ONLINE TENDER
FOR RATE CONTRACT FOR A PERIOD OF ONE YEAR FOR PROCUREMENT OF ANTI TB DRUGS FOR NTEP.

Tender No: CMSS/PROC/2023-24/NTEP/003
(National Competitive Bidding)
(FOR CLASS-1 and CLASS-II LOCAL SUPPLIERS ONLY)

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: cmss.gov.in, email- dgceocmss@cmss.gov.in, gmproc1@cmss.gov.in, agmproc3@gmail.com

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NOTICE INVITING E-TENDER
(E-PROCUREMENT)
Tender No- CMSS/PROC/2023-23/NTEP/003 Dated 03/05/2023

1. The Central Medical Services Society, an autonomous body under Ministry of Health and Family welfare, Government of India, for and on behalf of National Tuberculosis Elimination Programme of MoHFW, invites online tenders in prescribed format on Central Public Procurement Portal (CPPP), from eligible and qualified tenderers for establishing Rate contract and supply of following goods for National Tuberculosis Control Program to consignees spread across the country, as and when required by them during the validity of Rate Contract:

Schedule No.	Name of Item	Estimated Quantity likely to be procured against the Rate Contract	Unit of Measurement	Validity of Rate Contract	EMD in Rs.
I	Capsule Cycloserine 250mg	1,56,00,400	Capsules	One Year	43,00,000
II	Tablet Isoniazid 300mg	61,51,700	Tablets	One Year	2,00,000
III	Tablet Levofloxacin 250mg	65,89,200	Tablets	One Year	1,50,000
IV	Tablet Levofloxacin 500mg	67,93,900	Tablets	One Year	2,50,000
V	Tablet Linezolid 600mg	52,99,200	Tablets	One Year	6,00,000
VI	Tablet Pyrazinamide 500mg	1,01,94,700	Tablets	One Year	2,00,000
VII	Tablet Pyrazinamide 750mg	64,94,800	Tablets	One Year	2,00,000

Note: 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.

2. Tender timelines are as under:

Sr. No.	Description	Scheduled date
(a)	Availability of tender documents on CPPP for download	03/05/2023

(b)	Last date and time for receipt of pre-bid queries, if any	10/05/2023 at 5:00PM
(c)	Pre-bid meeting date, time and venue	10/05/2023 at 11:00AM Venue- Conference Hall, CMSS HQ New Delhi
(d)	Last date and time for bid submission	25/05/2023 at 4:00PM
(e)	Last date and time for submission of original documents	26/05/2023 at 3:00PM
(f)	Date and time for tender opening (technical bid)	26/05/2023 at 4:00PM

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'.

03/05/2023 **DG&CEO**

Section I: Instructions to Bidders (ITB)

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Notice Inviting Tender (NIT)

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.
2. 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 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. **2.** 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 fulfil 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 Organisation 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 -** 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 bidders** 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. **3.6 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. Aforesaid debarred bidders are not eligible to bid. **3.8 Qualification Criteria** – Only the bidders, who meet the qualification criteria as detailed in Section III of the bid document shall be considered for award of contract.

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 16.09.2020, 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, 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 16.09.2020. 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 III. 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 III. **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 as under: a) Items reserved for procurement from Class-I local suppliers under PPP-MII Order, 2017. For these, only Class-I local suppliers are eligible to bid irrespective of purchase value. Hence, Class-II local suppliers or Non-local suppliers, including MSEs falling in the category of Class-II local suppliers/ Non-local suppliers, are not eligible to bid. Possible scenarios can be as under: (i) L-1 is "MSE Class-I local supplier" - 100% of the tendered quantity is to be awarded to L-1. (ii) L-1 is "Non-MSE but Class-I local supplier" - Purchase preference is given to MSEs as per PPP-MSE Order. *Balance quantity,* may be awarded to the L-1 bidder. b) Items reserved exclusively for procurement from MSEs as per PPP MSE Order - These items are reserved exclusively for purchase from MSEs. Hence, non-MSEs are not eligible to bid for these items. Possible scenarios can be as under: (i) L-1 is "MSE Class-I local supplier" - 100% of the tendered quantity is to be awarded to L-1. (ii) L-1 is "MSE non-Class–I local supplier" - Purchase preference is to be given to Class-I local supplier as per PPP-MII Order. Balance quantity, may be awarded to L-1 bidder. c) Items not exclusively reserved for MSEs/ Class-local suppliers. Possible scenarios can be as under:

(i) L-1 is "MSE Class-I local supplier" - 100% of the tendered quantity is to be awarded to L-1.

(ii) L1 is "Non-MSE but Class-I local supplier" - Purchase preference is to be given to MSEs, if eligible, as per PPP-MSE Order. *Balance quantity* is to be awarded to L-1 bidder.

(iii) L-1 is "MSE but non-Class-I local supplier" – Purchase preference is to be given to Class-I local suppliers, if eligible, as per PPP-MII Order. *Balance quantity* is to be awarded to L-1 bidder.

(iv) L-1 is "Non-MSE non-Class-I local supplier" – Purchase preference is to be given to MSEs as per PPP-MSE Order. Thereafter, purchase preference is to be given to Class-I local suppliers for "50% of the tendered quantity minus quantity allotted to MSEs above" as per PPP-MII Order. For the *balance quantity*, contract is to be awarded to L-1bidder.

2. The terminology used in above paragraphs is defined as under:

Terminology	**Defined as**
"MSE Class-I local supplier"	Supplier is both MSE & Class-I local supplier.
"MSE but non-Class-I local supplier"	Supplier is MSE but not Class-I local supplier.
"Non-MSE but Class-I local supplier"	Supplier is not MSE but is Class-I local supplier.
"Non-MSE non-Class-I local supplier"	Supplier is neither MSE nor Class-I local.

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** if there is more than one schedule in Section IV: 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. However, Bidder shall submit bid for 100% 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 IV: 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 Procuring Entity's state-wise GSTINs are indicated in Section II BDS. **6.3.2 HSN Code and GST Rate:** **1.** 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. **2.** 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. **3.** 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. **4.** 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.

	5. 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. 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. 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.

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:** **9.2.1Techno-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': Following documentary evidence to establish the Bidder's qualifications as stipulated in Section III: 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 -III: "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 IV: '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. Bidder shall upload following documents with the compliance statement, along with any other supporting documents explicitly stipulated in bid documents: a. Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life. b. Any other document as stipulated in the Section V: "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- Checklist for the Bidders. Bidder must also upload the Checklist given in the Tender Document as Form 6 to confirm that he has complied with all the instructions in the Tender Document, and nothing is inadvertently left out. This checklist is only for general guidance and is not 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. : 32719062216**

	Bank Name: SBI Bank **Branch: Nirman Bhawan, Maulana Azad Road, New Delhi IFSC Code: SBIN0000583** 4. EMD Bank Guarantee format is given in **Section – VIII/ 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 / for a shorter period/lesser 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 lowest responsive bidder/s within 30 days from the date of signing the contract agreement and on the deposit of Security Deposit. 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/ upload a 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. 3. 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 4. 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. 2. 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 eProcurement Portal** The Procuring Entity is neither a party nor a principal in the relationship between Bidder and the organisation 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 5 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. **2.** 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, applicable, in addition to other punitive actions provided in the Tender Document for such misdemeanour.

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. **3.** The decision of the Procuring Entity shall be final in this regard. Bids with substantive deviations shall be rejected as nonresponsive. **4.** 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. **5.** 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 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 IV: 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 IV- 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 a date/time and venue for the opening of their financial bids shall be declared on the Portal and individually to all participant bidders 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. Unless the Procuring Entity decides this to be a case of Cartel/ Pool Rates, if more than one bidder quote the same total evaluated price, then the Procuring Entity reserves its

	right to distribute unequal quantities among the bidders - excluding one or more bidders, based on considerations like performance/ financial capabilities, the distance of destination godowns from the location of the factories, production capacities, any extra features/ benefits offered etc. **2.** 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** 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 IV: 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** Unless otherwise stipulated in BDS, there shall be no parallel orders or splitting quantities among more than one Bidders. **13.1.3 Additional Conditions for Rate Contracts** If stipulated expressly in the BDS that this is a Tender Process to enter into "Rate Contract(s)" for the supply of Goods, then the following additional conditions shall be applicable: **1**. The conditions governing the resultant Rate Contract would be as per G.C.C-clause 6.8. **2.** Unless otherwise specified, the currency of a Rate Contract would be for one year. **3. Parallel Rate Contracts:** The number of parallel Rate Contracts proposed to be concluded against these documents are detailed in **Bid Data Sheet**. If Bid Data Sheet stipulates award of more than one rate contract for the same Schedule/ Goods, the procedure for negotiation and counter-offering for concluding parallel rate contracts would be as follows. a. Initially, the rate contract would be awarded to the L-1 Bidder. Then the price of L-1 shall be counter-offered to the higher quoting responsive Bidders (under intimation to L-1), asking them to send their revised Bids online on the e-procurement portal to be opened at a specified place, date, and time (as per the standard procedure). L-1 Bidder would be specifically informed that it may, if it so desires, reduce its price and send its revised Bid accordingly. The Bidders, who accept the counter-offered rate or rate lower than that, would be awarded parallel rate contracts. If L-1 Bidder lowers its rate in its revised offer, the same would also be accepted with effect from that date, and its rate contract amended accordingly. b. In the case where parallel rate contracts are necessary, but even the lowest responsive Bidder (L-1) price is not reasonable. In that case, price negotiation may be

	conducted with L-1 Bidder in the first instance. If the L1 Bidder agrees to bring down the price to the desired level, a rate contract would be concluded with it, and parallel rate contracts would be concluded as per the sub-clause above. If, however, L1 Bidder does not agree to reduce its price in the first instance itself, then the price, which has been decided as reasonable, would be counter-offered to all the higher quoting responsive Bidders (including L-1) for further action on the above lines. c. All such parallel rate contracts would be released transparently and simultaneously. **4.** The quantities mentioned in the tender and Section-IV (Schedule of Requirements) are indicative without any commitment on a rate-contract basis, as detailed in G.C.C-clause 6.8. **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 online 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. The Procuring Entity, at its discretion, may directly issue the contract subject only to the furnishing of performance security, skipping the issue of LoA. **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- Deleted** **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.

Section II: 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, for and on behalf of National Tuberculosis Elimination Programme of MoHFW.</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 3.5</td><td>In accordance with DPIIT Public Procurement (Preference to Make in India) Order, 2017 dated 16.09.2020 read with DOP Circular F.No.31026/65/2020-MD dated 30.12.2020 as amended till date, only Class-I & 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. 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</td><td>Bidders have the option to submit its bid for any one or more schedules. However, Bidder shall mandatorily quote for 100% of the scheduled quantity. Bids for part quantity shall be summarily ignored.</td></tr>
<tr><td>ITB 6.3.1.5</td><td>The principal place of business for CMSS is Delhi. CMSS has GSTN registration no in 18 states including Delhi,

The list is given below

<table>
<tr><th>S no.</th><th>LOCATION</th><th>STATE</th><th>GSTIN</th><th>Address</th></tr>
<tr><td>1</td><td>AGARTALA</td><td>TRIPURA</td><td>16AABAC6275F1ZV</td><td>CMSS, CWC Complex, Hapania, Near ONGC complex, Opposite of Satsangha</td></tr>
</table>
</td></tr>
</table>

						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**

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

ITB 7.3	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. gmproc1@cmss.gov.in ; agmproc3@cmss.gov.in and dgceocmss@cmss.gov.in
ITB 8	Tender timelines are as under:

Sr. No.	Description	Scheduled date
(a)	Availability of tender documents on CPPP for download	03.05.2023
(b)	Last date and time for receipt of pre-bid queries, if any	10.05.2023 at 5:00PM The pre-bid queries should be addressed to Tender Inviting Authority at email

			Id agmproc3@cmss.gov.in with copy to gmproc1@cmss.gov.in and dgceocmss@cmss.gov.in
	(c)	Pre-bid meeting date, time and venue	10.05.2023 at 11.00 AM at CMSS, Conference Hall, New Delhi
	(d)	Last date and time for online bid submission	25.05.2023 at 4:00PM
	(e)	Last date and time for submission of Original Bid Securing Declaration/ EMD	26.05.2023 at 3:00PM
	(f)	Date and time for tender opening (technical bid)	26.05.2023 at 4:00PM

ITB 9.4

Schedule wise EMD shall be as under:

Sr. No.	Schedule No.	EMD Amount in INR
(a)	Schedule I	43,00,000
(b)	Schedule II	2,00,000
(c)	Schedule III	1,50,000
(d)	Schedule IV	2,50,000
(e)	Schedule V	6,00,000
(f)	Schedule VI	2,00,000
(g)	Schedule VII	2,00,000

ITB 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/2023-24/NTEP/003 Dated 03/05/2023 Scheduled to be opened on 26/05/2023 at 4:00 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 13.1.2

There shall be no parallel contracts or splitting of quantity amongst qualified bidders.

