short/ excess supplies or revision in prices or any other reason under the contract shall be submitted to the Procuring Entity in compliance with GST provisions. e) In case of Price Variation or Exchange Rate variation, or any other variation is applicable, GST shall be applicable on the net invoice value after the variation is taken into account. f) GST shall be paid as per the rate at which it is liable to be assessed or has been assessed provided the transaction of the sale is legally liable to such taxes and is payable as per

	the terms of the contract subject to the following conditions: i. The Procuring Entity shall not pay a higher GST rate if leviable due to any misclassification of HSN number or incorrect GST rate incorporated in the contract due to contractor's fault. Wherever the contractor invoices the Goods at GST rate or HSN number, which is different from that incorporated in the contract, payment shall be made as per GST rate, which is lower of the GST rates incorporated in the contract or billed. ii. However, the Procuring Entity shall not be responsible for the contractor's tax payment or duty under a misapprehension of the law. iii. Bidder is informed that he shall be required to adjust his basic price to the extent required by a higher tax rate billed as per invoice to match the all-inclusive price mentioned in the contract. iv. In case of profiteering by the contractor relating to GST tax, the Procuring Entity shall treat it as a violation of the Code of Integrity in the contract and avail any or all punitive actions thereunder, in addition to recovery and action by the GST authorities under the Act. v. The contractor should issue Receipt vouchers immediately on receipt of all types of payments along with tax invoices after adjusting advance payments, if any, as per Contractual terms and GST Provisions. 4) **Statutory Variation Clause:** Unless otherwise stated in the contract, statutory increase in applicable GST rate only during the original delivery period shall be to Procuring Entity's account. Any increase in the rates of GST beyond the original completion date during the extended delivery period shall be borne by the contractor. The benefit of any reduction in GST rate must be passed on to the Procuring Entity during the original and extended delivery period. However, GST rate amendments shall be considered for quoted HSN code only, against documentary evidence, provided such an increase of GST rates after the last date of bid submission. **5) Duties/ Taxes on Raw Materials** The Procuring Entity is not liable for any claim from the contractor on account of fresh imposition and/ or increase (including statutory

increase) of GST, customs duty, or other duties on raw materials and/ or components used directly in the manufacture of the contracted Goods taking place during the pendency of the contract unless such liability is expressly agreed to in terms of the contract.

6) Deleted.

10.3 Terms and Mode of Payment

10.3.1

1) The payments shall only be made in Indian Rupees.
2) The contractor shall send its claim for payment in writing as per GST compliant Invoice and documents, when contractually due, along with relevant documents etc., as stipulated in Contract and a manner as also specified therein.
3) While claiming payment, the contractor is also to certify in the bill that the payment being claimed is strictly in terms of the contract and all the obligations on the part of the contractor for claiming that payment has been fulfilled as required under the contract.
4) The usual payment term is 100% on receipt of goods and its acceptance by the consignee as per provisions of the contract on submission of the following documents:
    a) Copy of e-invoice generated from GST Portal.
    b) Packing list (with Goods Description) of supplied items.
    c) Copy of certificate of Analysis (COA)/Performance Evaluation Report (PER) as applicable for each batch supplied.
    d) Proof of delivery
        i) Lorry receipt duly signed, stamped and dated in case of CMSS Warehouse.
        ii) Lorry receipt duly signed, stamped and dated along with Original Consignee Receipt Certificate (CRC) in case of Goods Delivered at Consignee's Location other than CMSS Warehouses.
    e) Copy of e-Way Bill.
    f) Warranty Certificate
    g) Undertaking that the payment being claimed is strictly in terms of the contract and all the obligations on the part of the contractor for claiming that payment has been fulfilled as required under the contract.

	h) Undertaking for Fall Clause as per GCC 10.1.6 i) Local Content Certificate as per GCC 10.1.7 j) Such other documents as indicated in SCC 5) All bills/ Invoices should be raised in duplicate and the bills should be drawn in the name of Central Medical Services Society, 2nd Floor, Vishwa Yuvak Kendra, Pandit Uma Shankar Dikshit Road, Chanakyapuri, New Delhi-110021or in the name of any other authority as may be designated. Supplier has to mention e-aushadhi PO No. and tranche/ lot on the invoice. 6) The CMSS shall endeavour to make payment within 75 days in respect of items requiring sterility tests and within 60 days in respect of items requiring non- sterility test from the date of submission of invoice or from the date of receipt of material, whichever is later along with all the relevant documents of tender. 7) Lot/Tranche/PO vise Part payments for supply will be considered only after completion of supply of at least 50% quantity ordered in the individual Purchase Order/Lot/Tranche PROVIDED original consignee receipts are produced and the quality pass reports of Standard Quality on samples testing are received from approved laboratories of CMSS. 8) The payment will be made either by means of Cheque or through RTGS (Real Time Gross Settlement System)/ Core Banking/ NEFT. The Contractor shall give his consent in a mandate form for receipt of payment through NEFT. In case of non-payment through EFT, or where the EFT facility is not available, payment may be released through cheque. 9) The Tenderer shall furnish the relevant details in original in Bid Forms to make the payment through RTGS/Core Banking/ NEFT. The payment will be in INR only. 10) Supplier will integrate with e- aushadhi system of CMSS and Supplier Interface Module in which selected bidders shall be required to enter/upload batch no, qty, mfg. & expiry date, tranche no, invoice/challan copy etc. against PO no. 11) No advance payments towards costs of items will be made to the Tenderer. **10.3.2 – Deleted.** **10.3.3 - Deleted**

10.3.4 – Deleted.

10.4 Withholding and lien in respect of sums claimed:

1) Whenever any claim or claims for payment of a sum of money arises against the contractor, out of or under the contract, the Procuring Entity shall be entitled, and it shall be lawful on his part, to withhold and also have a lien to retain such sum or sums, in whole or in part pending finalization or adjudication of any such claim from-

a) any security or retention money, if any, deposited by the contractor.

b) any sum(s) payable till now or hereafter to the contractor under the same Contract or any other contract with the Procuring Entity if the security is insufficient or if no security has been taken from the contractor.

2) Where the contractor is a partnership firm or a limited company, the Procuring Entity shall be entitled, and it shall be lawful on his part, to withhold and also have a lien to retain towards such claimed amount or amounts in whole or in part from any sum found payable to any partner/ limited company, as the case may be, whether in his capacity or otherwise.

3) It is an agreed term of the contract that the sum(s) of money so withheld or retained under the lien referred above shall be kept withheld or retained till the claim arising out of or under the contract is determined under clause GCC 11 and/ or 12. The contractor shall have no claim for interest or damages whatsoever on any account in respect of such withholding or retention under the lien referred to supra and duly notified as such to the contractor.

4) **Lien in respect of Claims in other Contracts:** Any sum of money due and payable to the contractor (including the security deposit returnable to him) under the contract may be withheld or retained by way of lien by the Procuring Entity or Government against any claim of the Procuring Entity or Government in respect of payment of a sum of money arising out of or under any other contract made by the contractor with the Procuring Entity or Government.

10.5 Payment against Time-Barred Claims

All claims against the Procuring Entity shall be legally time-barred after three years calculated from the date when the payment falls due unless the payment claim has been under correspondence. The Procuring Entity

	is entitled to, and it shall be lawful for it to reject such claims. **10.6 – Deleted.**
11 Resolution of disputes	**Resolution of disputes** **11.1 Disputes and Excepted Matters** All disputes and differences between the parties hereto, as to the construction or operation of this contract, or the respective rights and liabilities of the parties on any matter in question; or any other account whatsoever, but excluding the Excepted Matters (detailed below); arising out of or in connection with the contract, within thirty (30) days from aggrieved Party notifying the other Party of such matters; whether before or after the completion/ termination of the contract, that cannot be resolved amicably between the Procurement Officer and the contractor within thirty (30) days from aggrieved Party notifying the other Party of such matters, shall be hereinafter called the "Dispute". The aggrieved party shall give a 'Notice of Dispute' indicating the Dispute and claims citing relevant Contractual clause to the designated authority and requesting for invoking the following dispute resolution mechanisms. The Dispute shall be resolved without recourse to courts through dispute resolution mechanisms detailed subsequently, in the sequence as mentioned below, and the next mechanism shall not be invoked unless the earlier mechanism has been invoked or has failed to resolve it within the deadline mentioned therein. 1) Adjudication 2) Conciliation 3) Arbitration **11.2 Excepted Matters** Matters for which provision has been made in any Clause of the contract shall be deemed as 'excepted matters' (matters not disputable/ arbitrable), and decisions of the Procuring Entity, thereon shall be final and binding on the contractor. The 'excepted matters' shall stand expressly excluded from the purview of the sub-clauses below, including Arbitration. However, where the Procuring Entity has raised the dispute, this sub-clause shall not apply. Unless otherwise stipulated in the contract, excepted matters shall include but not limited to: 1) any controversies or claims brought by a third party for bodily injury, death, property damage or any indirect or consequential loss arising out of or in any way related to the performance of this

Contract ("Third Party Claim"), including, but not limited to, a Party's right to seek contribution or indemnity from the other Party in respect of a Third-Party Claim.

2) Issues related to the pre-award tender process or conditions

3) Issues related to ambiguity in contract terms shall not be taken up after a contract has been signed. All such issues should be highlighted before the signing of the contract by the contractor.

4) Provisions incorporated in the contract, which are beyond the purview of The Procurement Entity or are in pursuance of policies of Government, including but not limited to

   a) Provisions of restrictions regarding local content and Purchase Preference to Local suppliers in terms of Make in India policy of the Government
   b) Provisions regarding restrictions on Entities from Countries having land-borders with India in terms of the Government's policies in this regard
   c) Purchase preference policies regarding MSEs and Start-ups

11.3 Adjudication

After exhausting efforts to resolve the Dispute with the Purchasing Officer executing the contract on behalf of the Procuring Entity, the contractor shall give a 'Notice of Adjudication' specifying the matters which are in question, or subject of the dispute or difference indicating the relevant contractual clause, as also the amount of claim item-wise to Head of Procurement or any other authority mentioned in the contract (hereinafter called the "Adjudicator") for invoking resolution of the dispute through Adjudication. During his adjudication, the Adjudicator shall give adequate opportunity to the contractor to present his case. Within 60 days after receiving the representation, the Adjudicator shall make and notify decisions in writing on all matters referred to him. The parties shall not initiate, during the adjudication proceedings, any conciliation or arbitral or judicial proceedings in respect of a dispute that is the subject matter of the adjudication proceedings. If not satisfied by the decision in adjudication, or if the adjudicator fails to notify his decision within the abovementioned time-frame, the contractor may proceed to invoke the process of Conciliation as follows.

11.4 Conciliation of disputes

1) Any party may invoke Conciliation by submitting "Notice of Conciliation" to the Head of the Procuring Organization. Since conciliation is a voluntary process, within 30 days of receipt of "Notice of Conciliation", the Head of the Procuring Organization shall notify a sole Conciliator if the other party is agreeable to

enter Conciliation. If the other party is not agreeable to Conciliation, the aggrieved party may invoke Arbitration.

2) The Conciliator shall proactively assist the parties to reach an amicable settlement independently and impartially within the terms of the contract, within 60 days from the date of appointment of the Conciliator.

3) If the parties reach an agreement on a dispute settlement, they shall draw up a written settlement agreement duly signed by the parties and conciliator. When the parties sign the settlement agreement, it shall be final and binding on the parties. The dispute shall be treated as resolved on the date of such agreement.

4) The parties shall not initiate, during the conciliation proceedings, any arbitral or judicial proceedings in respect of a dispute that is the subject matter of the conciliation proceedings.

5) Termination of Conciliation: Disputes shall remain alive if the conciliation is terminated as follows:

   a) By written declaration of the conciliator, after consultation with the parties, to the effect that further efforts at conciliation are no longer justified, on the date of such declaration; or
   b) By a written declaration of any party to the conciliator to the effect that the conciliation proceedings are terminated, on the date of such declaration; or
   c) If the parties fail to reach an agreement on a settlement of the dispute, within 60 days of the appointment of Conciliator

6) On termination of Conciliation, if the dispute is still alive, the aggrieved party shall be free to invoke Arbitration.

11.5 Arbitration Agreement

11.5.1 This Agreement

1) This Arbitration Agreement (hereinafter referred to as this "Agreement") relating to this Contract (hereinafter called the "Main Agreement" for this agreement) is made under the provisions of The Arbitration and Conciliation Act, 1996 as amended from time to time and the rules thereunder (hereinafter called The Arbitration Act). This Agreement shall continue to survive termination, completion, or closure of the Main Agreement for 120 days after that.

2) Subject to aforesaid provisions, relevant clauses of the contract shall apply to the appointment of arbitrators and arbitration proceedings under this Agreement.

3) The Micro, Small and Medium Enterprises Development (MSMED) Act, 2006 provides parties to a dispute (where one of the parties is a Micro or Small Enterprise) to be referred to Micro and Small Enterprises Facilitation Council if the dispute is regarding any amount due under Section 17 of the MSMED Act, 2006. If a Micro or Small Enterprise, being a party to dispute, refers to the provisions in MSMED Act 2006, these provisions shall prevail over this Agreement.

11.5.2 Notice for Arbitration

1) **Authority to Appoint Arbitrator(s)**: For this Arbitration Agreement 'The Appointing Authority', to appoint the arbitrator shall be Head of the Procuring Organization named in the contract and includes if there be no such authority, the officer who is for the time being discharging the functions of that authority, whether in addition to other functions or otherwise.

2) In the event of any dispute as per GCC-clause 11.1 above, if the Adjudicator fails to decide within 60 days (as referred in 11.3 above), or the Conciliation is terminated (as referred in sub-clause 11.4 above) then, parties to the contract, after 60 days but within 120 days of 'Notice of Dispute" (clause 11.1 above) shall request the Appointing Authority through a "Notice for Arbitration" in writing requesting that the dispute or difference be referred to arbitration.

3) The "Notice for arbitration" shall specify the matters in question or subject of the dispute or difference indicating the relevant contractual clause, as well as the amount of claim item-wise.

11.5.3 Reference to Arbitration

After appointing Arbitrator(s), the Appointing Authority shall refer the Dispute to them. Only such dispute or difference shall be referred to arbitration regarding which the demand has been made, together with counter-claims or set off. Other matters shall be beyond the jurisdiction of Arbitrator(s)

11.5.4 Appointment of Arbitrator

1) Qualification of Arbitrators:

a) In the case of retired officers of The Procuring organisation, he shall have retired in the rank of senior

	administrative grade (or equivalent) and shall have retired at least 1 year prior and must not be over 70 years of age on the date of Notice for arbitration. b) He/ they shall not have had an opportunity to deal with the matters to which the contract relates or who, in the course of his/ their duties as officers of the Procuring Organisation, expressed views on any or all of the matters under dispute or differences. A certification to this effect (as per Format 1.4) shall be taken from Arbitrators. The proceedings of the Arbitral tribunal or the award made by such Tribunal shall, however, not be invalid merely for the reason that one or more arbitrators had in the course of his service, an opportunity to deal with the matters to which the contract relates or who in the course of his/ their duties expressed views on all or any of the matters under dispute. c) An Arbitrator may be appointed notwithstanding the total no. of arbitration cases in which he has been appointed in the past. d) Not be other than the person appointed by The Appointing Authority and that if for any reason that is not possible, the matter shall not be referred to arbitration at all. **2) Replacement of Arbitrators** If one or more of the arbitrators appointed as above refuses to act as arbitrator, withdraws from his office as arbitrator, or in the event of the arbitrator dying, neglecting/ unable or unwilling or refusing to act for any reason, or his award being set aside by the court for any reason, or in the opinion of The Appointing Authority fails to act without undue delay, the Appointing Authority shall appoint new arbitrator/ arbitrators to act in his/ their place in the same manner in which the earlier arbitrator/ arbitrators had been appointed. Such a re-constituted Tribunal may, at its discretion, proceed with the reference from the stage at which it was left by the previous arbitrator (s). **3) Appointment of Arbitrator:** a) In cases where the total value of all claims in question added together does not exceed Rs 50,00,000/ - (Rupees Fifty Lakh only), the Arbitral Tribunal shall consist of sole Arbitrator. For this purpose, The Appointing Authority shall send to the contractor, within 60 days from the day of receipt of a written and valid notice for arbitration, a panel of at least four (4) names of retired officers, duly indicating their retirement dates.

b) The contractor shall be asked to nominate at least two names out of the panel for appointment as his nominee within 30 days from the dispatch date of the request by The Appointing Authority. The Appointing Authority shall appoint at least one out of them as the sole arbitrator within 30 days from the receipt of the names of the contractor's nominees.

c) In cases where the total value of all claims in question added together exceeds Rs 50,00,000/ - (Rupees Fifty Lakh only), the Arbitral Tribunal shall consist of three (3) retired Officers of the Procuring Organisation. For this purpose, The Appointing Authority shall send a panel of at least four (4) names of such Officer(s) empanelled to work as Arbitrators duly indicating their retirement date to the contractor within 60 days from the day when a written and The Appointing Authority receives valid demand for arbitration.

d) The contractor shall be asked to nominate at least 2 names out of the panel for appointment as his nominee within 30 days from the dispatch date of the request by The Appointing Authority. The Appointing Authority shall appoint at least one out of them as the contractor's nominee. It shall also simultaneously appoint the balance number of arbitrators either from the panel or outside the panel, duly indicating the 'Presiding Arbitrator' from amongst the 3 arbitrators so appointed, within 30 days from the receipt of the names of Contractor's nominees.

e) If the contractor does not suggest his nominees for the arbitral tribunal within the prescribed timeframe, The Appointing Authority shall proceed for appointment of the arbitral tribunal within 30 days of the expiry of such time provided to the contractor.

11.5.5 Failure to appoint Arbitrators.

If The Appointing Authority fails to appoint an arbitrator within 60 (sixty) days, then subject to the survival of this Arbitration Agreement, in international commercial arbitration, the Supreme Court of India shall designate the arbitral institution for the appointment of arbitrators. In case of national arbitrations, the High Court shall designate arbitral institutions. The Arbitration Council of India must have graded these arbitration institutions. These arbitral institutions must complete the selection process within thirty days of accepting the request for the arbitrator's appointment.

11.5.6 The Arbitral Procedure

	1) **Effective Date of Entering Reference:** The arbitral tribunal shall be deemed to have entered the reference on the date on which the arbitrator(s) have received notice of their appointment. All subsequent time limits shall be counted from such date. 2) **Seat and Venue of Arbitration:** The seat of arbitration shall be the place from which the Letter of Award or the contract is issued. The venue of arbitration shall be the same as the seat of arbitration. However, in terms of section 20 of The Arbitration Act, the arbitrator, at his discretion, may determine a venue other than the seat of the arbitration without in any way affecting the legal jurisdictional issues linked to the seat of the arbitration. 3) If the Adjudication and/ or Conciliation mechanisms had not been exhausted before such reference to Arbitration, the Arbitrator should ask the aggrieved party to approach designated authority for such mechanisms before the Arbitration proceedings are started. 4) The claimant shall submit to the Arbitrator(s) with copies to the respondent his claims stating the facts supporting the claims along with all the relevant documents and the relief or remedy sought against each claim within 30 days from the date of appointment of the Arbitral Tribunal unless otherwise extension has been granted by Arbitral Tribunal. 5) On receipt of such claims, the respondent shall submit its defence statement and counter claim(s), if any, within 60 days of receipt of the copy of claims, unless otherwise extension has been granted by Arbitral Tribunal. 6) No new claim shall be added during proceedings by either party. However, a party may amend or supplement the original claim or defence thereof during arbitration proceedings subject to acceptance by the Tribunal having due regard to the delay in making it. 7) Statement of claims, counterclaims and defence shall be completed within six months from the effective reference date. 8) **Oral arguments to be held on a day-to-day basis:** Oral arguments as far as possible shall be heard by the arbitral tribunal on a day-to-day basis, and no adjournments shall be granted without sufficient cause. The arbitrator (s) may impose an exemplary cost on the party seeking adjournment without sufficient cause.

	9) **Award within 12 (twelve) months:** The arbitral tribunal is statutorily bound to deliver an award within 12 (twelve) months from the date when the arbitral tribunal enters reference. The award can be delayed by a maximum of six months only under exceptional circumstances where all parties consent to such extension of time. The court's approval shall be required for further extension if the award is not made out within such an extended period. During the period of an application for extension of time is awaiting before the court, the arbitrator's proceedings shall continue until the disposal of the application. 10) **Fast Track Procedure:** The parties to arbitration may choose to opt for a fast-track procedure either before or after the commencement of the arbitration. The award in fast-track arbitration is to be made out within six months, and the arbitral tribunal shall be entitled to additional fees. The salient features of the fast-track arbitration are: a) The dispute is to be decided based on written pleadings only. b) Arbitral Tribunal shall have the power to call for clarifications in addition to the written pleadings where it deems necessary. c) An oral hearing may be held only if all the parties request or the arbitral tribunal considers it necessary. d) The parties are free to decide the fees of the arbitrator(s) for fast-track procedure. 11) **Powers of Arbitral Tribunal to grant Interim Relief:** The parties to arbitration may approach the arbitral tribunal for seeking interim relief on the grounds available under section 9 of the act. The tribunal has the powers of a court while making interim awards in the proceedings before it. 12) **Confidentiality:** As provided in Section 42A of The Arbitration Act, all the details and particulars of the arbitration proceedings shall be kept confidential, except in certain situations like if the disclosure is necessary for the implementation or execution of the arbitral award. 13) **Obligation During Pendency of Arbitration:** Performance of the contract shall, unless otherwise directed by the Procuring Entity, continue during the arbitration proceedings, and no payment due or payable by the Procuring Entity shall be withheld on account of such proceedings, provided; however, it shall be open for Arbitral Tribunal to consider and decide whether or not

	the performance of the contract or payment therein should continue during arbitration proceedings. **11.5.7 The Arbitral Award** In the case of the Tribunal, comprising of three members, any ruling on award shall be made by a majority of members of the Tribunal. In the absence of such a majority, the views of the Presiding Arbitrator shall prevail. The arbitral award shall state item-wise the sum and reasons upon which it is based. The analysis and reasons shall be detailed enough so that the award can be inferred from it. It is further a term of this arbitration agreement that where the arbitral award is for the payment of money, no interest shall be payable on whole or any part of the money for any period till the date on which the award is made in terms of Section 31 (7) (a) of The Arbitration Act. The award of the arbitrator shall be final and binding on the parties to this contract. A party may apply for corrections of any computational errors, typographical or clerical errors, or any other error of similar nature occurring in the award or interpretation of a specific point of the award to the Tribunal within 60 days of receipt of the award. A party may apply to the Tribunal within 60 days of receiving the award to make an additional award as to claims presented in the arbitral proceedings but omitted from the arbitral award. **11.5.8 Savings** The Arbitral Tribunal shall decide any matter related to Arbitration not covered under this Arbitration Agreement as per the provisions of The Arbitration Act. **11.5.9 Cost of Arbitration and fees of the Arbitrator(s)** 1) The concerned parties shall bear the cost of arbitration in terms of section 31 (A) of The Arbitration Act. The cost shall inter-alia include fees of the Arbitrator. Further, the fees payable to the Arbitrator shall be governed by instructions issued on the subject by the Procuring Entity and/ or the Government from time to time, in line with the Arbitration and Conciliation Act, irrespective of the fact whether the Arbitrator is appointed by the Procuring Entity or the Government under this clause or by any court of law unless directed explicitly by Hon'ble court otherwise on the matter. A sole arbitrator shall be entitled to a 25% extra fee over such a prescribed fee.