The contract shall be awarded to only lowest qualified bidder.

ITB 13.1.3

There shall be no parallel rate contracts amongst qualified bidders.

The rate contract shall be awarded to only lowest qualified bidder.

SECTION-III -QUALIFICATION CRITERIA

a) Tenderer must be a manufacturer of quoted product.

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 drug is in Indian Pharmacopoeia (IP), then the manufacturing license has to be submitted in IP only.

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 Market standing certificate issued by the Licensing Authority, as a Manufacturer of the item quoted, for at least last two financial years i.e. 2020-21 and 2021-22 OR 2021-22 and 2022-23. However, this would not apply to products which have been licensed by DCG (I) less than two years ago.

Note:

1. Unless otherwise stipulated in the Market standing certificate, the said certificate issued on a particular date shall be treated valid certificate for the financial year in which it has been issued. For example, Market Standing Certificate issued on 15.07.2022 for the period 15.07.2022 to 14.07.2023 shall be treated as Market Standing Certificate for the FY 22-23.
2. Market standing certificate should be for the same manufacturing premises from which quoted goods have been offered for supply.
3. Only for the drugs introduced in Indian Pharmacopoeia in the recent past, Market standing certificate for previously approved Pharmacopoeia or In-house Standards shall be accepted, as the case may be.

f) Tenderer must submit Non-Conviction Certificate issued by the Licensing Authority certifying that the tenderer (as well as the manufacturer firm in case of non-manufacturer bidders) has not been convicted i.e. 2020-21 and 2021-22 OR 2021-22 and 2022-23.

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 for the period 15.07.2022 to 14.07.2023 shall be treated as Non-Conviction Certificate for the FY 22-23.
2. Non-Conviction Certificate should be for the same manufacturing premises from which quoted goods have been offered for supply.

g) The tenderer must have supplied at least 20 % of the same or similar item of tentative qty. (Sch. Wise) during the last three financial years. In support of above, the tenderer shall submit details of past purchase orders executed by them in the proforma annexed at Annexure- Section VIII Form 4.2. The details shall be duly certified by the practicing Chartered Accountant. The certifying Chartered Accountant must indicate the details along with its UDIN. The copies of purchase orders and e-way bills (maximum 05 for each Purchase Order – the ones pertaining to for large consignments) shall be submitted.

Note: Similar item means Any Anti TB Drugs

h) The tenderer must have annual production capacity at least 1.5 times the tendered quantity. Annual capacity certificate, issued by the licensing authority, must be submitted along with the bid.

i) The tenderer must have average annual turnover of last three FY i.e. 2019-20, 2020-21 and 2021-22 OR 2020-21, 2021-22 and 2022-23 more than the followings:

Schedule No	Amount (in Rs.)
I	8,00,00,000
II	40,00,000
III	30,00,000
IV	60,00,000
V	1,20,00,000
VI	40,00,000
VII	40,00,000

Annual turnover statement for 3 years i.e. 2019-20, 2020-21 and 2021-22 OR 2020-21, 2021-22 and 2022-23 should be furnished in the format given in Section VIII Form 4.3 duly certified by the practicing Chartered Accountant. The certifying Chartered Accountant must indicate the details along with its UDIN.

j) 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. 2019-20, 2020-21 and 2021-22 OR 2020-21, 2021-22 and 2022-23 duly certified by a practicing Chartered Accountant, where ever applicable.

Section IV
Schedule of Requirement

Ref: Tender Document No. CMSS/PROC/2023-24/NTEP/003 Dated 03/05/2023

Tender Title: RATE CONTRACT FOR A PERIOD OF ONE YEAR FOR PROCUREMENT OF ANTI TB DRUGS FOR NTEP.

A. List of Products

Sch. No.	Item Description	Unit	Tentative Quantity likely to be procured during RC period	Inspection Methodology (PDI/Non-PDI)	Delivery Place	Terms of Delivery
I	Capsule Cycloserine 250mg	No. of Capsules	1,56,00,400	Non-PDI Items	All over India-Consignees spread across the country including the CMSS warehouses	DDP (Destination basis).
II	Tablet Isoniazid 300mg	No. of Tablets	61,51,700	Non-PDI Items	All over India-Consignees spread across the country including the CMSS warehouses	DDP (Destination basis).
III	Tablet Levofloxacin 250mg	No. of Tablets	65,89,200	Non-PDI Items	All over India-Consignees spread across the country including the CMSS warehouses	DDP (Destination basis).
IV	Tablet Levofloxacin	No. of	67,93,900	Non-PDI Items	All over India-Consignees	DDP (Destination basis).

Sch. No.	Item Description	Unit	Tentative Quantity likely to be procured during RC period	Inspection Methodology (PDI/Non-PDI)	Delivery Place	Terms of Delivery
	500mg	Tablets			spread across the country including the CMSS warehouses	
V	Tablet Linezolid 600mg	No. of Tablets	52,99,200	Non-PDI Items	All over India-Consignees spread across the country including the CMSS warehouses	DDP (Destination basis).
VI	Tablet Pyrazinamide 500mg	No. of Tablets	1,01,94,700	Non-PDI Items	All over India-Consignees spread across the country including the CMSS warehouses	DDP (Destination basis).
VII	Tablet Pyrazinamide 750mg	No. of Tablets	64,94,800	Non-PDI Items	All over India-Consignees spread across the country including the CMSS warehouses	DDP (Destination basis).

B. Delivery Schedule:-

1. Ist Tranche of supplies against the Rate contract of qty. of 54,60,140 Capsules (For Sch. I), 21,53,095 Tablets (For Sch. II), 23,06,220 Tablets (For Sch. III), 23,77,865 Tablets (For Sch. IV), 18,54,720 Tablets (For Sch. V), 35,68,145 Tablets (For Sch. VI) & 22,73,180 Tablets (For Sch. VII) is likely to be placed immediately after issuance of Rate Contract with a delivery schedule of 60 days.
2. For next tranche of the Purchase order also, the bidder should confirm the delivery qty. 54,60,140

Capsules (For Sch. I), 21,53,095 Tablets (For Sch. II), 23,06,220 Tablets (For Sch. III), 23,77,865 Tablets (For Sch. IV), 18,54,720 Tablets (For Sch. V), 35,68,145 Tablets (For Sch. VI) & 22,73,180 Tablets (For Sch. VII) within 60 days of receipt of purchase order.

3. TIA reserves the right to issue the purchase order as per the actual requirement of programme division within contract period.

C. Delivery Locations:

The details of CMSS warehouses are given below:-

CMSS Warehouse & Mapped States			
Sr No	**Warehouse Location**	**States/UT's covered by the Warehouse**	**Address**
1	Agartala	Tripura	Near ONGC Complex, PO-Hapania , Agartala-799014
2	Ahmadabad	Gujarat	Opp. P&T Colony, Shahalam, Ahmedabad-380028
3	Bangalore	Karnataka	APMC Yard, Yeswanthpur, Bangalore - 560022
4	Bhopal	Madhya Pradesh	Chhola Road, Near Nishatpura Cabin, Bhopal, M.P.
5	Chandigarh	Chandigarh Punjab Haryana Himanchal Pradesh Jammu & Kashmir, Leh Ladakh Uttarakhand	Central Medical Services Society Godown no. B014/3433, Near Vivekanand School,Godown area, Village Bhabat, Thana-Zirakpur, Dist: SAS Nagar-140603(Punjab)
6	Chennai	Tamil Nadu Pondicherry Andaman & Nicobar Islands	Chitalapakkam(P.O), Chennai - 600064, T.N.
7	Jajpur	Odisha	Dhawalgiri, Post-Jajpur Road, Dist-Jajpur, Odisha
8	Delhi	Delhi	Ware Housing Scheme Block No 2.,Kirti Nagar, New Delhi-110015.
9	Guwahati	Assam Arunachal Pradesh Meghalaya Nagaland Sikkim Manipur Mizoram	EPIP Complex, Amingaon, Guwahati-781031
10	Hyderabad	Telangana Andhra Pradesh	Behind Gandhibhavan, Nampally, Hyderabad-500001
11	Jaipur	Rajasthan	Plot no SPL-1296, EPIP Sitapura, Ind Area, Jaipur-302002
12	Kolkata	West Bengal	Rehabilitation Industries Corporation Estate, Bonhooghly, Kolkatta - 700 108

CMSS Warehouse & Mapped States			
Sr No	**Warehouse Location**	**States/UT's covered by the Warehouse**	**Address**
13	Lucknow	Uttar Pradesh	New Mandi Complex, Sitapur Road Lucknow-226020
14	Navi Mumbai	Maharastra	Sector-20 Near APMC Fruit Market , VashiNavi Mumbai-400613
		Goa	
		Dadra and Nagar Haveli	
		Daman and Diu	
15	Patna	Bihar	Bazar Sammittee , Katra Bazar, Patna city-800008
16	Raipur	Chattisgarh	Rawabhata , Raipur -493221
17	Ranchi	Jharkhand	Po-Hehal , Ratu Road , Dist-Ranchi-834005
18	Trivandrum	Kerala	Kinfra Apparel Park, Thumba, Palliphura(PO), Trivandrum-695586
		Lakshadweep	

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

Section V

Technical Specifications and Quality Assurance

Product Code 24 (Cap Cycloserine-250mg)

A. Specific requirements

Item:

Product Code 24 (PC 24) consists of Cycloserine (250 mg.) capsule. The drug contained in the product shall have valid registration in the country of manufacture and shall meet all requirements of the licensing authority of the country of manufacture. The drug contained in the product shall also have valid registration in India and shall meet all the requirements of the licensing authority in India.

Description:

Cycloserine Capsules contained in blisters of the strip shall conform to the general requirements of Capsules and the requirements under individual monograph given in IP or other Pharmacopoeia of equivalent accuracy in case of international transactions.

Cycloserine Capsules contain Cycloserine.
Each capsule shall contain - Cycloserine 250 mg, Pharmacopeia* (IP/ BP/USP/Other International pharmacopeia)

The quality of Cycloserine should conform to the requirements of the individual monograph given in IP or other Pharmacopoeia of equivalent accuracy in case of international transactions.

Protocols and Testing:

<u>For manufacturers outside India</u>:

Complete test protocols along with the samples of all the batches should be sent to the Head of a Testing laboratory identified and specified by the purchaser.

<u>For Indian manufacturers:</u>

Complete Test Protocol and samples are taken and sent to the laboratory (identified by the purchaser) by the Inspecting Officer duly sealed and signed by him or his authorized representative.
Protocols of tests should include the requirements given for Capsules and those included under individual monograph given in IP, besides the following tests.

**Only one of the selected pharmacopeia to be indicated*

Package Integrity Test:

Check 10 strips. Bundle up the strips and submerge them under water in a vacuum desiccator or equivalent device. Draw a vacuum of about 18k Pa and hold for a minute. Examine for the air leakage indicated by a fine stream of bubbles. Reestablish normal pressure and open strips to examine for water penetration.

Microbial Count:

When the test is conducted as per IP
-Total viable aerobic count- Not more than 10^3 bacteria and not more than 10^2 fungi per gram
-Absence of Escherichia coli.

The drug should be dispatched to the consignee only on clearance from the Testing Laboratory. The drug shall be released on the basis of Protocol scrutiny by the authorized representative of the Purchaser and testing of the drugs by authorized laboratory.
Each batch should be accompanied with a certificate from the manufacturer that the drugs meet the specified requirements.

B. Labelling:

General requirements of the labels:

- Shall meet WHO GMP standards.
- All the labels should be peel proof.
- **"NTEP- Central Government Supply- NOT FOR SALE"** to be imprinted on the labels of strips, Millboard/Greyboard Boxes & 5 Ply Shippers.
- **"Schedule H1 Drug"** to be imprinted on label of strips, Millboard/Greyboard Boxes & 5 Ply Shippers.

Labelling on Strip of Blisters:

The label shall indicate the content of Cycloserine IP in each capsule.
All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact.
The label shall incorporate manufacturing license no., batch no., date of mfg., date of expiry of the individual drug and storage requirements.

The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

Labelling on Millboard/Greyboard Box:

The label shall indicate the content of Cycloserine IP in each capsule.
The label shall incorporate manufacturing license no., batch no. date of mfg., date of expiry, of the drug and storage requirements along with the number of the strips. The label shall include bar Code and be tear proof, to be pasted on smooth surface to enable it to be read by Bar Code reader / Hand held device (Tablet computer / Smartphone).

The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

MILLBOARD/GREYBOARD BOX

National Tuberculosis Elimination Programme (NTEP)

MDR-TB TREATMENT DRUG CONTAINS PRODUCT CODE 24
CYCLOSERINE CAPSULES 250 mg (10 x 10 Caps)

Each Blister Strip Contains 10 Capsules of Cycloserine(250 mg)

Batch No:

Mfg. Date:

Exp. Date:

SCHEDULE H1 PRESCRIPTION DRUG – CAUTION
It is dangerous to take this preparation except in accordance with the medical advice.
Not to be sold by retail without the prescription of a Registered Medical Practitioner.

"NTEP – Central Government Supply – Not for Sale"

Manufacturer's Name

Manufacturing Lic. No.

Labelling on 5-Ply Shipper:

The labels on shipper package must be attached to at least two sides. The label should include the name of the product, the number of Millboard/Greyboard Boxes, the number of strips, the name of the manufacturer, batch number, Mfg. date & Expiry date of the drug. The label shall also include storage handling instructions. The label shall include Bar Code and be tear proof, to be pasted on smooth surface to enable it to be read by Bar Code reader / Hand held device (Tablet computer / Smartphone).

The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

5 – PLY SHIPPER

National Tuberculosis Elimination Programme (NTEP)

MDR-TB TREATMENT DRUG CONTAINS PRODUCT CODE 24

CYCLOSERINE CAPSULES 250 mg

20 Millboard/Greyboard Boxes

Batch No. :

Mfg. Date:

Exp. Date:

SCHEDULE H1 PRESCRIPTION DRUG – CAUTION
It is dangerous to take this preparation except in accordance with the medical advice.
Not to be sold by retail without the prescription of a Registered Medical Practitioner.

"NTEP - Central Government Supply – Not for Sale"

Manufacturer's Name

Manufacturing Lic. No.

Numbering of shipper packaging:

All 5 Ply Shippers should be numbered consecutively. Shipping documents should be included in the shipper numbered first (consignee wise).

C. 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 the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller; (d) meet the requirements of manufacturing legislation and regulation of pharmaceuticals in the country of origin; (e) are free from defects in workmanship and in materials and (f) the product has been manufactured as per WHO GMP requirements.

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 records with regards to process validation demonstrating batch to batch consistency.
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 provide evidence of basis for expiration dating and stability data concerning the commercial final package upon request.
The test data for raw materials, in-process, finished product and packaging material testing must be on record for each lot shipped and must be made available to Purchaser's representatives when requested.
Details of samples lifted for testing (such as quantity of strips, Millboard/Greyboard boxes, batch no. etc.) should be pasted on packing of 5 Ply Shipper and records to this effect be also made available to the purchaser.

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.
The successful Bidder will also be required to provide the Purchaser with access to its manufacturing facilities to inspect its facilities, quality control procedures for raw materials, test methods, in-process tests, and finished dosage forms.

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 the product.

D. Storage:

As per applicable Pharmacopoeia.

E. Shelf Life:

Shelf life should be minimum 24 months from the date of manufacture.

At least 5/6th of the total stipulated shelf life must remain at the time of arrival at the consignee's warehouse. The supplier will provide manufacturer's stability test data substantiating the claimed shelf life in the proposed package. Not only the pharmaceuticals, but also the packaging components should also conform to specifications suitable for use in a climate prevailing in India. The product supplied should have been subjected to long term stability conditions as per below requirements:

Study	Storage condition
Long Term Stability	25 °C ± 2 °C/60% RH ± 5% RH or 30 °C ± 2 °C/65% RH ± 5% RH

F. Qualification of the Manufacturer:

The Bidder shall furnish a certificate from the competent Regulatory Authority that the manufacturer of the pharmaceutical product is licensed to manufacture these products. The manufacturing facility must conform to WHO-GMP standards.

G. Recalls:

If products must be recalled because of problems with product quality or adverse reactions to the drug, the Supplier will be obliged to notify the purchaser providing full details about the reason leading to the recall and shall take steps to replace the product in question at its own cost with a fresh batch of acceptable quality, or withdraw and give a full refund if the product has been taken off the market due to safety problems.

H. Colour Coding:

The labels on Blisters, Millboard/Greyboard Boxes and 5 Ply Shipper package shall be identified by white background.

I. Bar Coding

Bar coding shall be used for better inventory management. It shall be printed on the labels of Millboard / Greyboard Boxes and 5 Ply Shippers containing all requisite information as per the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, New Delhi orders pertaining to Bar Code labeling in drugs, vide letter dated 14 January 2019 or as modified from time to time by the competent / regulatory authority.

The important information which shall be incorporated in bar code is:

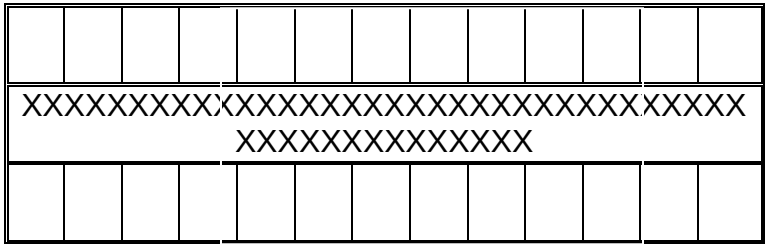
1) Product Name/content
2) Product Strength
3) Batch Number
4) Date of Manufacturing
5) Date of Expiry
6) Manufacturer Address
7) Manufacturer License number
8) Storage conditions requirement
9) Number of Capsules in a Blister Strip/ Millboard/Greyboard Boxes and 5 Ply Shipper

J. Packaging

The drug is initially packed in a Strip containing 10 capsules. 10 such strips would be further packed in white coloured Millboard/Grey board boxes and 20 such Boxes are ultimately packed in 5-Ply Shipper.
Individual capsules duly identified should be packed in an Aluminium / Aluminium strip. The strip should be tropicalized with regard to moisture barrier properties for drug stability under field conditions. Quality Assurance is according to Norm ISO 9001 for all the packaging material.

Aluminum foil: Hard tempered foil, VMCH coated, Thickness: 0.025mm.
Spacing between capsules should be enough so as to allow removal by patients with finger deformities.

Complex Constructions with PVC Films



TECHNICAL DATA FOR THE STANDARD COMPLEXES

Complex:

Rigid PVC film gauge (microns)	200
PE coating (microns)	25
PVdC coating (gsm)	60
Total weight (gsm)	356
Complex gauge (mm)	0.280

Water Vapour Transmission Rate (W V T R):

Temperature	**Relative Humidity**	**gsm/24h**	**Vapour Transmission rate**	
			Thermoformed	**Not thermoformed**
(^{0}C)	**% RH**			
20	85	gsm/24 h	0.15	0.06
38	90	gsm/24 h	0.7	0.4

Shrinkage longitudinally

T = 140^{o}C, t = 20 min. (%)	5 – 6
Application temperature (^{0}C)	68 – 74

Millboard/ Grey board Box:

Each box shall contain 10 strips. The boxes shall be labelled and fabricated from at least 3 mm corrugated cardboard surrounded on inside and outside by tightly affixed millboard of at least 400 gsm. The style of top and bottom shall be tuck-in-flap.

5-Ply Shipper Package:

Each 5 Ply Shipper shall contain 20 millboard/greyboard boxes. The boxes shall be packed in weather resistant, triple walled, insulated, corrugated, RSC (Universal) type 5-ply Shippers, each ply having strength of minimum 150gsm. It should be fabricated from virgin quality 'A' grade kraft paper. The overall dimension of the carton should be such that the product does not get damaged during transportation and storage.

Each shipping carton when packed should weigh not more than 50 kg.

K. Markings

All containers and invoices must bear the name of the product, expiry dates of and appropriate storage conditions.

Millboard/Greyboard Box:

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

- Manufacturer's name and registered address
- Manufacturer's License number
- Batch number of the drug
- Number of capsules/strips contained in the box
- Date of manufacture (month and year) of the drug
- Expiration date (month and year) of the drug
- Instructions for storage and handling
- Logo of DOTS
- Place of manufacture (Made in_____)

5 – Ply Shipper:

The following information shall be stenciled or labeled on 5 – Ply Shippers on all four sides in bold letters of at least **Arial font size 18** with waterproof indelible ink in a clearly legible manner which is acceptable to the Purchaser:

- Generic name of the product
- Batch number of the drug
- Date of manufacture of the drug (month and year)
- Expiration date of the drug (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 (if any)
- Contract number
- Number of Millboard/Greyboard Boxes contained in the carton (5 Ply Shipper)
- Gross weight of each carton (in kg)
- Instructions for storage and handling
- Logo of DOTS
- Place of manufacture (Made in____)

L. Documentation

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

M. Dimensions of the logos

MILLBOARD/GREYBOARD BOX

3.5x3cm 	**3.5x3cm** 

5 – Ply Shipper

5.5x4.7 cm	5.5x4.7 cm
	

Product Code 11 : Isoniazid-300mg

A. Specific requirements

Product Code 114 (PC-11) is for Isoniazid -300mg tablet. The drug contained in the product shall have valid registration in the country of manufacture and shall meet all requirements of the licensing authority of the country of manufacture. The drug contained in the product shall also have valid registration in India and shall meet all the requirements of the licensing authority in India.

Description:

Isoniazid Tablet contained in blisters of the strip shall conform to the general requirements of Tablets and the requirements under individual monograph given in IP or any other International Pharmacopoeia of equivalent accuracy.

Isoniazid Tablet contain Isoniazid.

Each tablet shall contain – Isoniazid 300mg, Pharmacopeia (IP/BP/USP/Other International Pharmacopeia)

The quality of tablet of Isoniazid should conform to the requirements of the individual monograph given in IP or any other International Pharmacopoeia of equivalent accuracy.