		The arbitrator shall be entitled to a 50 percent extra fee if the award is made within 6 months in terms of provisions contained in section 29(A) (2) of The Arbitration Act. Besides the above, Arbitrator shall also be entitled to this extra fee in cases where Fast Track Procedure in terms of section 29 (B) of The Arbitration Act is followed.
12	**Defaults, Breaches, Termination, and closure of Contract**	**12.1 Termination due to Breach, Default, and Insolvency** **12.1.1 Defaults and Breach of Contract** In case the contractor undergoes insolvency or receivership; neglects or defaults, or expresses inability or disinclination to honour his obligations relating to the performance of the contract or ethical standards or any other obligation that substantively affects the Procuring Entity's rights and benefits under the contract, it shall be treated as a breach of Contract. Such defaults could include inter-alia: 1) **Default in Performance and Obligations:** if the contractor fails to deliver any or all of the Goods or fails to perform any other contractual obligations (including Code of Integrity or obligation to maintain eligibility and Qualifications based on which contract was awarded) within the period stipulated in the contract or within any extension thereof granted by the Procuring Entity. 2) **Insolvency:** If the contractor being an individual or if a firm, any partner thereof, shall at any time, be adjudged insolvent or shall have a receiving order or order for the administration of his estate made against him or shall take any proceeding for composition under any Insolvency Act for the time being in force or make any conveyance or assignment of his effects or enter into any assignment or composition with his creditors or suspend payment or if the firm be dissolved under the Partnership Act, or 3) **Liquidation:** if the contractor is a company being wound up voluntarily or by order of a Court or a Receiver, Liquidator or Manager on behalf of the Debenture-holders is appointed, or circumstances shall have arisen which entitle the Court or Debenture-holders to appoint a Receiver, Liquidator or Manager **12.1.2 Notice for Default:** As soon as a breach of contract is noticed, a show-cause 'Notice of Default' shall be issued to the contractor, giving two weeks' notice, reserving the right to invoke contractual remedies. After such a show-cause notice, all payments to the contractor would be temporarily withheld to safeguard needed recoveries that may become due on

	invoking contractual remedies. **12.1.3 Terminations for Default** 1) **Notice for Termination for Default:** In the event of unsatisfactory resolution of 'Notice of Default' within two weeks of its issue as per sub-clause above, the Procuring Entity, if so decided, shall by written Notice of Termination for Default sent to the contractor, terminate the contract in whole or in part, without compensation to the contractor. 2) Such termination shall not prejudice or affect the rights and remedies, including under sub-clause below, which have accrued and/ or shall accrue to the Procuring Entity after that. 3) Unless otherwise instructed by the Procuring Entity, the contractor shall continue to perform the contract to the extent not terminated. 4) All warranty obligations, if any, shall continue to survive despite the termination. **12.1.4 Contractual Remedies for Breaches/Defaults or Termination for Default** If there is an unsatisfactory resolution within this period, the Procuring Entity shall take one; or more of the following contractual remedies. 1) Temporary withhold payments due to the contractor till recoveries due to invocation of other contractual remedies are complete. 2) Call back any loaned property or advances of payment, if any, with the levy of interest at the prevailing rate (MIBID - Mumbai Interbank Bid Rate). 3) Recover liquidated damages and invoke denial clause for delays. 4) Encash and/ or Forfeit performance or other contractual securities. 5) Prefer claims against insurances, if any. 6) Terminate contract for default, fully or partially including its right for Risk-and-Cost Procurement as per following sub-clause. 7) **Risk and Cost Procurement:** In addition to termination for default, the Procuring Entity shall be entitled, and it shall be lawful on his part, to procure Goods similar to those terminated, with such terms and conditions and in such manner as it deems fit at the "Risk and Cost" of the contractor. Such 'Risk and Cost Procurement' must be contracted within six months from the

	breach of Contract. The Contractor shall be liable for any loss which the Procuring Entity may sustain on that account provided the procurement, or, if there is an agreement to procure, such agreement is made. The Contractor shall not be entitled to any gain on such procurement, and the manner and method of such procurement shall be in the entire discretion of the Procuring Entity. It shall not be necessary for the Procuring Entity to notify the contractor of such procurement. It shall, however, be at the discretion of the Procuring Entity to collect or not the security deposit from the firm/ firms on whom the contract is placed at the risk and cost of the defaulted firm. Note: Regarding the Goods which are not readily available in the market and where procurement difficulties are experienced, the period for making risk procurement shall be nine months instead of six months provided above. 8) Initiate proceedings in a court of law for the transgression of the law, tort, and loss, not addressable by the above means. **12.1.5 Limitation of Liability** Except in cases of criminal negligence or wilful misconduct, the aggregate liability of the contractor to the Procuring Entity, whether under the contract, in tort or otherwise, shall not exceed the total Contract Price, provided that this limitation shall not apply to the cost of repairing or replacing defective equipment, or to any obligation of the contractor to indemnify the Procuring Entity concerning IPR infringement. **12.2 Termination for Default/ Convenience of Procuring Entity and Frustration** **12.2.1 Notice for Determination of Contract** 1) The Procuring Entity reserves the right to terminate the contract, in whole or in part for its (the Procuring Entity's) convenience or frustration of contract as per sub-clause below, by serving written 'Notice for Determination of Contract' on the contractor at any time during the currency of the contract. The notice shall specify that the termination is for the convenience of the Procuring Entity or the frustration of the contract. The notice shall also indicate inter-alia, the extent to which the contractor's performance under the contract is terminated, and the date with effect from which such termination shall become effective. 2) Such termination shall not prejudice or affect the rights and remedies accrued and/ or shall accrue after that to the Parties.

3) Unless otherwise instructed by the Procuring Entity, the contractor shall continue to perform the contract to the extent not terminated.

4) All warranty obligations, if any, shall continue to survive despite the termination.

5) The Goods and incidental Works/ Services that are complete and ready in terms of the contract for delivery and performance within thirty days after the contractor's receipt of the notice of termination shall be accepted by the Procuring Entity as per the contract terms. For the remaining Goods and incidental Works/ Services, the Procuring Entity may decide:

   a) To get any portion of the balance completed and delivered at the contract terms, conditions, and prices; and/ or
   b) To cancel the remaining portion of the Goods and incidental Works/ Services and compensate the contractor by paying an agreed amount for the cost incurred by the contractor, if any, towards the remaining portion of the Goods and incidental Works/ Services.

12.2.2 Frustration of Contract

1) **Notice of Frustration Event:** Upon a supervening cause occurring after the effective date of the contract, including a change in law, beyond the control of either party whether as a result of the Force Majeure clause or within the scope of section 56 of the Indian Contract Act, 1872, that makes it impossible to perform the contract within a reasonable timeframe, the affected party shall give a 'Notice of Frustration Event' to the other party giving justification. The parties shall use reasonable efforts to agree to amend the contract, as may be necessary to complete its performance. However, if the parties cannot reach a mutual agreement within 60 days of the initial notice, the Procuring Entity shall issue a 'Notice for Determining the contract' and terminate the contract due to its frustration as in the sub-clause above.

2) However, the following shall not be considered as such a supervening cause.

a) Lack of commercial feasibility or viability or profitability or availability of funds
b) if caused by either party's breach of its obligations under this Contract or failure to act in good faith or use commercially reasonable due diligence to prevent such an event.

	12.3 Closure of Contract **12.3.1 No Claim Certificate and Release of Contract Securities** After mutual reconciliations of outstanding payments and assets on either side, the contractor shall submit a 'No-claim certificate' to the Procuring Entity requesting the release of its contractual securities, if any. The Procuring Entity shall release the contractual securities without any interest if no outstanding obligation, asset, or payments are due from the contractor. The contractor shall not be entitled to make any claim whatsoever against the Procuring Entity under or arising out of this Contract, nor shall the Procuring Entity entertain or consider any such claim, if made by the contractor, after he shall have signed a "No Claim" Certificate in favour of the Procuring Entity. The Contractor shall be debarred from disputing the correctness of the items covered by the "No Claim" Certificate or demanding a clearance to arbitration in respect thereof. **12.3.2 Closure of Contract** The contract shall stand closed upon 1) successful performance of all obligations by both parties, including completion of warrantee obligations and final payment. 2) termination and settlements after that, if any, as per GCC-clause 12.1 or 12.2 above.
13 Code of Integrity in Public Procurement; Misdemeanors and Penalties	**13.1 Code of Integrity** Procuring authorities as well as bidders, suppliers, contractors, and consultants - should observe the highest standard of ethics and should not indulge in following prohibited practices, either directly or indirectly, at any stage during the Tender Process or during the execution of resultant contracts: 1) **"Corrupt practice"** - making offer, solicitation or acceptance of a bribe, reward or gift or any material benefit, in exchange for an unfair advantage in the Tender Process or to otherwise influence the Tender Process; 2) **"Fraudulent practice"** - any omission or misrepresentation that may mislead or attempt to mislead so that financial or other benefits may be obtained or an obligation avoided. Such practices include a false declaration or false information for participation in a tender process or to secure a contract or in the execution of the contract; 3) **"Anti-competitive practice"** - any collusion, bid-rigging or anti-competitive arrangement, or any other practice coming under the

	purview of the Competition Act, 2002, between two or more bidders, with or without the knowledge of the Procuring Entity, that may impair the transparency, fairness, and the progress of the Tender Process or to establish bid prices at artificial, non-competitive levels; 4) **"Coercive practice"** - harming or threatening to harm persons or their property to influence their participation in the Tender Process or affect the execution of a contract; 5) **"Conflict of interest"** –participation by a bidding firm or any of its affiliates who are either involved in the Consultancy Contract to which this procurement is linked; or if they are part of more than one bid in the procurement; or if their personnel have a relationship or financial or business transactions with any official of procuring entity who are directly or indirectly related to tender or execution process of contract; or improper use of information obtained by the (prospective) bidder from the Procuring Entity with an intent to gain unfair advantage in the Tender Process or for personal gain; 6) **"Obstructive practice"** - materially impede procuring entity's investigation into allegations of one or more of the above mentioned prohibited practices either by deliberately destroying, falsifying, altering; or by concealing of evidence material to the investigation; or by making false statements to investigators and/ or by coercive practices mentioned above, to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or by impeding the Procuring Entity's rights of audit or access to information; **13.2 Obligations for Proactive Disclosures:** 1) Procuring authorities, bidders, suppliers, contractors, and consultants are obliged under this Code of Integrity to suo-moto proactively declare any conflict of interest (coming under the definition mentioned above - pre-existing or as and as soon as these arise at any stage) in any Tender Process or execution of the contract. Failure to do so shall amount to a violation of this code of integrity. 2) Any bidder must declare, whether asked or not in a bid-document, any previous transgressions of such code of integrity during the last three years or of being under any category of debarment by the Central Government or by the Ministry/ Department of the Procuring Organization from participation in Tender Processes.

Failure to do so shall amount to a violation of this code of integrity.

13.3 Misdemeanors and Penalties

The following shall be considered misdemeanors - if a bidder/ contractor either directly or indirectly, at any stage during the Tender Process or during the execution of resultant contracts:

1) commits any of the following misdemeanors:

a) violates the code of Integrity mentioned in GCC-clause 13.1 or GCC-Clause 10.1.6 (Fall clause) or the Integrity Pact if included in the Tender/ Contract;

b) any other misdemeanor, e.g., supply of sub-standard quality of material/ services/ work or non-performance or abandonment of contract or failure to abide by 'Bid Securing Declaration'.

2) commits any of the following misdemeanors:

a) has been convicted of an offence:

i. under the Prevention of Corruption Act, 1988; or

ii. the Indian Penal Code or any other law for the time being in force for causing any loss of life or property or causing a threat to public health as part of the execution of a public procurement contract.

b) is determined by the Government of India to have doubtful loyalty to the country or national security consideration.

c) Employs a government servant, who has been dismissed or removed on account of corruption or employs a non-official convicted for an offence involving corruption or abetment of such an offence, in a position where he could corrupt government servants or employs a government officer within one year of his retirement, who has had business dealings with him in an official capacity before retirement.

13.4 Penalties for Misdemeanors

Without prejudice to and in addition to the rights of the Procuring Entity to other remedies as per the Tender-documents or the contract, If the Procuring Entity concludes that a (prospective) bidder/ contractor directly or through an agent has committed a misdemeanor in competing for the tender or in executing a contract, the Procuring Entity shall be entitled, and it shall be lawful on his part to take appropriate measures, including the following:

13.4.1 If his bids are under consideration in any procurement

	1) Enforcement of Bid Securing Declaration in lieu of forfeiture or encashment of Bid Security. 2) calling off of any pre-contract negotiations, and; 3) rejection and exclusion of Bidder from the Tender Process **13.4.2 If a contract has already been awarded** 1) Termination of Contract for Default and availing all remedies prescribed thereunder; 2) Encashment and/ or Forfeiture of any contractual security or bond relating to the procurement; 3) Recovery of payments including advance payments, if any, made by the Procuring Entity along with interest thereon at the prevailing rate (MIBID - Mumbai Interbank Bid Rate); **13.4.3 Remedies in addition to the above:** In addition to the above penalties, the Procuring Entity shall be entitled, and it shall be lawful on his part to: File information against Bidder or any of its successors, with the Competition Commission of India for further processing, in case of anti-competitive practices; Initiate proceedings in a court of law against Bidder or any of its successors, under the Prevention of Corruption Act, 1988 or the Indian Penal Code or any other law for transgression not addressable by other remedies listed in this sub-clause. Remove Bidder or any of its successors from the list of registered suppliers for a period not exceeding two years. Suppliers removed from the list of registered vendors or their related entities may be allowed to apply afresh for registration after the expiry of the period of removal. Initiation of suitable disciplinary or criminal proceedings against any individual or staff found responsible. Debar a bidder / contractor from participation in future procurements without prejudice to Procuring Entity's legal rights and remedies. Debarment shall automatically extend to all the allied firms of the debarred firm. In the case of Joint Venture/ consortium, all its members shall also stand similarly debarred: a) A Ministry/ Department (or any of its CPSUs, attached offices, autonomous bodies) may debar a bidder or any of its successors from participating in any Tender Process undertaken by all its procuring entities for a period not exceeding two years commencing from the date of

	debarment for misdemeanors listed in sub-clause GCC 13.3 -1) above. The Ministry/Department shall maintain such a list which shall also be displayed on their website. b) Central Government (Department of Expenditure (DoE), Ministry of Finance) may debar a bidder or any of its successors from participating in any Tender Process undertaken by all its procuring entities for a period not exceeding three years commencing from the date of debarment for misdemeanors listed in sub-clause GCC 13.3 - 2) above. DoE shall maintain such a list which shall be displayed on Central Public Procurement Portal (CPPP).