Protocols and Testing:

For manufacturer outside India:

Complete test protocols along with the samples of all the batches should be sent to the Head of a Testing laboratory identified and specified by the purchaser.

For Indian manufacturer:

Complete Test Protocol and samples are taken and sent to the laboratory (identified by the purchaser) by the Inspecting Officer duly sealed and signed by him or his authorized representative.
Protocols of tests should include the requirements given for Tablets and those included under individual monograph given in IP or any other International Pharmacopoeia, besides the following tests.

Package Integrity Test:

Check 10 strips. Bundle up the strips and submerge them under water in a vacuum desiccator or equivalent device. Draw a vacuum of about 18k Pa and hold for a minute. Examine for the air leakage indicated by a fine stream of bubbles. Reestablish normal pressure and open strips to examine for water penetration.

Microbial Count:

When the test is conducted as per IP
-Total viable aerobic count- Not more than 10^3 bacteria and not more than 10^2 fungi per gram
-Absence of Escherichia coli.

The drug should be dispatched to the consignee only on clearance from the Testing Laboratory. The drug shall be released on the basis of Protocol scrutiny by the authorized representative of the Purchaser and testing of the drugs by authorized laboratory.
Each batch should be accompanied with a certificate from the manufacturer that the drugs meet the specified requirements.

B. Labelling:

General requirements of the labels:

- Shall meet WHO GMP standards.
- All the labels should be peel proof.
- **"NTEP- Central Government Supply- NOT FOR SALE"** to be imprinted on the labels of strips, Millboard/Greyboard Boxes & 5 Ply Shippers.
- **"Schedule H1 Drug"** to be imprinted on label of strips, Millboard/Greyboard Boxes & 5 Ply Shippers.

Labelling on Strip of Blisters:

The label shall indicate the content of Isoniazid in each tablet.
All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact.
The label shall incorporate manufacturing license no., batch no., date of mfg., date of expiry of the individual drug and storage requirements.

The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

Labelling on Millboard/Greyboard Box:

The label shall indicate the content of Isoniazid in each tablet.

The label shall incorporate manufacturing license no., batch no., date of mfg., date of expiry of the drug and storage requirements along with the number of the strips. The label shall include Bar Code and be tear proof, to be pasted on smooth surface to enable it to be read by Bar Code reader / Hand held device (Tablet computer / Smartphone).

The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

National Tuberculosis Elimination Program (NTEP)
TB TREATMENT DRUG CONTAINS PRODUCT CODE 11
ISONIAZID-300mg (10x 10 Tablet)

Each Blister Strip contains 10 Tablets of Isoniazid-300 mg

Batch No.:
Mfg. Date:
Exp. Date:

SCHEDULE H1 PRESCRIPTION DRUG – CAUTION
It is dangerous to take this preparation except in accordance with the medical advice.
Not to be sold by retail without the prescription of a Registered Medical Practitioner.

"NTEP Central Government Supply NOT FOR SALE"

Manufacturer's Name
Manufacturing Lic. No.

Labelling on 5-Ply Shipper:

The labels on shipper package must be attached to at least two sides. The label should include the name of the product, the number of Millboard/Greyboard Boxes, the number of strips, the name of the manufacturer, batch number, Mfg. date & Expiry date of the drug. The label shall also include storage handling instructions. The label shall include Bar Code and be tear proof, to be pasted on smooth surface to enable it to be read by Bar Code reader / Hand held device (Tablet computer / Smartphone). The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

Labelling for 5 – Ply Shipper packaging:

5 – Ply Shipper

National Tuberculosis Elimination Program (NTEP)

TB TREATMENT DRUG CONTAINS PRODUCT CODE 11
ISONIAZID-300mg TABLETS

20 Millboard/Greyboard Boxes

Batch No:
Mfg. Date:
Exp. Date:

SCHEDULE H1 PRESCRIPTION DRUG – CAUTION
It is dangerous to take this preparation except in accordance with the medical advice.
Not to be sold by retail without the prescription of a Registered Medical Practitioner.

"NTEP Central Government Supply
NOT FOR SALE"

Manufacturer's Name
Manufacturing Lic. No.

Numbering of shipper packaging:

All 5 Ply Shippers should be numbered consecutively. Shipping documents should be included in the shipper numbered first (consignee wise).

C. 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 the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller; (d) meet the requirements of manufacturing legislation and regulation of pharmaceuticals in the country of origin; (e) are free from defects in workmanship and in materials and (f)) the product has been manufactured as per WHO GMP requirements.

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 records with regards to process validation demonstrating batch to batch consistency.
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 provide evidence of basis for expiration dating and stability data concerning the commercial final package upon request.

The test data for raw materials, in-process, finished product and packaging material testing must be on record for each lot shipped and must be made available to Purchaser's representatives when requested.
Details of samples lifted for testing (such as quantity of strips, Millboard/Greyboard boxes, batch no. etc.) should be pasted on packing of 5 Ply Shipper and records to this effect be also made available to the purchaser.

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.
The successful Bidder will also be required to provide the Purchaser with access to its manufacturing facilities to inspect its facilities, quality control procedures for raw materials, test methods, in-process tests, and finished dosage forms.

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 the product.

D. Storage:

As per applicable Pharmacopoeia.

E. Shelf Life:

Shelf life should be minimum 36 months from the date of manufacture.

At least 5/6th of the total stipulated shelf life must remain at the time of arrival at the consignee's warehouse. The supplier will provide manufacturer's stability test data substantiating the claimed shelf life in the proposed package. Not only the pharmaceuticals, but also the packaging components should also conform to specifications suitable for use in a climate prevailing in India. The product supplied should have been subjected to long term stability conditions as per below requirements:

Study	Storage condition
Long Term Stability	25 °C ± 2 °C/60% RH ± 5% RH or 30 °C ± 2 °C/65% RH ± 5% RH

F. Qualification of the Manufacturer:

The Bidder shall furnish a certificate from the competent Regulatory Authority that the manufacturer of the pharmaceutical product is licensed to manufacture these products. The manufacturing facility must conform to WHO-GMP standards.

G. Recalls:

If products must be recalled because of problems with product quality or adverse reactions to the drug, the Supplier will be obliged to notify the purchaser providing full details about the reason leading to the recall and shall take steps to replace the product in question at its own cost with a fresh batch of acceptable quality, or withdraw and give a full refund if the product has been taken off the market due to safety problems.

H. Colour Coding:

The labels on Blisters, Millboard/Greyboard Boxes and 5 Ply Shipper package shall be identified by white background.

I. Bar Coding

Bar coding shall be used for better inventory management. It shall be printed on the labels of Millboard / Greyboard Boxes and 5 Ply Shippers containing all requisite information as per the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, New Delhi orders pertaining to Bar Code labeling in drugs, vide letter dated 14 January 2019 or as modified from time to time by the competent / regulatory authority.

The important information which shall be incorporated in bar code is:

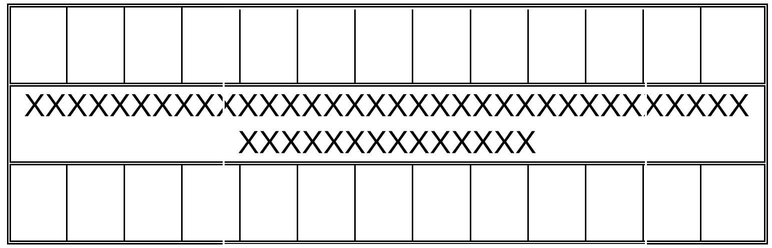
1) Product Name/content
2) Product Strength
3) Batch Number
4) Date of Manufacturing
5) Date of Expiry
6) Manufacturer Address
7) Manufacturer License number
8) Storage conditions requirement
9) Number of Tablets in a Blister Strip/ Millboard/Greyboard Boxes and 5 Ply Shipper

J. Packaging

The drug is initially packed in a Blister Strip each containing 10 tablets. 10 such strips would be further packed in white coloured Millboard/Grey board boxes and 20 such Boxes are ultimately packed in 5-Ply Shipper.
A strip consisting of individual blister of the drugs duly identified should be packed in an Aluminium-PVC blister pack. The blister should be tropicalized with regard to moisture barrier properties for drug stability under field conditions. Quality Assurance is according to Norm ISO 9001 for all the packaging material.
Aluminium-PVC Blister:
PVC Film: Transparent, clear /amber, food grade, blister forming PVC film, film gauge- 200microns, PE coating: 25 microns, PVdC coating: 60gsm.

Aluminium foil: Hard tempered Blister foil, VMCH coated,Thickness: 0.025mm.
Spacing between tablets should be enough so as to allow removal by patients with finger deformities.

Complex Constructions with PVC Films



TECHNICAL DATA FOR THE STANDARD COMPLEXES

Complex:

Rigid PVC film gauge (microns)	200
PE coating (microns)	25
PVdC coating (gsm)	60
Total weight (gsm)	356
Complex gauge (mm)	0.280

Water Vapour Transmission Rate (W V T R):

Temperature (^{0}C)	Relative Humidity % RH	gsm/24h	Vapour Transmission rate Thermoformed	Not thermoformed
20	85	gsm/24 h	0.15	0.06
38	90	gsm/24 h	0.7	0.4

Shrinkage longitudinally

T = 140^{o}C, t = 20 min. (%) 5 – 6
Application temperature (^{0}C) 68 – 74

Millboard/ Grey board Box:

Each box shall contain 10 strips. The boxes shall be labelled and fabricated from 3 mm corrugated cardboard surrounded on inside and outside by tightly affixed millboard of at least 400 gsm. The style of top and bottom shall be tuck-in-flap.

5-Ply Shipper Package:

Each 5 Ply Shipper shall contain 20 millboard/greyboard boxes. The boxes shall be packed in weather resistant, triple walled, insulated, corrugated, RSC (Universal) type 5-ply Shippers, each ply having strength of minimum 150gsm. It should be fabricated from virgin quality 'A' grade kraft paper. The overall dimension of the carton should be such that the product does not get damaged during transportation and storage.
Each shipping carton when packed should weigh not more than 50 kg.

K. Markings

All containers and invoices must bear the name of the product, expiry dates of and appropriate storage conditions.

Millboard/Greyboard Box:

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

- Manufacturer's name and registered address
- Manufacturer's License number
- Batch number of the drug
- Number of Tablets/strips contained in the box
- Date of manufacture (month and year) of the drug
- Expiration date (month and year) of the drug
- Instructions for storage and handling
- Logo of DOTS
- Place of manufacture (Made in_____)

5 – Ply Shipper:

The following information shall be stenciled or labeled on 5 – Ply Shippers on all four sides in bold letters of at least **Arial font size 18** with waterproof indelible ink in a clearly legible manner which is acceptable to the Purchaser:

- Generic name of the product
- Batch number of the drug
- Date of manufacture of the drug (month and year)
- Expiration date of the drug (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 (if any)
- Contract number
- Number of Millboard/Greyboard Boxes contained in the carton (5 Ply Shipper)
- Gross weight of each carton (in kg)
- Instructions for storage and handling
- Logo of DOTS
- Place of manufacture (Made in____)

L. Documentation

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

M. Dimensions of the logos

MILLBOARD/GREYBOARD BOX

3.5x3cm 	**3.5x3cm** 

5 – Ply Shipper

5.5x4.7 cm 	**5.5x4.7 cm** 

Product Code 28 (Tab Levofloxacin 250 mg)

A. Specific requirements

Item:
Product Code 28 (PC 28) consists of Levofloxacin 250 mg tablets. The drug contained in the product shall have valid registration in the country of manufacture and shall meet all requirements of the licensing authority of the country of manufacture. The drug contained in the product shall also have valid registration in India and shall meet all the requirements of the licensing authority in India.

Description:
Levofloxacin Tablets contained in blisters of the strip shall conform to the general requirements of Tablets and the requirements under individual monograph given in IP or other Pharmacopoeia of equivalent accuracy in case of international transactions.

Levofloxacin Tablets contain Levofloxacin.
Each tablet shall contain - Levofloxacin 250 mg, Pharmacopeia* (IP/ BP/USP/Other International Pharmacopeia)

The quality of Levofloxacin should conform to the requirements of the individual monograph given in IP or other Pharmacopoeia of equivalent accuracy in case of international transactions.

Protocols and Testing:
For manufacturers outside India:
Complete test protocols along with the samples of all the batches should be sent to the Head of a Testing laboratory identified and specified by the purchaser.
For Indian manufacturers:
Complete Test Protocol and samples are taken and sent to the laboratory (identified by the purchaser) by the Inspecting Officer duly sealed and signed by him or his authorized representative.
Protocols of tests should include the requirements given for Tablets and those included under individual monograph given in IP, besides the following tests.

Package Integrity Test:
Check 10 strips. Bundle up the strips and submerge them under water in a vacuum desiccator or equivalent device. Draw a vacuum of about 18k Pa and hold for a minute. Examine for the air leakage indicated by a fine stream of bubbles. Reestablish normal pressure and open strips to examine for water penetration.

**Only one of the selected pharmacopeia to be indicated.*

Microbial Count:
When the test is conducted as per IP
-Total viable aerobic count- Not more than 10^3 bacteria and not more than 10^2 fungi per gram
-Absence of Escherichia coli.

The drug should be dispatched to the consignee only on clearance from the Testing Laboratory. The drug shall be released on the basis of Protocol scrutiny by the authorized representative of the Purchaser and testing of the drugs by authorized laboratory.
Each batch should be accompanied with a certificate from the manufacturer that the drugs meet the specified requirements.

B. Labelling:

General requirements of the labels:

- Shall meet WHO GMP standards.
- All the labels should be peel proof.
- **"NTEP- Central Government Supply- NOT FOR SALE"** to be imprinted on the labels of strips, Millboard/Greyboard Boxes & 5 Ply Shippers.
- **"Schedule H1 Drug"** to be imprinted on label of strips, Millboard/Greyboard Boxes & 5 Ply Shippers.

Labelling on Strip of Blisters:

The label shall indicate the content of Levofloxacin IP in each tablet.
All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact.
The label shall incorporate manufacturing license no., batch no., date of mfg., date of expiry of the individual drug and storage requirements.

The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

Labelling on Millboard/Greyboard Box:
The label shall indicate the content of Levofloxacin IP in each tablet.
The label shall incorporate manufacturing license no., batch no. date of mfg., date of expiry, of the drug and storage requirements along with the number of the strips. The label shall include Bar Code and be tear proof, to be pasted on smooth surface to enable it to be read by Bar Code reader / Hand held device (Tablet computer / Smartphone).

The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

MILLBOARD/GREYBOARD BOX

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National Tuberculosis Elimination Programme (NTEP)

MDR-TB TREATMENT DRUG CONTAINS PRODUCT CODE 28

LEVOFLOXACIN TABLETS 250 mg (10 x 10 Tablets)

Each Blister Strip Contains 10 Tablets of Levofloxacin (250 mg)

Batch No:

Mfg. Date:

Exp. Date:

SCHEDULE H1 PRESCRIPTION DRUG – CAUTION
It is dangerous to take this preparation except in accordance with the medical advice.
Not to be sold by retail without the prescription of a Registered Medical Practitioner.

"NTEP – Central Government Supply – Not for Sale"

Manufacturer's Name

Manufacturing Lic. No.

Labelling on 5-Ply Shipper:

The labels on shipper package must be attached to at least two sides. The label should include the name of the product, the number of Millboard/Greyboard Boxes, the number of strips, the name of the manufacturer, batch number, Mfg. date & Expiry date of the drug. The label shall also include storage handling instructions. The label shall include Bar Code and be tear proof, to be pasted on smooth surface to enable it to be read by Bar Code reader / Hand held device (Tablet computer / Smartphone).

The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

5 – PLY SHIPPER

National Tuberculosis Elimination Programme (NTEP)

MDR-TB TREATMENT DRUG CONTAINS PRODUCT CODE 28

LEVOFLOXACIN TABLETS 250 mg

20 Millboard/Greyboard Boxes

Batch No. :

Mfg. Date:

Exp. Date:

SCHEDULE H1 PRESCRIPTION DRUG – CAUTION
It is dangerous to take this preparation except in accordance with the medical advice.
Not to be sold by retail without the prescription of a Registered Medical Practitioner.

"NTEP - Central Government Supply – Not for Sale"

Manufacturer's Name

Manufacturing Lic. No.

Numbering of shipper packaging:

All 5 Ply Shippers should be numbered consecutively. Shipping documents should be included in the shipper numbered first (consignee wise).

C. 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 the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller; (d) meet the requirements of manufacturing legislation and regulation of pharmaceuticals in the country of origin; (e) are free from defects in workmanship and in materials and (f) the product has been manufactured as per WHO GMP requirements.

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 records with regards to process validation demonstrating batch to batch consistency.

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 provide evidence of basis for expiration dating and stability data concerning the commercial final package upon request.

The test data for raw materials, in-process, finished product and packaging material testing must be on record for each lot shipped and must be made available to Purchaser's representatives when requested.

Details of samples lifted for testing (such as quantity of strips, Millboard/Greyboard boxes, batch no. etc.) should be pasted on packing of 5 Ply Shipper and records to this effect be also made available to the purchaser.

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.

The successful Bidder will also be required to provide the Purchaser with access to its manufacturing facilities to inspect its facilities, quality control procedures for raw materials, test methods, in-process tests, and finished dosage forms.

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 the product.

D. Storage:

As per applicable Pharmacopoeia.

E. Shelf Life:

Shelf life should be minimum 36 months from the date of manufacture.

At least 5/6th of the total stipulated shelf life must remain at the time of arrival at the consignee's warehouse. The supplier will provide manufacturer's stability test data substantiating the claimed shelf life in the proposed package. Not only the pharmaceuticals, but also the packaging components should also conform to specifications suitable for use in a climate prevailing in India. The product supplied should have been subjected to long term stability conditions as per below requirements:

Study	Storage condition
Long Term Stability	25 °C ± 2 °C/60% RH ± 5% RH or 30 °C ± 2 °C/65% RH ± 5% RH

F. Qualification of the Manufacturer:

The Bidder shall furnish a certificate from the competent Regulatory Authority that the manufacturer of the pharmaceutical product is licensed to manufacture these products. The manufacturing facility must conform to WHO-GMP standards.

G. Recalls:

If products must be recalled because of problems with product quality or adverse reactions to the drug, the Supplier will be obliged to notify the purchaser providing full details about the reason leading to the recall and shall take steps to replace the product in question at its own cost with a fresh batch of acceptable quality, or withdraw and give a full refund if the product has been taken off the market due to safety problems.

H. Colour Coding:

The labels on Blisters, Millboard/Greyboard Boxes and 5 Ply Shipper package shall be identified by white background.

I. Bar Coding

Bar coding shall be used for better inventory management. It shall be printed on the labels of Millboard / Greyboard Boxes and 5 Ply Shippers containing all requisite information as per the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, New Delhi orders pertaining to Bar Code labeling in drugs, vide letter dated 14 January 2019 or as modified from time to time by the competent / regulatory authority.

The important information which shall be incorporated in bar code is:

1) Product Name/content
2) Product Strength
3) Batch Number
4) Date of Manufacturing
5) Date of Expiry
6) Manufacturer Address
7) Manufacturer License number
8) Storage conditions requirement
9) Number of Tablets in a Blister Strip/ Millboard/Greyboard Boxes and 5 Ply Shipper

J. Packing

The drug is initially packed in a Blister Strip each containing 10 tablets. 10 such strips would be further packed in white coloured Millboard/Grey board boxes and 20 such Boxes are ultimately packed in 5-Ply Shipper.

A strip consisting of individual blister of the drugs duly identified should be packed in an Aluminium-PVC blister pack. The blister should be tropicalized with regard to moisture barrier properties for drug stability under field conditions. Quality Assurance is according to Norm ISO 9001 for all the packaging material.

Aluminium-PVC Blister:

PVC Film: Transparent, clear /amber, food grade, blister forming PVC film, film gauge- 200microns, PE coating: 25 microns, PVdC coating: 60gsm.
Aluminium foil: Hard tempered Blister foil, VMCH coated, Thickness: 0.025mm.
Spacing between tablets should be enough so as to allow removal by patients with finger deformities.

Complex Constructions with PVC Films

XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXX

<u>TECHNICAL DATA FOR THE STANDARD COMPLEXES</u>

Complex:

Rigid PVC film gauge (microns)	200
PE coating (microns)	25
PVdC coating (gsm)	60
Total weight (gsm)	356
Complex gauge (mm)	0.280

Water Vapour Transmission Rate (W V T R):

Temperature	**Relative Humidity**	**gsm/24h**	**Vapour Transmission rate**	
			Thermoformed	**Not thermoformed**
(^{0}C)	**% RH**			
20	85	gsm/24 h	0.15	0.06
38	90	gsm/24 h	0.7	0.4

Shrinkage longitudinally

T = 140^{o}C, t = 20 min. (%) 5 – 6
Application temperature (^{0}C) 68 – 74

Millboard/ Grey board Box:

Each box shall contain 10 strips. The boxes shall be labelled and fabricated from 3 mm corrugated cardboard surrounded on inside and outside by tightly affixed millboard of at least 400 gsm. The style of top and bottom shall be tuck-in-flap.

5-Ply Shipper Package:

Each 5 Ply Shipper shall contain 20 millboard/greyboard boxes. The boxes shall be packed in weather resistant, triple walled, insulated, corrugated, RSC (Universal) type 5-ply Shippers, each ply having strength of minimum 150gsm. It should be fabricated from virgin quality 'A' grade kraft paper. The overall dimension of the carton should be such that the product does not get damaged during transportation and storage.
Each shipping carton when packed should weigh not more than 50 kg.

K. Markings

All containers and invoices must bear the name of the product, expiry dates of and appropriate storage conditions.

Millboard/Greyboard Box:

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

- Manufacturer's name and registered address
- Manufacturer's License number
- Batch number of the drug
- Number of tablets/strips contained in the box
- Date of manufacture (month and year) of the drug
- Expiration date (month and year) of the drug
- Instructions for storage and handling
- Logo of DOTS
- Place of manufacture (Made in_____)

5 – Ply Shipper:

The following information shall be stenciled or labeled on 5 – Ply Shippers on all four sides in bold letters of at least **Arial font size 18** with waterproof indelible ink in a clearly legible manner which is acceptable to the Purchaser:

- Generic name of the product
- Batch number of the drug
- Date of manufacture of the drug (month and year)
- Expiration date of the drug (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 (if any)
- Contract number
- Number of Millboard/Greyboard Boxes contained in the carton (5 Ply Shipper)
- Gross weight of each carton (in kg)
- Instructions for storage and handling
- Logo of DOTS
- Place of manufacture (Made in____)

L. Documentation

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

M. Dimensions of the logos

MILLBOARD/GREYBOARD BOX

3.5x3cm 	**3.5x3cm** 

5 – Ply Shipper

5.5x4.7 cm	**5.5x4.7 cm**
	

Product Code 29 (Tab Levofloxacin 500 mg)

A. Specific requirements

Item:
Product Code 29 (PC 29) is for Levofloxacin (500 mg.) tablets. The drug contained in the product shall have valid registration in the country of manufacture and shall meet all requirements of the licensing authority of the country of manufacture. The drug contained in the product shall also have valid registration in India and shall meet all the requirements of the licensing authority in India.