SECTION VIII: SPECIAL CONDITIONS OF CONTRACT

Reference GCC Section	Description
GCC 2.4	The details of Procuring Entity and Contractor are as under: Procuring Entity - The Central Medical Services Society, an autonomous body under Ministry of Health and Family welfare, Government of India Contractor -
GCC 5.8	Within fourteen days after the issue of Letter of Award (LoA or the contract, if LoA is skipped) by the Procuring Entity, the contractor shall furnish to the Procuring Entity performance security for an amount equivalent to 3% of the contract value valid till expiry of shelf life of the last consignment supplied under the contract. **PBG validity will be 790 days from the last date of delivery of the product/item.**
GCC 7.1.7	The goods supplied under the contract shall be subjected to Pre-Delivery Inspection at manufacturer's manufacturing premises before dispatch.
GCC 8.2	The suppliers are required to supply the product(s) with printed text "GOVERNMENT OF INDIA SUPPLIES – NOT FOR SALE"
GCC 8.7.5	The contractor shall ensure that at least 5/6th of shelf-life remains balance on delivery date.

SECTION IX- BIDDING FORMS

Form 1: Bid Form (Covering Letter)
(Ref ITB-clause 9.2)
(To be submitted as part of technical bid, along with supporting documents, if any)
(On Bidder's Letter-head)
(Strike out alternative phrases not relevant to you)
Bidder's Name_____
[Address and Contact Details]
Bidder's Reference No._____ Date…….
To
DG & CEO, Central Medical Services Society, Ministry of Health and Family welfare, Government of India, New Delhi
Address: 2nd floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Road, Opposite Police Station Chanakaya Puri,
New Delhi-110021
Telephones: 011-21410905, 21410906
Ref: Your Tender Document No. Tender No./ xxxx; Tender Title: GOODS

Sir/ Madam
Having examined the above-mentioned Tender Document, we, the undersigned, hereby submit/ upload our Techno-commercial and financial bid (Price Schedule) for the supply of Goods and incidental Works/ Services in conformity with the said Tender Documents.

1) Our Credentials:

a) We are submitting this bid: -

☐ on our behalf, and there are no agents/ dealers involved in this tender, and hence no agency agreement or payments/ commissions/ gratuity is involved. Our company law and taxation regulatory requirements and authorization for signatories and related documents are submitted in Form 1.1 (Bidder Information).

b) We…….. hereby certify that ☐ We are proven, established, and reputed manufacturers with factories at …… which are fitted with modern equipment and where the production methods, quality control, and testing of all materials and parts manufactured or used by us shall be open to inspection by the representative of the Procuring Entity.

2) Our Eligibility and Qualifications to participate

We comply with all the eligibility criteria stipulated in this Tender Document, and the relevant declarations are made along with documents in Form 1.2 of this bid-form. We fully meet the qualification criteria stipulated in this Tender Document, and the relevant details are submitted along with documents in Form 4: 'Qualification Criteria - Compliance.

3) Our Bid to supply Goods:

We offer to supply the subject Goods of requisite quality and within Delivery Schedules in conformity with the Tender Document. The relevant details are submitted in Form 2: 'Schedule of Requirements - Compliance and Form3: 'Technical Specifications and Quality Assurance - Compliance.' The details of schedule wise quantity offered against this tender are given below in tabular form:

Schedule No.	Item Name	UOM	Tendered Quantity	Quoted Quantity
I				

4) Prices:

We hereby offer to perform the Services at our lowest prices and rates mentioned in the separately uploaded Price-Schedule. It is hereby confirmed that the prices quoted therein by us are:

a) based on terms of delivery and delivery schedule confirmed by us; and
b) Cost break-up of the quoted cost, showing inter-alia costs (including taxes and duties thereon) of all the included incidental Goods/ Works considered necessary to make the proposal self-contained and complete, has been indicated therein, and
c) based on the terms and mode of payment as stipulated in the Tender Document. We have understood that if we quote any deviation to terms and mode of payment, our bid is liable to be rejected as nonresponsive, and
d) have been arrived at independently, without restricting competition, any consultation, communication, or agreement with any other bidder or competitor relating to:

   i) those prices; or
   ii) the intention to submit an offer; or
   iii) the methods or factors used to calculate the prices offered.

e) have neither been nor shall be knowingly disclosed by us, directly or indirectly, to any other bidder or competitor before bid opening or contract award unless otherwise required by law.

5) Affirmation to terms and conditions of the Tender Document:

We have understood the complete terms and conditions of the Tender Document. We accept and comply with these terms and conditions without reservations, although we are not signing and submitting some of the sections of the Tender Document. Deviations, if any, are submitted by us in Form 5: 'Terms and Conditions - Compliance'. We also explicitly confirm acceptance of the Arbitration Agreement as given in the Tender Document.

6) Bid Security/Bid Securing Declaration

We have submitted the Bid Security (applicable for all bidders except MSEs and Startups) in stipulated format vide Form 7A / Bid Securing Declaration (applicable for MSEs and Startups) in lieu of Bid Security in stipulated format vide Form 7: 'Documents Relating to bid security.'

7) Abiding by the Bid Validity

We agree to keep our bid valid for acceptance for a period up to 150 days, as required in the Tender Document or for a subsequently extended period, if any, agreed to by us and are aware of penalties in this regard stipulated in the Tender Document in case we fail to do so.

8) Non-tempering of Downloaded Tender Document and Uploaded Scanned Copies

We confirm that we have not changed/ edited the contents of the downloaded Tender Document. We realise that any such change noticed at any stage, including after the contract award, shall be liable to punitive action in this regard stipulated in the Tender Document. We also confirm that scanned copies of documents/ affidavits/ undertakings uploaded along with our Technical bid are valid, true, and correct to the best of our knowledge and belief. If any dispute arises related to the validity and truthfulness of such documents/ affidavits/ undertakings, we shall be responsible for the same. We undertake to submit for scrutiny, on-demand by the Procuring Entity, originals, and self-certified copies of all such certificates, documents, affidavits/ undertakings.

9) A Binding Contract:

We further confirm that, if our bid is accepted, all such terms and conditions shall continue to be acceptable and applicable to the resultant contract, even though some of these documents may not be included in the contract Documents submitted by us. We do hereby undertake that this bid together with your written acceptance of the same shall constitute a binding contract between us.

10) Performance Guarantee and Signing the contract

We further confirm that, if our bid is accepted, we shall provide you with performance security of the required amount stipulated in the Tender Document for the due performance of the contract. We are fully aware that in the event of our failure to deposit the required security amount and/ or failure to execute the agreement, the Procuring Entity has the right to avail any or all punitive actions laid down in this regard, stipulated in the Tender Document.

11) Signatories:

We confirm that we are duly authorized to submit this bid and make commitments on behalf of the Bidder. Supporting documents are submitted in Form 1.1 annexed herewith. We acknowledge that our digital/digitized signature is valid and legally binding.

12) Rights of the Procuring Entity to Reject bid(s):

We further understand that you are not bound to accept the lowest or any bid you may receive against your above-referred Tender Document.

……..
(Signature with date)
……..
(Name and designation)
Duly authorized to sign bid for and on behalf of
[name & address of Bidder and seal of company]

Form 1.1: Bidder Information
(Ref 8.2 of ITB)
(To be submitted as part of technical bid)
(On Company Letter-head)
(Along with supporting documents, if any)
Bidder's Name_____
[Address and Contact Details]
Bidder's Reference No._____ Date…….
Ref: Your Tender Document No. Tender No./ xxxx; Tender Title: GOODS

Note: Bidder shall fill in this Form following the instructions indicated below. No alterations to its format shall be permitted, and no substitutions shall be accepted. Bidder shall enclose certified copies of the documentary proof/ evidence to substantiate the corresponding statement wherever necessary and applicable. Bidder's wrong or misleading information shall be treated as a violation of the Code of Integrity. Such Bids shall be liable to be rejected as nonresponsive, in addition to other punitive actions provided for such misdemeanours in the Tender Document.

(Please tick appropriate boxes or strike out sentences/ phrases not applicable to you)

1) Bidder/ Contractor particulars:

a) Name of the Company:…….
b) Corporate Identity No. (CIN): ……..
c) Registration, if any, with The Procuring Entity: ……..
d) GeM Supplier ID (if registered with GeM, it is mandatory at the time of placement of Contract)
e) Place of Registration/ Principal place of business/ manufacture …….
f) Complete Postal Address: ……..
g) Pin code/ ZIP code: …….
h) Telephone nos. (with country/ area codes): ……
i) Mobile Nos.: (with country/ area codes): ……..
j) Contact persons/ Designation: …….
k) Email IDs: …….

Submit documents to demonstrate eligibility viz. In case of a partnership firm – Deed of Partnership; in case of Company – Notarized and certified copy of its registration certificate; and in case of Society – its Byelaws and registration certificate of the firm.

2) Taxation Registrations:

a) PAN number: …….
b) Type of GST Registration as per the Act (Normal Taxpayer, Composition, Casual Taxable Person, SEZ, etc.): …….
c) GSTIN number: ……. in Consignor and Consignee States
d) Registered/ Certified Works/ Factory where the Goods would be mainly manufactured and Place of Consignor for GST Purpose: …….
e) Contact Names, Nos. & email IDs for GST matters (Please mention primary and secondary contacts): ……

☐ We solemnly declare that our GST rating on the GST portal/ Govt. official

website is not negative/ blacklisted.

Documents to be submitted: Self-attested Copies of PAN card and GSTIN Registration.

3) Authorization of Person(s) signing the bid on behalf of the Bidder

a) Full Name: _____
b) Designation: _____
c) Signing as:

☐ A sole proprietorship firm. The person signing the bid is the sole proprietor/ constituted attorney of the sole proprietor,

☐ A partnership firm. The person signing the bid is duly authorised being a partner to do so, under the partnership agreement or the general power of attorney,

☐ A company. The person signing the bid is the constituted attorney by a resolution passed by the Board of Directors or in pursuance of the Authority conferred by Memorandum of Association.

Documents to be submitted: Partnership Agreement/ Power of Attorney/ Registration Certificate/ Memorandum of Association/ Board Resolution

4) Bidder's Authorized Representative Information

a) Name:
b) Address:
c) Telephone/ Mobile numbers:
d) Email Address:

5) Bidder's Account Details

a) Bank Name:
b) IFSC Code:
c) Account No. :
d) Branch Address:
e) Email Address/ Contact No.:

With a copy of cancelled cheque

(Signature with date)
……..
(Name and designation)
Duly authorized to sign bid for and on behalf of
[name & address of Bidder and seal of company], DA: As above

Form 1.2: Eligibility Declarations
(Ref ITB-clause 9.2)
(To be submitted as part of Technical bid)
(On Company Letter-head)
(Along with supporting documents, if any)
Ref: Your Tender Document No. Tender No./ xxxx; Tender Title: GOODS
Bidder's Name_____
[Address and Contact Details]
Bidder's Reference No._____ Date…….
Note: The list below is indicative only. You may attach more documents as required to confirm your eligibility criteria.

Eligibility Declarations

(Please tick appropriate boxes or cross out any declaration not applicable to the Bidder)
We hereby confirm that we are comply with all the stipulation of bid document and declare as under and shall provide evidence of our continued eligibility to the Procuring Entity as may be requested:

1) Legal Entity of Bidder: _____

2) We solemnly declare that we (including our affiliates or subsidiaries or constituents):

a) are not insolvent, in receivership, bankrupt or being wound up, not have our affairs administered by a court or a judicial officer, not have our business activities suspended and are not the subject of legal proceedings for any of these reasons;
b) (including our Contractors/ subcontractors for any part of the contract):

i. Do not stand declared ineligible/ blacklisted/ banned/ debarred by the Central Medical Services Society or Ministry of Health and Family Welfare, Government of India from participation in its Tender Processes as a whole or for the product offered; and/ or
ii. Are not convicted or stand declared ineligible/ suspended/ blacklisted/ banned/ debarred by appropriate agencies of Government of India from participation in Tender Processes of all of its entities, for offences mentioned in Tender Document in this regard. We have neither changed our name nor created a new "Allied Firm", consequent to the above disqualifications.

c) Do not have any association (as bidder/ partner/ Director/ employee in any capacity) with such retired public official or near relations of such officials of Procuring Entity, as counter-indicated, in the Tender Document.
d) We certify that we fulfil any other additional eligibility condition if prescribed in Tender Document.
e) We have no conflict of interest, which substantially affects fair competition. The prices quoted are competitive and without adopting any unfair/ unethical/ anti-competitive means. No attempt has been made or shall be made by us to induce any other bidder to submit or not to submit an offer to restrict competition.