Description:
Levofloxacin Tablets contained in blisters of the strip shall conform to the general requirements of Tablets and the requirements under individual monograph given in IP or other Pharmacopoeia of equivalent accuracy in case of international transactions.

Levofloxacin Tablets contain Levofloxacin.
Each tablet shall contain - Levofloxacin 500 mg, Pharmacopeia* (IP/ BP/USP/Other International Pharmacopeia)

The quality of Levofloxacin should conform to the requirements of the individual monograph given in IP or other Pharmacopoeia of equivalent accuracy in case of international transactions.

Protocols and Testing:
For manufacturers outside India:
Complete test protocols along with the samples of all the batches should be sent to the Head of a Testing laboratory identified and specified by the purchaser.
For Indian manufacturers:
Complete Test Protocol and samples are taken and sent to the laboratory (identified by the purchaser) by the Inspecting Officer duly sealed and signed by him or his authorized representative.
Protocols of tests should include the requirements given for Tablets and those included under individual monograph given in IP, besides the following tests.

Package Integrity Test:
Check 10 strips. Bundle up the strips and submerge them under water in a vacuum desiccator or equivalent device. Draw a vacuum of about 18k Pa and hold for a minute. Examine for the air leakage indicated by a fine stream of bubbles. Reestablish normal pressure and open strips to examine for water penetration.

**Only one of the selected pharmacopeia to be indicated.*

Microbial Count:
When the test is conducted as per IP
-Total viable aerobic count- Not more than 10^3 bacteria and not more than 10^2 fungi per gram
-Absence of Escherichia coli.

The drug should be dispatched to the consignee only on clearance from the Testing Laboratory. The drug shall be released on the basis of Protocol scrutiny by the authorized representative of the Purchaser and testing of the drugs by authorized laboratory.
Each batch should be accompanied with a certificate from the manufacturer that the drugs meet the specified requirements.

B. Labelling:

General requirements of the labels:

- Shall meet WHO GMP standards.
- All the labels should be peel proof.
- **"NTEP- Central Government Supply- NOT FOR SALE"** to be imprinted on the labels of strips, Millboard/Greyboard Boxes & 5 Ply Shippers.
- **"Schedule H1 Drug"** to be imprinted on label of strips, Millboard/Greyboard Boxes & 5 Ply Shippers.

Labelling on Strip of Blisters:

The label shall indicate the content of Levofloxacin IP in each tablet.
All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact.
The label shall incorporate manufacturing license no., batch no., date of mfg., date of expiry of the individual drug and storage requirements.

The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

Labelling on Millboard/Greyboard Box:
The label shall indicate the content of Levofloxacin in each tablet.
The label shall incorporate manufacturing license no., batch no. date of mfg., date of expiry, of the drug and storage requirements along with the number of the strips. The label shall include Bar Code and be tear proof, to be pasted on smooth surface to enable it to be read by Bar Code reader / Hand held device (Tablet computer / Smartphone).

The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

MILLBOARD/GREYBOARD BOX

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National Tuberculosis Elimination Programme (NTEP)

MDR-TB TREATMENT DRUG CONTAINS PRODUCT CODE 29
LEVOFLOXACIN TABLETS 500 mg (10 x 10 Tablets)

Each Blister Strip Contains 10 Tablets of Levofloxacin (500 mg)

Batch No:

Mfg. Date:

Exp. Date:

SCHEDULE H1 PRESCRIPTION DRUG – CAUTION
It is dangerous to take this preparation except in accordance with the medical advice.
Not to be sold by retail without the prescription of a Registered Medical Practitioner.

"NTEP – Central Government Supply – Not for Sale"

Manufacturer's Name
Manufacturing Lic. No.

Labelling on 5-Ply Shipper:

The labels on shipper package must be attached to at least two sides. The label should include the name of the product, the number of Millboard/Greyboard Boxes, the number of strips, the name of the manufacturer, batch number, Mfg. date & Expiry date of the drug. The label shall also include storage handling instructions. The label shall include Bar Code and be tear proof, to be pasted on smooth surface to enable it to be read by Bar Code reader / Hand held device (Tablet computer / Smartphone). The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

5 – PLY SHIPPER

National Tuberculosis Elimination Programme (NTEP)

MDR-TB TREATMENT DRUG CONTAINS PRODUCT CODE 29
LEVOFLOXACIN TABLETS 500 mg

20 Millboard/Greyboard Boxes

Batch No. :
Mfg. Date:
Exp. Date:

SCHEDULE H1 PRESCRIPTION DRUG – CAUTION
It is dangerous to take this preparation except in accordance with the medical advice.
Not to be sold by retail without the prescription of a Registered Medical Practitioner.

"NTEP - Central Government Supply – Not for Sale"

Manufacturer's Name

Manufacturing Lic. No.

Numbering of shipper packaging:

All 5 Ply Shippers should be numbered consecutively. Shipping documents should be included in the shipper numbered first (consignee wise).

C. 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 the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller; (d) meet the requirements of manufacturing legislation and regulation of pharmaceuticals in the country of origin; (e) are free from defects in workmanship and in materials and (f) the product has been manufactured as per WHO GMP requirements.

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 records with regards to process validation demonstrating batch to batch consistency.

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 provide evidence of basis for expiration dating and stability data concerning the commercial final package upon request.

The test data for raw materials, in-process, finished product and packaging material testing must be on record for each lot shipped and must be made available to Purchaser's representatives when requested.

Details of samples lifted for testing (such as quantity of strips, Millboard/Greyboard boxes, batch no. etc.) should be pasted on packing of 5 Ply Shipper and records to this effect be also made available to the purchaser.

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.

The successful Bidder will also be required to provide the Purchaser with access to its manufacturing facilities to inspect its facilities, quality control procedures for raw materials, test methods, in-process tests, and finished dosage forms.

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 the product.

D. Storage:

As per applicable Pharmacopoeia.

E. Shelf Life:

Shelf life should be minimum 36 months from the date of manufacture.

At least 5/6th of the total stipulated shelf life must remain at the time of arrival at the consignee's warehouse. The supplier will provide manufacturer's stability test data substantiating the claimed shelf life in the proposed package. Not only the pharmaceuticals, but also the packaging components should also conform to specifications suitable for use in a climate prevailing in India. The product supplied should have been subjected to long term stability conditions as per below requirements:

Study	Storage condition
Long Term Stability	25 °C ± 2 °C/60% RH ± 5% RH or 30 °C ± 2 °C/65% RH ± 5% RH

F. Qualification of the Manufacturer:

The Bidder shall furnish a certificate from the competent Regulatory Authority that the manufacturer of the pharmaceutical product is licensed to manufacture these products. The manufacturing facility must conform to WHO-GMP standards.

G. Recalls:

If products must be recalled because of problems with product quality or adverse reactions to the drug, the Supplier will be obliged to notify the purchaser providing full details about the reason leading to the recall and shall take steps to replace the product in question at its own cost with a fresh batch of acceptable quality, or withdraw and give a full refund if the product has been taken off the market due to safety problems.

H. Colour Coding:

The labels on Blisters, Millboard/Greyboard Boxes and 5 Ply Shipper package shall be identified by white background.

I. Bar Coding

Bar coding shall be used for better inventory management. It shall be printed on the labels of Millboard / Greyboard Boxes and 5 Ply Shippers containing all requisite information as per the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, New Delhi orders pertaining to Bar Code labeling in drugs, vide letter dated 14 January 2019 or as modified from time to time by the competent / regulatory authority.

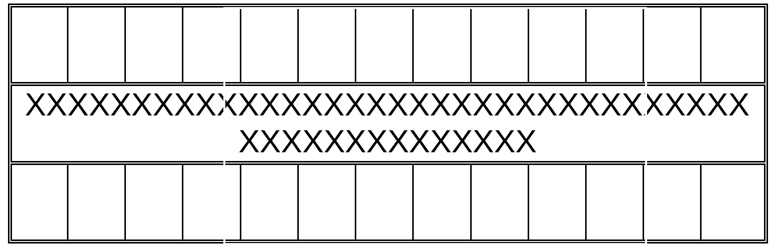
The important information which shall be incorporated in bar code is:

1) Product Name/content
2) Product Strength
3) Batch Number
4) Date of Manufacturing
5) Date of Expiry
6) Manufacturer Address
7) Manufacturer License number
8) Storage conditions requirement
9) Number of Tablets in a Blister Strip/ Millboard/Greyboard Boxes and 5 Ply Shipper

J. Packing

The drug is initially packed in a Blister Strip each containing 10 tablets. 10 such strips would be further packed in white coloured Millboard/Grey board boxes and 20 such Boxes are ultimately packed in 5-Ply Shipper.
A strip consisting of individual blister of the drugs duly identified should be packed in an Aluminium-PVC blister pack. The blister should be tropicalized with regard to moisture barrier properties for drug stability under field conditions. Quality Assurance is according to Norm ISO 9001 for all the packaging material.
Aluminium-PVC Blister:
PVC Film: Transparent, clear /amber, food grade, blister forming PVC film, film gauge- 200microns, PE coating: 25 microns, PVdC coating: 60gsm.
Aluminium foil: Hard tempered Blister foil, VMCH coated, Thickness: 0.025mm.
Spacing between tablets should be enough so as to allow removal by patients with finger deformities.

Complex Constructions with PVC Films



TECHNICAL DATA FOR THE STANDARD COMPLEXES

Complex:

Rigid PVC film gauge (microns)	200
PE coating (microns)	25
PVdC coating (gsm)	60
Total weight (gsm)	356
Complex gauge (mm)	0.280

Water Vapour Transmission Rate (W V T R):

Temperature (°C)	**Relative Humidity** % RH	**gsm/24h**	**Vapour Transmission rate** Thermoformed	Not thermoformed
20	85	gsm/24 h	0.15	0.06
38	90	gsm/24 h	0.7	0.4

Shrinkage longitudinally

T = 140°C, t = 20 min. (%) 5 – 6
Application temperature (°C) 68 – 74

Millboard/ Grey board Box:

Each box shall contain 10 strips. The boxes shall be labelled and fabricated from at least 3 mm corrugated cardboard surrounded on inside and outside by tightly affixed millboard of at least 400 gsm. The style of top and bottom shall be tuck-in-flap.

5-Ply Shipper Package:
Each 5 Ply Shipper shall contain 20 millboard/greyboard boxes. The boxes shall be packed in weather resistant, triple walled, insulated, corrugated, RSC (Universal) type 5-ply Shippers, each ply having strength of minimum 150gsm. It should be fabricated from virgin quality 'A' grade kraft paper. The overall dimension of the carton should be such that the product does not get damaged during transportation and storage.
Each shipping carton when packed should weigh not more than 50 kg.

K. Markings

All containers and invoices must bear the name of the product, expiry dates of and appropriate storage conditions.