3) Restrictions on procurement from bidders from a country or countries, or a class of countries under Rule 144 (xi) of the General Financial Rules 2017: We certify as under:

"We have read the clause regarding restrictions on procurement from entities having beneficial ownership of a country which shares a land border with India and on sub-contracting to contractors from such countries, as stipulated vide Department of Expenditure Order No F.7/10/2021-PPD (1), dated 23.02.2023 as amended till date of bid submission, and solemnly certify that we fulfil all requirements in this regard and are eligible to be considered. We certify that:

a) we are not from such a country or, if from such a country, we are registered with the Competent Authority (copy enclosed). and;
b) we shall not subcontract any work to a contractor from such countries unless such contractor is registered with the Competent Authority.

4) MSME Status:

Having read and understood the Public Procurement Policy for Micro and Small Enterprises (MSEs) Order, 2012 (as amended and revised till date), and solemnly declare the following:

a) We are - Micro/ Small/ Medium Enterprise/ SSI/ Govt. Deptt. / PSU/ Others:……
b) We attach herewith, Udhyam Registration Certificate with the Udhyam Registration Number as proof of our being MSE registered on the Udhyam Registration Portal. The certificate is the latest up to the deadline for submission of the bid.
c) Whether Proprietor/ Partner belongs to SC/ ST or Women category. (Please specify names and percentage of shares held by SC/ ST Partners):…….

5) Start-up Status

we confirm that we ☐ are/ ☐ are not a Start-up entity as per the definition of the Department of Promotion of Industrial and Internal Trade – DPIIT.

6) Make in India Status:

Having read and understood the Public Procurement (Preference to Make in India PPP - MII) Order, 2017 (as amended and revised till date) and related notifications from the relevant Nodal Ministry/ Department, and solemnly declare the following:

(a) Self-Certification for the category of suppliers:

(Provide a certificate from statutory auditors/ cost accountant in case of Tenders above Rs 10 Crore for Class-I or Class-II Local Suppliers). Details of local content and location(s) at which value addition is made are as follows:

Sr. No.	Name of Item	Percentage Local Content	Location of value addition

Therefore, we certify that we qualify for the following category of the supplier (tick the appropriate category):

 Class-I Local Supplier/
 Class-II Local Supplier/
 Non-Local Supplier.

I confirm that local content has been calculated in accordance with provisions of PPP-MII Order dated 19.07.2024 read with Department of Pharmaceutical Notification No. **31026/65/2020-MD dated 30.12.2020** / F.No.31026/36/2016-MD dated 16.02.2021. I undertake to produce relevant records before the procuring entity or any authority so nominated by the Department of Pharmaceuticals, Government of India for the purpose of assessing the local content.

7) Integrity Pact

Having read and understood the provisions of Integrity Pact, as detailed in ITB 16, we confirm that we accept the same. Integrity Pact, in prescribed proforma, duly signed is enclosed, with the bid.

8) Penalties for false or misleading declarations:

We hereby confirm that the particulars given above are factually correct and nothing is concealed and undertake to advise any future changes to the above details. We understand that any wrong or misleading self-declaration would violate the Code of Integrity and attract penalties as mentioned in this Tender Document.

……..
(Signature with date)
……..
(Name and designation)
Duly authorized to sign bid for and on behalf of
…….
…….
[name & address of Bidder and seal of company]
DA: As in Sr 9 to 14 above, as applicable

Form 1.3: Local Content Declaration- Compliance
(Certificate to be given by Statutory Auditors for purchases above INR 10 Crores)

Tender Reference No: Date:

Based upon the documents placed before us, we certify that M/s…….. (name of the bidder) having manufacturing premises at ……. (manufacturing place of the bidder) have the following local contents in the goods quoted by them against subject tender enquiry:

Sr. No.	Name of Item	Percentage Local Content	Location of value addition

We confirm that local content has been calculated in accordance with provisions of PPP-MII Order dated 19.07.2024 read with Department of Pharmaceutical Notification No. **31026/65/2020-MD dated 30.12.2020** / F.No.31026/36/2016-MD dated 16.02.2021. We undertake to produce relevant records before the procuring entity or any authority so nominated by the Department of Pharmaceuticals, Government of India for the purpose of assessing the local content.

Statutory Auditor for Companies/ Chartered Accountant for others
(with Seal/Stamp)
UDIN ……

Form 1.4 **Integrity Pact Format**

INTEGRITY PACT

Between

[the Procuring Organisation] hereinafter referred to as **"The Principal,"** and _____ hereinafter referred to as **"The Bidder/ Contractor."**

Preamble

The Principal intends to award contract/s for_____, under laid down organizational procedures, The Principal values full compliance with all relevant laws of the land, rules, regulations, economical use of resources, and fairness / transparency in its relations with its Bidder(s) and / or Contractor(s).

To achieve these goals, the Principal shall appoint Independent External Monitors (IEMs) who shall monitor the tender process and the execution of the contract for compliance with the abovementioned principles.

Section 1 – Commitments of the Principal

1) The Principal commits itself to take all measures necessary to prevent corruption and to observe the following principles: -
   a. No employee of the Principal, personally or through family members, shall in connection with the tender for, or the execution of a contract, demand, take a promise for or accept, for self or third person, any material or immaterial benefit which the person is not legally entitled to.
   b. The Principal shall treat all Bidder(s) with equity and reason during the tender process. The Principal shall, in particular, before and during the tender process, provide to all Bidder(s) the same information and shall not provide to any Bidder(s) confidential / additional information through which the Bidder(s) could obtain an advantage in the tender process or the contract execution.
   c. The Principal shall exclude from the process all known persons having conflict of interest.

2) If the Principal obtains information on the conduct of any of its employees which is a criminal offence under the IPC/PC Act, or if there be a substantive suspicion in this regard, the Principal shall inform the Chief Vigilance Officer and in addition shall initiate disciplinary proceedings.

Section 2 – Commitments of the Bidder(s)/ Contractor(s)

1) The Bidder(s)/ Contractor(s) commits themselves to take all measures necessary to prevent corruption. The Bidder(s)/ Contractor(s) commits themselves to observe the following principles during participation in the tender process and the contract execution.

   a. The Bidder(s)/ Contractor(s) shall not, directly or through any other person or firm, offer, promise, or give to any of the Principal's employees involved in the tender process or the execution of the contract or to any third person any material or other benefit which they are not legally entitled to, in order to obtain in exchange any advantage of any kind whatsoever during the tender process or the execution of the contract.

   b. The Bidder(s)/ Contractor(s) shall not enter with other Bidders into any undisclosed agreement or understanding, whether formal or informal, in violation of the Competition Act, 2002 (as amended from time to time). This applies in particular to prices, specifications, certifications, subsidiary contracts, submission or non-submission of bids or any other actions to restrict competitiveness or to introduce cartelisation in the tender process.

c. The Bidder(s)/ Contractor(s) shall not commit any offence under the relevant IPC/PC Act; further, the Bidder(s)/ Contractor(s) shall not use improperly, for purposes of competition or personal gain, or pass on to others, any information or document provided by the Principal as part of the business relationship, regarding plans, technical proposals, and business details, including information contained or transmitted electronically.

d. The Bidder(s)/Contractors(s) of foreign origin shall disclose the name and address of the Agents/representatives in India, if any. Similarly, the Bidder(s)/Contractors(s) of Indian Nationality shall furnish the name and address of the foreign principals, if any. Further details, as mentioned in the "Guidelines on Indian Agents of Foreign Suppliers," shall be disclosed by the Bidder(s)/Contractor(s). Further, as mentioned in the Guidelines, all the payments made to the Indian agent/representative must be in Indian Rupees only. Copy of the "Guidelines on Indian Agents of Foreign Suppliers" is placed on Annex hereto.

e. The Bidder(s)/ Contractor(s) shall, when presenting their bid, disclose any and all payments made, is committed to, or intends to make to agents, brokers, or any other intermediaries in connection with the award of the contract.

f. Bidder(s) /Contractor(s) who have signed the Integrity Pact shall not approach the Courts while representing the matter to IEMs and shall wait for their decision.

2) The Bidder(s)/ Contractor(s) shall not instigate third persons to commit offences outlined above or be an accessory to such offences.

Section 3 - Disqualification from the tender process and exclusion from future contracts

If the Bidder(s)/Contractor(s), before award or during execution, has committed a transgression through a violation of Section 2, above or in any other form such as to put their reliability or credibility in question, the Principal is entitled to disqualify the Bidder(s)/Contractor(s) from the tender process or take action as per laid down procedure to debar the Bidder(s)/Contractor(s) from participating in the future procurement processes of the Government of India.

Section 4 – Compensation for Damages

1) If the Principal has disqualified the Bidder(s) from the tender process before the award according to Section 3, the Principal is entitled to demand and recover the damages equivalent to Earnest Money Deposit/ Bid Security.

2) If the Principal has terminated the contract according to Section 3, or if the Principal is entitled to terminate the contract according to Section 3, the Principal shall be entitled to demand and recover from the Contractor liquidated damages of the Contract value or the amount equivalent to Performance Bank Guarantee.

Section 5 – Previous transgression

1) The Bidder declares that no previous transgressions occurred in the last three years with any other Company in any country conforming to the anti-corruption approach or with any Public Sector Enterprise in India that could justify his exclusion from the tender process.

2) If the Bidder makes an incorrect statement on this subject, the Principal shall act like para 2) of Section 4 above.

Section 6 – Equal treatment of all Bidders / Contractors / Subcontractors

In the case of Sub-contracting, the Principal Contractor shall take responsibility for adopting the Integrity Pact by the Sub-contractor.

a. The Principal shall enter into agreements with identical conditions as this one with all Bidders and Contractors.

b. The Principal shall disqualify from the tender process all bidders who do not sign this Pact or violate its provisions.

Section 7 – Criminal charges against violating Bidder(s) / Contractor(s) / Subcontractor(s)

If the Principal obtains knowledge of the conduct of a Bidder, Contractor, or Subcontractor, or of an employee or a representative or an allied firm of a Bidder, Contractor or Subcontractor which constitutes corruption, or if the Principal has substantive suspicion in this regard, the Principal shall inform the same to the Chief Vigilance Officer.

Section 8 – Independent External Monitor

1) The Principal shall appoint competent and credible Independent External Monitor(s) for this Pact after approval by the Central Vigilance Commission. The task of the Monitor is to review, independently and objectively, whether and to what extent the parties comply with the obligations under this agreement.

2) The Monitor is not subject to instructions by the parties' representatives and performs their functions neutrally and independently. The Monitor would have access to all Contract documents whenever required. It shall be obligatory for them to treat the information and documents of the Bidders/Contractors as confidential. They report to the Management of the Principal.

3) The Bidder(s)/Contractor(s) accepts that the Monitor has the right to access without restriction, all Project documentation of the Principal, including that provided by the Contractor. Upon their request and demonstration of a valid interest, the Contractor shall also grant the Monitor unrestricted and unconditional access to their project documentation. The same applies to Subcontractors.

4) The Monitor is under contractual obligation to treat the information and documents of the Bidder(s)/ Contractor(s)/ Sub-contractor(s) with confidentiality. The Monitor has also signed declarations on 'Non-Disclosure of Confidential Information' and 'Absence of Conflict of Interest.' In case of any conflict of interest arising later, the IEM shall inform the Management of the Principal and recuse themselves from that case.

5) The Principal shall provide the Monitor with sufficient information about all meetings among the parties related to the Project, provided such meetings could impact the contractual relations between the Principal and the Contractor. The parties offer the Monitor the option to participate in such meetings.

6) As soon as the Monitor notices, or believes to notice, a violation of this agreement, they shall inform the Management of the Principal and request the Management to discontinue or take corrective action or other relevant action. The Monitor can, in this regard, submit non-binding recommendations. Beyond this, the Monitor has no right to demand from the parties that they act in a specific manner, refrain from action, or tolerate action.

7) The Monitor shall submit a written report to the Management of the Principal, within 8 to 10 weeks from the date of reference or intimation to him by the Principal and, should the occasion arise, submit proposals for correcting problematic situations.

8) If the Monitor has reported to the Management of the Principal a substantiated suspicion of an offence under the relevant IPC/ PC Act, and the Management of the Principal has not, within the reasonable time, taken visible action to proceed against such offence or reported it to the Chief Vigilance Officer, the Monitor may also transmit this information directly to the Central Vigilance Commissioner.

9) The word **'Monitor'** would include both singular and plural.

Section 9 – Pact Duration

This Pact begins when both parties have legally signed it. It expires for the Contractor 12 months after the last payment under the contract, and for all other Bidders, 6 months after the contract has been awarded. Any violation of the same would entail disqualifying the bidders and exclusion from future business dealings.

If any claim is made / lodged during this time, the same shall be binding and continue to be valid despite the lapse of this Pact as specified above, unless it is discharged / determined by the Management of the Principal.

Section 10 – Other provisions

1) This agreement is subject to Indian Law. The place of performance and jurisdiction is the place from where the Tender/ Contract is issued.
2) Changes, supplements, and termination notices must be submitted in writing. Side agreements have not been made.
3) If the Contractor is a partnership or a consortium, this agreement must be signed by all partners or consortium members.
4) Should one or several provisions of this agreement turn out to be invalid, the remainder of this agreement remains valid. In this case, the parties shall strive to come to an agreement according to their original intentions.
5) Issues like Warranty / Guarantee, etc., shall be outside the purview of IEMs.
6) In the event of any contradiction between the Integrity Pact and its Annex, the Clause in the Integrity Pact shall prevail.

_____	_____
(For & On behalf of the Principal)	(For and on behalf of Bidder/ Contractor)
(Office Seal)	(Office Seal)
Place ---------- Date ----------	
Witness 1: _____	Witness 1: _____
(Name & Address)	(Name & Address)

Form 2: Schedule of Requirements – Compliance & Deviation
Schedule of Requirements
(Ref ITB-clause 9.2, Schedule V: Schedule of Requirements)
(To be submitted as part of Technical bid)
(on Company Letter-head)
Ref: Your Tender Document No. Tender No./ xxxx; Tender Title: GOODS
Bidder's Name_____
[Address and Contact Details]
Bidder's Reference No._____ Date…….
Note to Bidders: Fill up this Form regarding Section V: Schedule of Requirements maintaining the same numbering and structure. Add additional details not covered elsewhere in your bid in this regard.

Tender Title				
Tender Reference No		Tend No./ xxxx		
Schedule	**Description of Goods**	**Local Content (%)**	**HSN Code**	**Bidder's GSTIN**
1	2	3	4	5
I				
II				
III				

We shall comply with, abide by, and accept without variation, deviation, or reservation all requirements detailed in Section V: Schedule of Requirements in the Tender Document, including delivery schedule & terms of delivery except those mentioned below.

a) ……
b) ……..

We understand that if contrary terms and conditions are mentioned elsewhere in our bid, same shall not be recognized and shall be null and void.
(Signature with date)
……..
(Name and designation)
Duly authorized to sign bid for and on behalf of
…….
[name & address of Bidder and seal of company]

Form 3: Technical Specifications and Quality Assurance – Compliance & Deviation
(Ref ITB-clause 9.2, Schedule VI: Technical Specifications and Quality Assurance)
(To be submitted as part of Technical bid)
(on Company Letter-head)
Ref: Your Tender Document No. Tender No./ xxxx; Tender Title: GOODS
Bidder's Name_____
[Address and Contact Details]
Bidder's Reference No._____ Date…….
Note to Bidders: Highlight in this form deviations, if any, from Section VI: Technical Specifications and Quality Assurance, maintaining the same numbering and structure. Add additional details not covered elsewhere in your bid in this regard.

Sl. No.	**Technical specification as per tender**	**Comply (Yes/No)**

Note: - Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life and Certificate of Analysis of one batch of the quoted product should be submitted.
We shall comply with, abide by, and accept without variation, deviation, or reservation all Technical Specifications including artworks, Quality Assurance and Warranty requirements in the Tender Document, except those mentioned below.

a) ……..
b) ……..

We understand that if contrary terms and conditions are mentioned elsewhere in our bid, same shall not be recognized and shall be null and void.

……..
(Signature with date)
……..
(Name and designation)
Duly authorized to sign bid for and on behalf of
…….
[name & address of Bidder and seal of company]
DA: Relevant documents like technical data, literature, drawings, and other documents

Form 4: Qualification Criteria – Compliance & Deviation
(Ref ITB-clause 9.2, Schedule IV Qualification Criteria)
(To be submitted as part of Technical bid)
(on Company Letter-head)
Ref: Your Tender Document No. Tender No./ xxxx; Tender Title: GOODS
Bidder's Name_____
[Address and Contact Details]
Bidder's Reference No._____ Date…….
Note to Bidders: Furnish statements and documents to confirm conformity to Qualification Criteria may be mentioned/ attached here. The list below is indicative only. You may attach more documents as required for qualification criteria. Add additional details not covered elsewhere in your bid in this regard. Non-submission or incomplete submission of documents may lead to rejection of the bid as nonresponsive. Also highlight in this form deviations, if any, from Section IV: Qualification Criteria.
1.

Ref of Qualification Criteria Clause	**Confirmation Yes/No**
Clause (a)	
Clause (b)	
Clause (c)	
Clause (d)	
……	

2. Documents Attached supporting the compliance to qualification criteria:

Sr	**Document Attached, duly filled, signed, and copies self-attested**
1	
2	
3	

We shall comply with, abide by, and accept without variation, deviation, or reservation all the Qualification Criteria mentioned in the Tender Document, except those mentioned below.

a) ……
b) ……..

We understand that if contrary terms and conditions are mentioned elsewhere in our bid, same shall not be recognised and shall be null and void.

……..
(Signature with date)
……..
(Name and designation)
Duly authorized to sign bid for and on behalf of
…….
[name & address of Bidder and seal of company]
DA: As above, if any

Form 4.1: PROFORMA FOR PERFORMANCE STATEMENT

(FOR A PERIOD OF LAST 2 YEARS)

Name of Bidder with Address_____
Manufacturer with Address_____
Tender No. & Date_____
Sr. No. of the Quoted Product _____
Name of the Quoted Product _____

Financial Year 2022-23								
Domestic Purchase Orders								
GST Invoice No. and Date	E-Way Bill No. and Date	Purchase Order No and Date	Description of Goods	Unit	Qty.	Unit Price All Incl.	Total Value	Name of Purchaser with Contact Details
Export Purchase Orders								
Bill of lading/ Airway Bill No. and Date	Any other document issued by Custom Authority	Purchase Order No and Date	Description of Goods	Unit	Qty.	Unit Price All Incl.	Total Value	Name of Purchaser with Contact Details
Financial Year 2023-24								
Domestic Purchase Orders								
GST Invoice No. and Date	E-Way Bill No. and Date	Purchase Order No and Date	Description of Goods	Unit	Qty.	Unit Price All Incl.	Total Value	Name of Purchaser with Contact Details
Export Purchase Orders								
Bill of lading/ Airway Bill No. and Date	Any other document issued by Custom Authority	Purchase Order No and Date	Description of Goods	Unit	Qty.	Unit Price All Incl.	Total Value	Name of Purchaser with Contact Details

Note:

1. The copies of GST invoice and E-way bill against the proof of execution of order for every submitted Purchase Order must be submitted. If GST invoice is not applicable for any Purchase Order, the affidavit to that effect on stamp paper of Rs. 100/- should be submitted.
2. For the supply of export, bidder should submit the copy of invoice, bill of lading/airway bill/any other document issued by custom authority against the proof of execution of order for every submitted Purchase Order.

Signature of Tenderer	Signature of Practicing Chartered Accountant
Name in Capitals	Name in Capitals
Date:	Date
Seal:	Seal
	UDIN-

Form 4.2: ANNUAL TURN OVER STATEMENT

The Annual Turnover (Sales) of M/s._____ for the past three years are given below and certified that the statement is true and correct.

Sl. No.	Financial Year	Turnover in Lakhs (Rs)
1.	2019-2020 / 2020-21	-
2.	2020-2021/ 2021-22	-
3.	2021-2022 /2022-23	-

Total - Rs. _____ Lakhs.

Average Turnover Per Annum in the last three years mentioned above - Rs._____ Lakh

Date:
Seal: Signature of Auditor/Chartered Accountant
(Name in Capital)
UDIN-

Form 5: Terms and Conditions - Compliance
(Ref ITB-clause 9.2)
(To be submitted as part of Technical bid)
(on Company Letter-head)
Bidder's Name_____
[Address and Contact Details]
Bidder's Reference No._____ Date…….
Ref: Your Tender Document No. Tender No./ xxxx; Tender Title: GOODS
Note to Bidders: Fill up this Form regarding Terms and Conditions in the Tender Document, maintaining the same numbering and structure. Add additional details not covered elsewhere in your bid in this regard.
We shall comply with, abide by, and accept without variation, deviation, or reservation of the entire terms & conditions of tender document including all Corrigendum, Pre-bid Minutes of the Tender Document etc, except those mentioned below.

a) ……
b) ……..

We understand that if contrary terms and conditions are mentioned elsewhere in our bid, same shall not be recognised and shall be null and void.
……..
(Signature with date)
……..
(Name and designation)
Duly authorized to sign bid for and on behalf of
…….
…….
[name & address of Bidder and seal of company]
DA: If any, at the option of the Bidder.

Form6: Bid Summary

Bid Summary : M/s……
CMSS Tender No. : ……
Tender Name : ……..
CPP/GeM Id No. : ……..
Tender Opening Date : ……

S.No.	Description
1.	**Bidder Information**

S.No.	Item Description	Details
1(a)	Name of Bidder	
1(b)	PAN No.	
1(c)	GST No.	
1(d)	Registered Address	
1(e)	Operating Address	
1(f)	Telephone No.	
1(g)	Emails	
1(h)	Name of Person Signing the Bid	
1(i)	Designation	

Attached Documents

S.No.	Documents	Reference Bid page No.
1(j)	Bidder Information Form (Form 1.1 of Bid Document)	
1(k)	Copy of PAN	
1(l)	Copy of GST	
1(m)	Copy of Power of Attorney	

2. **Quoted Items**

S. No.	Schedule No.	Item Name
2 (a)		
2 (b)		
2 (c)		
2 (d)		

Attached Documents

S.No.	Documents	Reference Bid page No.
2 (e)	Bid Form (Form 1 of Bid Document)	

3 **Bid Security/ Bid Securing Declaration**

S. No.	Schedule No.	Bid Security/ Bid Securing Declaration Details (Bank Guarantee Number & Date/ NEFT/ RTGS/ Bid Securing Declaration Details)
3 (a)		
3 (b)		
3 (c)		
3 (d)		

Attached Documents

S. No.	Documents	Reference Bid page No.
3 (e)	Bid Security/ Bid Securing Declaration	

4. **Eligibility Requirement**

S.No.	Item Description	Yes/No	If Yes, Details thereof
4 (a)	Blacklisted/Debarred/Banned		
4 (b)	Relation with Officials of Procuring Entity		
4 (c)	Conflict of Interest		
4 (d)	Beneficial Ownership in Land Boarder Sharing Country [GFR Rule 144 (xi)]		DPIIT Registration No. : _____ Dated :_____ Valid Till :_____
4 (e)	MSME Status		Class : Micro/Small/Medium MSME Udhyam Reg. No. : _____ Dated : _____ Valid Till : _____ Udhyam Registration Classification S.No. | Classification Year | Enterprise Type | Classification Date | | | | | | | | | | | | | | | | | | | |
4 (f)	Startup		DPIIT Startup Reg. No. :_____ Dated :_____ Valid Till :_____

4(g)	Integrity Pact		

4 (h) Local Content for Item Quoted

Schedule No.	Name of Item	Percentage Local Content	Location of Value Addition

Attached Documents

S. No.	Documents	Reference Bid page No., If Applicable
4 (i)	Eligibility Declaration (Form 1.2 of Bid Document)	
4 (j)	Blacklisting / Debarring/ Banning Order, If Any.	
4 (k)	Details of relationship with procuring entity, If Any.	
4 (l)	Details of Conflict of Interest, If Any.	
4 (m)	Copy of DPIIT Registration Certification under GFR Rule 144 (xi), if Beneficial Ownership in Land Boarder Sharing Country	
4 (n)	MSME Udhyam Registration Certificate, If MSE	
4 (o)	DPIIT Startup Registration Certificate, If Startup.	
4 (p)	Statutory Auditors Certificate for Local Content, If Purchase Value More than INR 10 Crore. Local Content Declaration Compliance. (Form 1.3 of Bid Document)	
4(q)	Integrity Pact (Form 1.4 of Bid Document)	

Note: Details in respect of Para 4 to 7 below are to be filled up separately for each of the schedule quoted.