Millboard/Greyboard Box:

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

- Manufacturer's name and registered address
- Manufacturer's License number
- Batch number of the drug
- Number of tablets/strips contained in the box
- Date of manufacture (month and year) of the drug
- Expiration date (month and year) of the drug
- Instructions for storage and handling
- Logo of DOTS
- Place of manufacture (Made in_____)

5 – Ply Shipper:

The following information shall be stenciled or labeled on 5 – Ply Shippers on all four sides in bold letters of at least **Arial font size 18** with waterproof indelible ink in a clearly legible manner which is acceptable to the Purchaser:

- Generic name of the product
- Batch number of the drug

- Date of manufacture of the drug (month and year)
- Expiration date of the drug (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 (if any)
- Contract number
- Number of Millboard/Greyboard Boxes contained in the carton (5 Ply Shipper)
- Gross weight of each carton (in kg)
- Instructions for storage and handling
- Logo of DOTS
- Place of manufacture (Made in____)

L. Documentation

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

M. Dimensions of the logos

MILLBOARD/GREYBOARD BOX

3.5x3cm	**3.5x3cm**
	

5 – Ply Shipper

5.5x4.7 cm	5.5x4.7 cm
	

Product Code 38 (Tab Linezolid-600mg)

A. Specific requirements

Item:

Product Code 38 (PC 38) consists of blister strips of Linezolid Tablets. The drug contained in the product shall have valid registration in the country of manufacture and shall meet all requirements of the licensing authority of the country of manufacture. The drug contained in the product shall also have valid registration in India and shall meet all the requirements of the licensing authority in India.

Description:

Linezolid Tablets contained in blisters of the strip shall conform to the general requirements of Tablets and the requirements under individual monograph given in IP or other Pharmacopoeia of equivalent accuracy in case of international transactions.

Each tablet shall contain - Linezolid 600 mg, Pharmacopeia* (IP/ BP/USP/Other International Pharmacopeia)

The quality of Linezolid should conform to the requirements of the individual monograph given in IP or other Pharmacopoeia of equivalent accuracy in case of international transactions.

Protocols and Testing:

For manufacturers outside India:

Complete test protocols along with the samples of all the batches should be sent to the Head of a Testing laboratory identified and specified by the purchaser.

For Indian manufacturers:

Complete Test Protocol and samples are taken and sent to the laboratory (identified by the purchaser) by the Inspecting Officer duly sealed and signed by him or his authorized representative.
Protocols of tests should include the requirements given for Tablets and those included under individual monograph given in IP, besides the following tests.

**Only one of the selected pharmacopeia to be indicated.*

Package Integrity Test:

Check 10 strips. Bundle up the strips and submerge them under water in a vacuum desiccator or equivalent device. Draw a vacuum of about 18k Pa (-0.18 bar) and hold for a minute. Examine for the air leakage indicated by a fine stream of bubbles. Reestablish normal pressure and open strips to examine for water penetration.

Microbial Count:

When the test is conducted as per IP
-Total viable aerobic count- Not more than 10^3 bacteria and not more than 10^2 fungi per gram
-Absence of Escherichia coli.

The drug should be dispatched to the consignee only on clearance from the Testing Laboratory. The drug shall be released on the basis of Protocol scrutiny by the authorized representative of the Purchaser and testing of the drugs by authorized laboratory.
Each batch should be accompanied with a certificate from the manufacturer that the drugs meet the specified requirements.

B. Labelling:

General requirements of the labels:

- Shall meet WHO GMP standards.
- All the labels should be peel proof.
- **"NTEP- Central Government Supply- NOT FOR SALE" and "Schedule H Drug"** to be imprinted on the labels of strips, Millboard/Greyboard Boxes and 5 Ply Shippers.

Labelling on Strip of Blisters:
The label shall indicate the content of Linezolid IP in each tablet.
All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact.
The label shall incorporate manufacturing license no., batch no., date of mfg., date of expiry of the individual drug and storage requirements.

The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

Labelling on Millboard/Greyboard Box:

The label shall indicate the content of Linezolid IP in each tablet.

The label shall incorporate manufacturing license no., batch no. date of mfg., date of expiry, of the drug and storage requirements along with the number of the strips. The label shall include Bar Code and be tear proof, to be pasted on smooth surface to enable it to be read by Bar Code reader / Hand held device (Tablet computer / Smartphone).

The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

MILLBOARD/GREYBOARD BOX

National Tuberculosis Elimination Programme (NTEP)

MDR-TB TREATMENT DRUG CONTAINS PRODUCT CODE 38
LINEZOLID TABLETS 500 mg (10 x 10 Tablets)

Each Blister Strip Contains 10 Tablets of Linezolid(600 mg)

Batch No.:
Mfg. Date:
Exp. Date:

SCHEDULE H PRESCRIPTION DRUG – CAUTION
Not to be sold by retail without the prescription of a Registered Medical Practitioner.

NTEP – Central Government Supply
– Not for Sale"

Manufacturer's Name
Manufacturing Lic. No.

Labelling on 5- Ply Shipper:

The labels on shipper package must be attached to at least two sides. The label should include the name of the product, the number of Millboard/Greyboard Boxes, the number of strips, the name of the manufacturer, batch number/Mfg. date/Expiry date of the drug. The label shall also include storage/handling instructions. The label shall include Bar Code

and be tear proof, to be pasted on smooth surface to enable it to be read by Bar Code reader / Hand held device (Tablet computer / Smartphone).

The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

5 – PLY SHIPPER

National Tuberculosis Elimination Programme (NTEP)

MDR-TB TREATMENT DRUG CONTAINS PRODUCT CODE 38

LINEZOLID TABLETS 600 mg

20 Millboard/Greyboard Boxes

Batch No. :

Mfg. Date:

Exp. Date:

SCHEDULE H PRESCRIPTION DRUG – CAUTION
Not to be sold by retail without the prescription of a Registered Medical Practitioner.

"NTEP - Central Government Supply – Not for Sale"

Manufacturer's Name

Manufacturing Lic. No.

Numbering of shipper packaging:

All 5 Ply Shippers should be numbered consecutively. Shipping documents should be included in the shipper numbered first (consignee wise).

C. 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 the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller; (d) meet the requirements of manufacturing legislation and regulation of pharmaceuticals in the country of origin; (e) are free from defects in workmanship and in materials and (f)) the product has been manufactured as per WHO GMP requirements.

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 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 provide evidence of basis for expiration dating and stability data concerning the commercial final package upon request.
The test data for raw materials, in-process, finished product and packaging material testing must be on record for each lot shipped and must be made available to Purchaser's representatives when requested.
Details of samples lifted for testing (such as quantity of strips, Millboard/Greyboard boxes, batch no. etc.) should be pasted on packing of 5 Ply Shipper and records to this effect be also made available to the purchaser.

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.
The successful Bidder will also be required to provide the Purchaser with access to its manufacturing facilities to inspect its facilities, quality control procedures for raw materials, test methods, in-process tests, and finished dosage forms.

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 the product.

D. Storage:

As per applicable Pharmacopoeia.

E. Shelf Life:

Shelf life should be minimum 36 months from the date of manufacture.

At least **5/6th** of the total stipulated shelf life must remain at the time of arrival at the consignee's warehouse. The supplier will provide manufacturer's stability test data substantiating the claimed shelf life in the proposed package. Not only the pharmaceuticals, but also the packaging components should also conform to specifications suitable for use in a climate prevailing in India. The product supplied should have been subjected to long term stability conditions as per below requirements:

Study	Storage condition
Long Term Stability	25 °C ± 2 °C/60% RH ± 5% RH or 30 °C ± 2 °C/65% RH ± 5% RH

F. Qualification of the Manufacturer:

The Bidder shall furnish a certificate from the competent Regulatory Authority that the manufacturer of the pharmaceutical product is licensed to manufacture these products. The manufacturing facility must conform to WHO-GMP standards.

G. Recalls:

If products must be recalled because of problems with product quality or adverse reactions to the drug, the Supplier will be obliged to notify the purchaser providing full details about the reason leading to the recall and shall take steps to replace the product in question at its own cost with a fresh batch of acceptable quality, or withdraw and give a full refund if the product has been taken off the market due to safety problems.

H. Colour Coding:

The labels on Blisters, Millboard/Greyboard Boxes and 5 Ply Shipper package shall be identified by white background.

I. Bar Coding

Bar coding shall be used for better inventory management. It shall be printed on the labels of Millboard / Greyboard Boxes and 5 Ply Shippers containing all requisite information as per the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, New Delhi orders pertaining to Bar Code labeling in drugs, vide letter dated 14 January 2019 or as modified from time to time by the competent / regulatory authority.

The important information which shall be incorporated in bar code is:

1) Product Name/content
2) Product Strength
3) Batch Number
4) Date of Manufacturing
5) Date of Expiry
6) Manufacturer Address
7) Manufacturer License number
8) Storage conditions requirement
9) Number of Tablets in a Blister Strip/ Millboard/Greyboard Boxes and 5 Ply Shipper

J. Packaging

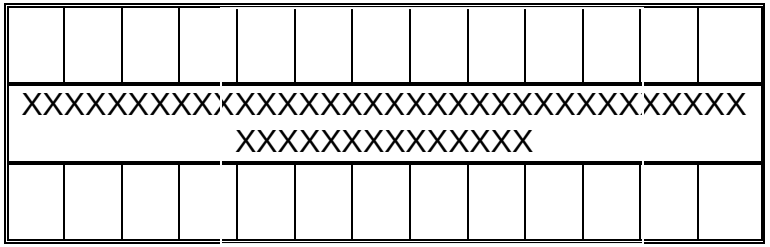
The drug is initially packed in a Blister Strip each containing 10 tablets. 10 such strips would be further packed in white coloured Millboard/Grey board boxes and 20 such Boxes are ultimately packed in 5-Ply Shipper.

A strip consisting of individual blister of the drugs duly identified should be packed in an Aluminium-PVC blister pack. The blister blister should be tropicalized with regard to moisture barrier properties for drug stability under field conditions. Quality Assurance is according to Norm ISO 9001 for all the packaging material.

Aluminium-PVC Blister:

PVC Film: Transparent, clear /amber, food grade, blister forming PVC film, film gauge- 200microns, PE coating: 25 microns, PVdC coating: 60gsm.
Aluminium foil: Hard tempered Blister foil, VMCH coated, Thickness: 0.025mm.
Spacing between capsules should be enough so as to allow removal by patients with finger deformities.

Complex Constructions with PVC Films



TECHNICAL DATA FOR THE STANDARD COMPLEXES

Complex:

Rigid PVC film gauge (microns)	200
PE coating (microns)	25
PVdC coating (gsm)	60
Total weight (gsm)	356
Complex gauge (mm)	0.280

Water Vapour Transmission Rate (W V T R):

Temperature (^{0}C)	**Relative Humidity % RH**	**gsm/24h**	**Vapour Transmission rate**	
			Thermoformed	**Not thermoformed**
20	85	gsm/24 h	0.15	0.06
38	90	gsm/24 h	0.7	0.4

Shrinkage longitudinally

T = 140^{o}C, t = 20 min. (%) 5 – 6
Application temperature (^{0}C) 68 – 74

Millboard/ Grey board Box:

Each box shall contain 10 strips. The boxes shall be labelled and fabricated from 3 mm corrugated cardboard surrounded on inside and outside by tightly affixed millboard of at least 400 gsm. The style of top and bottom shall be tuck-in-flap.

5-Ply Shipper Package:

Each 5 Ply Shipper shall contain 20 millboard/greyboard boxes. The boxes shall be packed in weather resistant, triple walled, insulated, corrugated, RSC (Universal) type 5-ply Shippers, each ply having strength of minimum 150gsm. It should be fabricated from virgin quality 'A' grade kraft paper. The overall dimension of the carton should be such that the product does not get damaged during transportation and storage. Each shipping carton when packed should weigh not more than 50 kg.

K. Markings

All containers and invoices must bear the name of the product, expiry dates of and appropriate storage conditions.