5. **Schedule of Requirement Compliance**

S.No.	Complies with schedule of Requirement	Yes/No	If No, Details thereof
5 (a)			

Attached Documents

S.No.	Documents	Reference Bid page No.
5 (b)	Schedule of Requirement- Compliance & Deviation (Form 2 of Bid Document)	

6. **Technical Specification Compliance**

S.No.	Compliance with Technical Specification as Indicated in the Tender Documents	Yes/No	If No, Details thereof
6 (a)			

Attached Documents

S.No.	Documents	Reference Bid page No.
6 (b)	Technical Specifications & Quality Assurance- Compliance & Deviation (Form 3 of Bid Document)	
6 (c)	Long Term Stability Data in accordance with ITB Clause 9.2.1 (5)	

7. **Terms & Conditions Compliance**

S.No.	Compliance with Tender Terms & Conditions	Yes/No	If No, Details thereof
7 (a)			

Attached Documents

S.No.	Documents	Reference Bid page No.
7 (b)	Terms & Conditions Compliance (Form 5 of Bid Document)	

8. **Qualification Criteria Compliance**

S.No.	Description	Details
8 (a)	Bidder is Manufacturer	If No, Details thereof
8 (b)	Manufacturing License Details	License No. : _____ License Date : _____ License Validity : _____ Mfg. Address : _____ Issuing Authority : _____
8 (c)	WHO GMP Details	WHO GMP Certificate No. : _____ Date : _____ Valid Till : _____ License for which WHO GMP has been Issued : _____ Manufacturing Premises for which WHO GMP is Applicable : _____ Issuing Authority : _____
8 (d)	COPP Certificate Details	COPP Certificate No. : _____ Date : _____ Valid Till : _____ Item for which COPP Certificate has been Issued : _____ License for which COPP has been Issued : _____ Issuing Authority : _____
8 (f)	Non-Conviction Certificate	Non-Conviction Certificate Valid for F.Y. : _____&_____ Non-Conviction Certificate No. : _____ Date : _____ Valid Till : _____ License for which Non Conviction Certificate has been Issued : _____ Issuing Authority :_____
8 (h)	Manufacturing Capacity	Annual Production Capacity : _____ Mfg. License No. : _____ Licensing Authority Certificate No.: _____ Date : _____ Issuing Authority : _____
8 (i)	Turnover	F.Y. | Annual Turnover (Rs.) 2021-22 | 2022-23 | 2023-24 |

		Average Annual Turnover | Chartered Accountant Name : _____ Membership No. : _____ UDIN No. : _____ Date : _____
8 (j)	Successful Past Supplier of Quoted Item	Yes/No If Yes, details thereof

Attached Documents

S.No.	Document	Reference Bid Page No.
8 (k)	Manufacturing License	
8 (l)	If the item is not available in IP, Bidder's undertaking that the drug is not available in IP OR any other approve Pharmacopoeia	
8 (m)	WHO GMP Certificate	
8 (n)	COPP Certificate	
8 (o)	Market Standing Certificate	
8 (p)	Non-Conviction Certificate	
8 (q)	**Past Supplies Details**	
	Past Supplies POs	
	GST Invoices	
	E-way Bills	
	Document issued by Custom Authority, If Applicable	
	Affidavit, If Applicable	
	Past Performance Details in the Prescribed Proforma (Form 4.1 of Bid Document)	
8 (r)	Manufacturing Capacity Certificate	
8 (s)	Annual Turnover Statement in the Prescribed Proforma (Form 4.2 of Bid Document)	
8 (t)	Audited Annual Report	
8 (u)	CMSS P.O. Copy Executed Successfully	

……..
(Signature with date)

……..
(Name and designation)
Duly authorized to sign bid for and on behalf of…….

[name & address of Bidder and seal of company]

Form 7: Documents relating to Bid Security.

(Ref ITB-clause 9.2)

Note: To be submitted as part of Technical bid, along with supporting documents, if any. Submit as Form 7 as part of Technical bid, a Bid Securing Declaration In lieu of bid security in the following format. Bidders exempted from submission of bid security are also required to submit this.

Bid Securing Declaration *(Should be notarised on Rs. 100 stamp papers)*

(on Company Letter-head)

Bidder's Name_____

[Address and Contact Details]

Bidder's Reference No._____ Date…….

To

DG & CEO, Central Medical Services Society, Ministry of Health and Family welfare, Government of India, New Delhi

Address: 2nd floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Road, Opposite Police Station Chanakaya Puri,

New Delhi-110021

Telephones: 011-21410905, 21410906

Ref: Your Tender Document No. Tender No./ xxxx; Tender Title: GOODS

Sir/ Madam

We, the undersigned, solemnly declare that:

We understand that according to the conditions of this Tender Document, for MSEs and Startups bidders, and Organization or Firm having annual financial turnover, equal to or greater than Rs. 500Cr. in any of the past three financial years, the bid must be supported by a Bid Securing Declaration in lieu of Bid Security.

We confirm that we are MSE/Startups/ Organization or Firm having annual financial turnover, equal to or greater than Rs. 500Cr. and unconditionally accept the conditions of this Bid Securing Declaration. We understand that we shall stand automatically suspended from being eligible for bidding in any tender in Procuring Organisation for 2 years from the date of opening of this bid if we breach our obligation(s) under the tender conditions if we:

1) withdraw/ amend/ impair/ derogate, in any respect, from our bid, within the bid validity; or

2) being notified within the bid validity of the acceptance of our bid by the Procuring Entity:

a) refused to or failed to produce the original documents for scrutiny or the required Performance Security within the stipulated time under the conditions of the Tender Document.
b) Fail or refuse to sign the contract.

We know that this bid-Securing Declaration shall expire if the contract is not awarded to us, upon:

1) receipt by us of your notification

a) of cancellation of the entire tender process or rejection of all bids or
b) of the name of the successful bidder or

2) forty-five days after the expiration of the bid validity or any extension to it.

(Signature with date)
……..
(Name and designation)
Duly authorized to sign bid for and on behalf of…….
[name & address of Bidder and seal of company]
Dated on ……. day of …….. [insert date of signing]
Place……[insert place of signing]
DA:……

Form 7A : **Bank Guarantee for EMD (Format)**

Instruction to BG Issuing Bank – The Bank Guarantee should be through SFMS (Structured Financial Messaging System) & the following fields should be filled with the details given below.

FMS Field Number	SFMS Field Details	Details to be filled
7034	Name Of Beneficiary And His Details	**CENTRAL MEDICAL SERVICES SOCIETY** 2ND FLOOR, VISHWA YUVAK KENDRA CHANKAYA PURI, NEW DELHI-110021
7035	Beneficiary IFSC	**HDFC0000003**
7036	Beneficiary Branch Name And Address	HDFC Bank Ltd 209-214 KAILASH BUILDING 26 KASTURBA GANDHI MARG NEW DELHI 110001
7037	Sender To Receiver Information	**CENTRALYCX**

This is captured in both IFN760 COV (BG Issuance) / IFN767 COV (BG Amendment, if any).

[The Bank shall fill in this Bank Guarantee Form in accordance with the instructions indicated.]

_____
*[insert **Bank's Name**, and **Address** of Issuing Branch or Office]*
Beneficiary: *[insert **Name and Address of Purchaser**]*
Date: _____
BID GUARANTEE No.: _____

We have been informed that*[insert **name of the Tenderer**]* (hereinafter called "the Tenderer ") has submitted to you its bid dated (hereinafter called "the Bid")for the execution of *[insert **name of contract]*** under Tender No……
Furthermore, we understand that, according to your conditions, bids must be supported by a EMD.

At the request of the Tenderer, we *[insert **name of Bank]*** hereby irrevocably under take to pay you any sum or sums not exceeding in total an amount of *[insert **amount in figures]*** (*[insert **amount in words]***) upon receipt by us of your first demand in writing accompanied by a written statement stating that the Tenderer is in breach of its obligation(s) under the bid conditions, because the Tenderer:

a) has withdrawn its Bid during the period of bid validity specified by the Tenderer in the Form of Bid; or
b) having been notified of the acceptance of its Bid by the Purchaser during the period of bid validity, (i) fails or refuses to execute the Contract Form, if required, or(ii)fails or refuses to furnish the security deposit, in accordance with the Instructions to Tenderer s.
c) does not accept the correction of the Bid Price

d) This guarantee will expire: (a) if the Tenderer is the successful tenderer ,upon our receipt to copies of the contract signed by the Tenderer and the performance security issued to you upon the instruction of the Tenderer ; or(b) if the Tenderer is not the successful tenderer ,upon the earlier of (i) our receipt of a copy of your notification to the Tenderer of the name of the successful tenderer ;or (ii) Twenty Eight days after the expiration of the Tenderer 's Bid.

Consequently, any demand for payment under this guarantee must be received by us at the office on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No. 758.

_____

[signature(s)

FORMATS

Format 1: Letter of Acceptance
(Ref Clause 13.2.5 of ITB)

LETTER OF ACCEPTANCE

No: CMSS/PROC/2024-25/___/___ Date _____

To,
M/s _____
Address: _____
Attn: _____
Phone: _____
Email _____

(Kind Attn: _____(Name), _____ Designation)

Sub: Acceptance of Tender for supply of _____

Ref: 1) CMSS Tender No. **CMSS/PROC/2024-25/____/____** opened on _____
2) Your Ref. No. _____ dated _____ in response to above mentioned tender.

Dear Sir,

I am pleased to inform you that your offer in response to above mentioned tender for supply of _____has been accepted for following items:

Sch No.	Items Description	Quantity	Unit	Ex-Works per Unit (Rs.)	GST (%)	GST (Rs)	Transport & any other charges (Rs.)	Total unit price (all incl) (Rs.)	Grand Total (Rs.)
1									
2									
								Grand Total	

2. You are requested to deposit Security Deposit @ 3% of the total value by NEFT/ RTGS/ Bank Guarantee/Demand Draft/ Banker's Cheque and enter into an Agreement, as per the format given in **Annexure-X** of the Tender document, within 15 days from the date of receipt of this letter. The Security Deposit shall be valid for 1260 days from the date of commencement.

3. Please convey your acceptance to this LOA within 03 days of issue, else it will be presumed that you are not keen to accept the LOA and CMSS may proceed for allocation of quantity to other bidder and with other actions stipulated in referred Tender document.

4. All other terms and conditions will be applicable as per Tender document no. CMSS/PROC/2023-24/___/____ and subsequent amendments to it.

GM/Procurement

Annexure A to LOA No:
Supplier: M/s _____

Annexure-A

LIST OF MANUFACTURING LICENSES & SITE ADDRESSES					
Sr. No.	**Item Code**	**Item Description**	**Manufacturing Site Address**	**Manufacturing License No.**	**Remarks**
1					
2					
3					

Format 1A: Long Term Agreement (LTA)
(Ref Clause 13.2.5 of ITB)

LONG TERM AGREEMENT (LTA) NO.: CMSS/PROC/2024-25/____/LTA/_____
E- STAMP CERTIFICATE NO.:
LTA Validity: From _____ to _____

TERMS OF AGREEMENT

THIS AGREEMENT made the..... day of ....., year between **Central Medical Services Society, 2nd Floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Marg, Opposite Police Station Chankaya Puri, New Delhi-110021** (here in after "the Purchaser") of the one part and ..... (Name of Supplier) of..... (Address and Country of Supplier) (Here in after called "the Supplier") of the other part:

WHEREAS the Purchaser is desirous that certain Goods and ancillary services viz;
Procurement of _____

in the Tender Reference No. **CMSS/PROC/2024-25/___/____, Dt**_____(Brief Description of Goods and Services) and has accepted a bid by the Supplier for the supply of those goods and services for the sum of..... (Contract Price in Words and Figures) (Hereinafter called "the Contract Price").

WHEREAS the Supplier confirms that it is qualified, ready, willing and able to supply/services the **Procurement of** _____, in accordance with the terms and conditions of this Agreement.

1. DEFINITIONS

Commencement Date means _____

Expiry Date means _____

Products, in singular form Product, means the item(s), as described and detailed above, provided by the Supplier to CMSS from time to time pursuant to this agreement.

Tender means Tender No. Tender No: **CMSS/PROC/2024-25/____/____** from CMSS to the Supplier, to quote for the cost of supply of the Products to CMSS.

Long Term Agreement, as abbreviated to Agreement or LTA, means this Agreement between the Parties, to provide Products, including its Annexure, however with due consideration of the order of precedence among the LTA and individual Annexure.
Parties means CMSS and the Supplier, their successors and assigns and where not repugnant to the context, their servants or agents.

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:

1. **LTA DOCUMENTS:**

The following documents shall be deemed to form and be read and construed as part of this Agreement, viz.:

(a) This LTA
(b) The Notice Inviting Tender
(c) Terms and Conditions of Tender Document as given in Tender No: **CMSS/PROC/2024-25/___/___**, dt. _____
(d) The Minutes of Pre-Bid meeting and corrigendum issued.
(e) Schedule of Requirement.
(f) The Technical Specification
(g) The Supplier's Offer including Enclosures, Annexure etc.
(h) Any other document listed in the supplier's bid and replies to queries, clarifications issued by the purchaser, such confirmations given by the tenderer which are acceptable to the purchaser and the entire Addendum issued as forming part of the contract.
(i) The Letter of Acceptance issued by the purchaser.
(j) Integrity Pact

2. **PURPOSE OF LTA:**

2.1 The Purchaser hereby covenants to pay the Supplier in consideration of the provision of the goods, the Contract Price at the times and in the manner prescribed by this Agreement.

2.2 Brief particulars of the Products or goods which shall be supplied / provided by the Supplier are as under.

Sch No.	Items Description	Quantity	Unit	Ex-Works per Unit (Rs.)	GST (%)	GST (Rs)	Transport & any other charges (Rs.)	Total unit price (all incl) (Rs.)	Grand Total (Rs.)
1									
2									
								Grand Total	

2.3 The supplier agrees that his supplies are subject to terms and conditions details contained in LTA documents mentioned above. The supplier appreciates that the supplies are meant for public health system in the country and hence will agree to supply the goods of good quality as per standards in a timely manner as specified as per tender terms and conditions. The supplier has already given its no deviation (clause-by-

clause compliance) for the subject terms and conditions.

3 . Manufacturing License and Site License and Site Address: As per Annexure A.

IN WITNESS where of the parties here to have caused this Agreement to be executed in accordance with their respective laws the day and year first above written.

Signed, Sealed and Delivered by the said..... (For the Purchaser)
in the presence of .....

Signature
Name
Address

Signed, Sealed and Delivered by the Said ..... (For the Supplier)
in the presence of .....

Signature
Name
Address
Annexure A to LTA No:
Supplier: M/s

Annexure-A

Annexure A to LTA No:
Supplier: M/s

LIST OF MANUFACTURING LICENSES & SITE ADDRESSES					
Sr. No.	**Item Code**	**Item Description**	**Manufacturing Site Address**	**Manufacturing License No.**	**Remarks**
1					
2					
3					

Format 1B: Purchase Order (PO)
(Ref Clause 13.2.5 of ITB)

PURCHASE ORDER

PO No: CMSS/PROC/2024-25/___/____ **Dated: _____**

To,

M/s _____
Address: _____
Attn: _____
Phone: _____
Email _____

Subject: ***Purchase Order for supply of _____***
Ref: Long Term Agreement No: CMSS/PROC/2024-25/___/___ /LTA/..... dated_____

Dear Sir,

Please supply following quantities for the items specified as per the technical specifications and terms & conditions of the Long Term Agreement referred above:

Sr. No.	Item Code	Item Description	Quantity Accepted by the Purchaser	Unit	Ex Works Price per Unit (Rs)	GST (%)	GST (Rs)	Transportation Charges (Rs)	Rate Per Unit (Landed Price)(Rs)	Total Value (Rs)	Destination
1											As per Annex 1
2											As per Annex-1

1. All the Terms & Conditions of the Agreement signed by you on acceptance of your tender are applicable.
2. Delivery Period: As per Annexure A of the tender document
3. Manufacturing license as per Annexure A and site address as per Annexure B.
4. Payment Terms: Within 75 days of supplies in respect of items requiring sterility tests and within 60 days of supplies for other items.

General Manager (Procurement)

Copy to :

1. *General Manager (LSC), CMSS*
2. *General Manager (QA), CMSS*
3. *General Manager (Finance), CMSS*
4. *All Consignees (CMSS Warehouses) concerned.*

Annexure-A

Annexure A to PO No:
Supplier: M/s

CONSIGNEE-LIST						
Sr. No.	**Item Description**	**Consignee Location**	**Consignee Address**	**Quantity**	**UOM**	**Remarks**
1						
2						
3						

Annexure-B

Annexure B to PO No:
Supplier: M/s

LIST OF MANUFACTURING LICENSES & SITE ADDRESSES					
Sr. No.	**Item Code**	**Item Description**	**Manufacturing Site Address**	**Manufacturing License No.**	**Remarks**
1					
2					

3					

Format 1.1: **Bank Guarantee Format for Performance Security**

Instruction to BG Issuing Bank – The Bank Guarantee should be through SFMS (Structured Financial Messaging System) & the following fields should be filled with the details given below.

FMS Field Number	SFMS Field Details	Details to be filled
7034	Name Of Beneficiary And His Details	**CENTRAL MEDICAL SERVICES SOCIETY** 2ND FLOOR, VISHWA YUVAK KENDRA CHANKAYA PURI, NEW DELHI-110021
7035	Beneficiary IFSC	**HDFC0000003**
7036	Beneficiary Branch Name And Address	HDFC Bank Ltd 209-214 KAILASH BUILDING 26 KASTURBA GANDHI MARG NEW DELHI 110001
7037	Sender To Receiver Information	**CENTRALYCX**

This is captured in both IFN760 COV (BG Issuance) / IFN767 COV (BG Amendment, if any).

(Ref Clause 9.4 of ITB and clause 5.8 of GCC)

To
DG & CEO, Central Medical Services Society, Ministry of Health and Family welfare, Government of India, New Delhi
Address: 2nd floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Road, Opposite Police Station Chanakaya Puri,
New Delhi-110021
Telephones: 011-21410905, 21410906
Ref: Your Tender Document No. Tender No./ xxxx; Tender Title: GOODS

Whereas…… (name and address of the contractor) (hereinafter called "the contractor") has undertaken, in pursuance of contract no …….. date……. to supply …… (description of goods and Works/ Services) (hereinafter called "the contract").
And Whereas you have stipulated it in the said contract that the contractor shall furnish you with a bank guarantee by a Commercial bank for the sum specified therein as security for compliance with its obligations as per the contract;

And Whereas we have agreed to give the contractor such a bank guarantee.

Now Therefore we hereby affirm that we are guarantors and responsible to you, on behalf of the contractor, up to a total of ……(amount of the guarantee in words and figures), and we undertake to pay you, upon your first written demand declaring the contractor to be in default under the contract and without cavil or argument, any sum or sums within the limits of (amount of guarantee) as aforesaid, without your needing to prove or to show grounds or reasons for your demand or the sum specified therein.

We hereby waive the necessity of your demanding the sail debt from the contractor before presenting us with demand.

We further agree that no change or addition to or other modification of the terms of the contract to be performed there under or of any of the contract documents which may be made between you and the contractor shall in any way release us from any liability under this guarantee, and we hereby waive notice of any such change, addition, or modification.

This guarantee shall be valid until the …….day of …….20……

Our…….branch at……*(Name & Address of the ……..……..*(branch) is liable to pay the guaranteed amount depending on the filing of a claim and any part thereof under this Bank Guarantee only and only if you serve upon us at our ……* branch a written claim or demand and received by us at our ……..* branch on or before Dt…….. otherwise, the bank shall be discharged of all liabilities under this guarantee after that.

(Signature of the authorized officer of the Bank)

…….

…….

Name and designation of the officer

……

Seal, name & address of the Bank and address of Branch

*Preferably at the headquarters of the authority competent to sanction the expenditure for the procurement of goods or at the concerned district headquarters or the state headquarters.

Format 1.2: No Claim Certificate
(Refer Clause 12.3.1 of GCC)
(On company Letter-head)
Contractor's Name_____
[Address and Contact Details]
Contractor's Reference No._____ Date…….
To

DG & CEO, Central Medical Services Society,
Ministry of Health and Family Welfare,
Government of India, New Delhi
Address: 2nd floor, Vishwa Yuvak Kendra,
Pt. Uma Shankar Dikshit Marg, Teen Murti Road, Opposite Police Station Chanakaya Puri,
New Delhi-110021
Telephones: 011-21410905, 21410906

No Claim Certificate

Sub: Contract Agreement no. ---------- dated ----------for the supply of ----------

We have received the sum of Rs. (Rupees _____only) as final settlement due to us for the supply of_____
under the abovementioned contract agreement.

We have received all the amounts payable to us with this payment and have no outstanding dispute of any description whatsoever regarding the amounts worked out as payable to us and received by us.

We hereby unconditionally and without any reservation whatsoever, certify that we shall have no further claim whatsoever, of any description, on any account, against the Procuring Entity, under contract above. We shall continue to be bound by the terms and conditions of the contract agreement regarding its performance.

Yours faithfully,

Signatures of contractor or
officer authorised to sign the contract documents.
on behalf of the contractor

(company Seal)

Date:_____
Place:_____

Format 1.3: Certification by Prospective Arbitrators
(Ref Clause 11.5.4 of GCC)
To
DG & CEO, Central Medical Services Society,
Ministry of Health and Family welfare, Government of India, New Delhi
Address: 2nd floor, Vishwa Yuvak Kendra,
Pt. Uma Shankar Dikshit Marg, Teen Murti Road,
Opposite Police Station Chanakaya Puri,
New Delhi-110021
Telephones: 011-21410905, 21410906

Certification by Prospective Arbitrators

1. Name: _____
2. Contact Details: _____
3. I hereby certify that I am retired officer of *[Name of Organisation]* retired as_____in_____grade.
4. I have no past or present relationship concerning the subject matter in dispute, whether financial, business, and professional or another kind.

Or

I have past or present relationships concerning the subject matter in dispute, whether financial, business, professional or another kind. The list of such interests is as under:------

5. I have no past or present relationship/ interest financial, business, professional or other, in any of the parties, which may raise justifiable doubts about my independence or impartiality in terms of the Arbitration and Conciliation Act 1996 amended from time to time.

Or

I have past or present relationship/ interest financial, business, professional or other, in any of the parties, which may raise justifiable doubts about my independence or impartiality in terms of the Arbitration and Conciliation Act 1996 as amended from to time. The details of such relationship or interest are as under:----------

6. There are no concurrent circumstances that are likely to affect my ability to devote sufficient time to the arbitration and finish the entire arbitration within twelve months.

Or

Some circumstances are likely to affect my ability to devote sufficient time to the arbitration and finish the entire arbitration within twelve months. The list of such circumstances is as under:----------

Signature)
(Name & Designation)

Format 2: Authorization for Attending Pre-bid Conference

(Refer ITB-Clause 8)

(on Company Official Letter Head)

Bidder's Name_____

[Address and Contact Details]

Bidder's Reference No._____ Date…….

To

DG & CEO, Central Medical Services Society, Ministry of Health and Family welfare, Government of India, New Delhi

Address: 2nd floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Road, Opposite Police Station Chanakaya Puri,

New Delhi-110021

Telephones: 011-21410905, 21410906

Ref: Your Tender Document No. Tender No./ xxxx; Tender Title: GOODS

Subject: Authorization for attending Pre-bid Conference on _____ (date).

Following persons are hereby authorized to attend the Pre-bid Conference for the tender mentioned above on behalf of _____ (Bidder) in order of preference given below.

Sr.	Name	Government Photo ID Type/ Number
I.		
II.		
Alternate Representative		

Note:

1. Maximum of two representatives (carrying valid Government photo IDs) shall be permitted to attend the Pre-bid opening. An alternate representative shall be permitted when regular representatives are not able to attend.

2. Permission to enter the hall where the pre-bid conference is conducted may be refused if authorization as prescribed above is not submitted.

Signatures of bidder

or

Officer authorized to sign the bid.

Documents on behalf of the bidder

[name & address of Bidder and seal of company]

Format 3: CONSIGNEE RECEIPT CERTIFICATE

(To be given by consignee's authorized representative)

The following store(s) has/have been received in good condition:

1) P.O No. & date:_____
2) Supplier's Name:_____
3) Consignee's Name & Address with telephone No. & Fax No. : _____

   _____

   _____
4) Name of the items/equipment supplied:_____
5) Quantity of items/equipment Supplied:_____
6) Date of Receipt of items/equipment by the Consignee:_____
7) Stock Book page no. where the items have been entered: _____
8) Name and designation of Authorized Representative of Consignee :_____
9) Signature of Authorized Representative of Consignee with date:_____
10) Counter Signed by Director/MS/Dean of the concerned Hospital/Institute:_____

11) Seal of the Consignee:_____