Millboard/Greyboard Box:

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

- Manufacturer's name and registered address
- Manufacturer's License number
- Batch number of the drug
- Number of tablets/strips contained in the box
- Date of manufacture (month and year) of the drug
- Expiration date (month and year) of the drug
- Instructions for storage and handling
- Logo of DOTS
- Place of manufacture (Made in_____)

5 – Ply Shipper:

The following information shall be stenciled or labeled on 5 – Ply Shippers on all four sides in bold letters of at least **Arial font size 18** with waterproof indelible ink in a clearly legible manner which is acceptable to the Purchaser:

- Generic name of the product
- Batch number of the drug
- Date of manufacture of the drug (month and year)
- Expiration date of the drug (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 (if any)
- Contract number
- Number of Millboard/Greyboard Boxes contained in the carton (5 Ply Shipper)
- Gross weight of each carton (in kg)
- Instructions for storage and handling
- Logo of DOTS
- Place of manufacture (Made in____)

L. Documentation

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

M. Dimensions of the logos

MILLBOARD/GREYBOARD BOX

3.5x3cm	3.5x3cm
	

5 – Ply Shipper

5.5x4.7 cm	5.5x4.7 cm
	

Product Code 08 : Pyrazinamide-500mg

A. Specific requirements

Product Code 08 (PC-08) is for Pyrazinamide -500mg. The drug contained in the product shall have valid registration in the country of manufacture and shall meet all requirements of the licensing authority of the country of manufacture. The drug contained in the product shall also have valid registration in India and shall meet all the requirements of the licensing authority in India.

Description:

Pyrazinamide Tablets contained in blisters of the strip shall conform to the general requirements of Tablets and the requirements under individual monograph given in IP or any other International Pharmacopoeia of equivalent accuracy.

Pyrazinamide Tablets contain Pyrazinamide.

Each tablet shall contain– Pyrazinamide-500mg, Pharmacopeia* (IP/ BP/USP/Other International Pharmacopeia

The quality of Pyrazinamide should conform to the requirements of the individual monograph given in IP or any other International Pharmacopoeia of equivalent accuracy.

Protocols and Testing:

For manufacturer outside India:

Complete test protocols along with the samples of all the batches should be sent to the Head of a Testing laboratory identified and specified by the purchaser.

For Indian manufacturer:

Complete Test Protocol and samples are taken and sent to the laboratory (identified by the purchaser) by the Inspecting Officer duly sealed and signed by him or his authorized representative.
Protocols of tests should include the requirements given for Tablets and those included under individual monograph given in IP or any other International Pharmacopoeia, besides the following tests.

**Only one of the selected pharmacopeia to be indicated.*

Package Integrity Test:

Check 10 strips. Bundle up the strips and submerge them under water in a vacuum desiccator or equivalent device. Draw a vacuum of about 18k Pa and hold for a minute. Examine for the air leakage indicated by a fine stream of bubbles. Reestablish normal pressure and open strips to examine for water penetration.

Microbial Count:

When the test is conducted as per IP
-Total viable aerobic count- Not more than 10^3 bacteria and not more than 10^2 fungi per gram
-Absence of Escherichia coli.

The drug should be dispatched to the consignee only on clearance from the Testing Laboratory. The drug shall be released on the basis of Protocol scrutiny by the authorized representative of the Purchaser and testing of the drugs by authorized laboratory.
Each batch should be accompanied with a certificate from the manufacturer that the drugs meet the specified requirements.

B. Labelling:

General requirements of the labels:

- Shall meet WHO GMP standards.
- All the labels should be peel proof.
- **"NTEP- Central Government Supply- NOT FOR SALE"** to be imprinted on the labels of strips, Millboard/Greyboard Boxes & 5 Ply Shippers.
- **"Schedule H1 Drug"** to be imprinted on label of strips, Millboard/Greyboard Boxes & 5 Ply Shippers.

Labelling on Strip of Blisters:

The label shall indicate the content of Pyrazinamide in each tablet.
All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact.
The label shall incorporate manufacturing license no., batch no., date of mfg., date of expiry of the individual drug and storage requirements.

The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

Labelling on Millboard/Greyboard Box:

The label shall indicate the content of Pyrazinamide in each tablet.

The label shall incorporate manufacturing license no., batch no., date of mfg., date of expiry of the drug and storage requirements along with the number of the strips. The label shall include Bar Code and be tear proof, to be pasted on smooth surface to enable it to be read by Bar Code reader / Hand held device (Tablet computer / Smartphone).

The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

National Tuberculosis Elimination Program (NTEP)

TB TREATMENT DRUG CONTAINS PRODUCT CODE 08

PYRAZINAMIDE 500 mg (10 x10 TABLET)

Each Blister Strip contains 10 Tablets of Pyrazinamide-500mg

Batch No.:
Mfg. Date:
Exp. Date:

SCHEDULE H1 PRESCRIPTION DRUG – CAUTION
It is dangerous to take this preparation except in accordance with the medical advice.
Not to be sold by retail without the prescription of a Registered Medical Practitioner.

"NTEP Central Government Supply
NOT FOR SALE"

Manufacturer's Name
Manufacturing Lic. No.

Labelling on 5-Ply Shipper:

The labels on shipper package must be attached to at least two sides. The label should include the name of the product, the number of Millboard/Greyboard Boxes, the number of strips, the name of the manufacturer, batch number, Mfg. date & Expiry date of the drug. The label shall also include storage handling instructions. The label shall include Bar Code and be tear proof, to be pasted on smooth surface to enable it to be read by Bar Code reader / Hand held device (Tablet computer / Smartphone). The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

Labelling for 5 – Ply Shipper packaging:

5 – Ply Shipper

National Tuberculosis Elimination Program (NTEP)

TB TREATMENT DRUG CONTAINS PRODUCT CODE 08
PYRAZINAMIDE TABLETS 500 mg

20 Millboard/Greyboard Boxes

Batch No:
Mfg. Date:
Exp. Date:

SCHEDULE H1 PRESCRIPTION DRUG – CAUTION
It is dangerous to take this preparation except in accordance with the medical advice.
Not to be sold by retail without the prescription of a Registered Medical Practitioner.

"NTEP Central Government Supply
NOT FOR SALE"

Manufacturer's Name
Manufacturing Lic. No.

4

Numbering of shipper packaging:

All 5 Ply Shippers should be numbered consecutively. Shipping documents should be included in the shipper numbered first (consignee wise).

C. 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 the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller; (d) meet the requirements of manufacturing legislation and regulation of pharmaceuticals in the country of origin; (e) are free from defects in workmanship and in materials and (f)) the product has been manufactured as per WHO GMP requirements.

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 records with regards to process validation demonstrating batch to batch consistency.
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 provide evidence of basis for expiration dating and stability data concerning the commercial final package upon request.

The test data for raw materials, in-process, finished product and packaging material testing must be on record for each lot shipped and must be made available to Purchaser's representatives when requested.
Details of samples lifted for testing (such as quantity of strips, Millboard/Greyboard boxes, batch no. etc.) should be pasted on packing of 5 Ply Shipper and records to this effect be also made available to the purchaser.

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.
The successful Bidder will also be required to provide the Purchaser with access to its manufacturing facilities to inspect its facilities, quality control procedures for raw materials, test methods, in-process tests, and finished dosage forms.

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 the product.

D. Storage:

As per applicable Pharmacopoeia.

E. Shelf Life:

Shelf life should be minimum 36 months from the date of manufacture.

At least 5/6th of the total stipulated shelf life must remain at the time of arrival at the consignee's warehouse. The supplier will provide manufacturer's stability test data substantiating the claimed shelf life in the proposed package. Not only the pharmaceuticals, but also the packaging components should also conform to specifications suitable for use in a climate prevailing in India. The product supplied should have been subjected to long term stability conditions as per below requirements:

Study	Storage condition
Long Term Stability	25 °C ± 2 °C/60% RH ± 5% RH or 30 °C ± 2 °C/65% RH ± 5% RH

F. Qualification of the Manufacturer:

The Bidder shall furnish a certificate from the competent Regulatory Authority that the manufacturer of the pharmaceutical product is licensed to manufacture these products. The manufacturing facility must conform to WHO-GMP standards.

G. Recalls:

If products must be recalled because of problems with product quality or adverse reactions to the drug, the Supplier will be obliged to notify the purchaser providing full details about the reason leading to the recall and shall take steps to replace the product in question at its own cost with a fresh batch of acceptable quality, or withdraw and give a full refund if the product has been taken off the market due to safety problems.

H. Colour Coding:

The labels on Blisters, Millboard/Greyboard Boxes and 5 Ply Shipper package shall be identified by white background.

I. Bar Coding

Bar coding shall be used for better inventory management. It shall be printed on the labels of Millboard / Greyboard Boxes and 5 Ply Shippers containing all requisite information as per the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, New Delhi orders pertaining to Bar Code labeling in drugs, vide letter dated 14 January 2019 or as modified from time to time by the competent / regulatory authority.

The important information which shall be incorporated in bar code is:

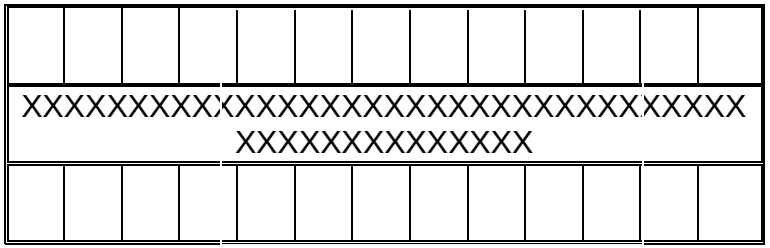
1) Product Name/content
2) Product Strength
3) Batch Number
4) Date of Manufacturing
5) Date of Expiry
6) Manufacturer Address
7) Manufacturer License number
8) Storage conditions requirement
9) Number of Tablets in a Blister Strip/ Millboard/Greyboard Boxes and 5 Ply Shipper

J. Packaging

The drug is initially packed in a Blister Strip each containing 10 tablets. 10 such strips would be further packed in white coloured Millboard/Grey board boxes and 20 such Boxes are ultimately packed in 5-Ply Shipper.
A strip consisting of individual blister of the drugs duly identified should be packed in an Aluminium-PVC blister pack. The blister should be tropicalized with regard to moisture barrier properties for drug stability under field conditions. Quality Assurance is according to Norm ISO 9001 for all the packaging material.
Aluminium-PVC Blister:

PVC Film: Transparent, clear /amber, food grade, blister forming PVC film, film gauge- 200microns, PE coating: 25 microns, PVdC coating: 60gsm.
Aluminium foil: Hard tempered Blister foil, VMCH coated,Thickness: 0.025mm.
Spacing between tablets should be enough so as to allow removal by patients with finger deformities.

Complex Constructions with PVC Films



TECHNICAL DATA FOR THE STANDARD COMPLEXES

Complex:

Rigid PVC film gauge (microns)	200	
PE coating (microns)		25
PVdC coating (gsm)	60	
Total weight (gsm)	356	
Complex gauge (mm)		0.280

Water Vapour Transmission Rate (W V T R):

Temperature	**Relative Humidity**	**gsm/24h**	**Vapour Transmission rate**	
			Thermoformed	**Not thermoformed**
(^{0}C)	**% RH**			
20	85	gsm/24 h	0.15	0.06
38	90	gsm/24 h	0.7	0.4

Shrinkage longitudinally

T = 140^{o}C, t = 20 min. (%)	5 – 6
Application temperature (^{0}C)	68 – 74

Millboard/ Grey board Box:

Each box shall contain 10 strips. The boxes shall be labelled and fabricated from 3 mm corrugated cardboard surrounded on inside and outside by tightly affixed millboard of at least 400 gsm. The style of top and bottom shall be tuck-in-flap.

5-Ply Shipper Package:

Each 5 Ply Shipper shall contain 20 millboard/greyboard boxes. The boxes shall be packed in weather resistant, triple walled, insulated, corrugated, RSC (Universal) type 5-ply Shippers, each ply having strength of minimum 150gsm. It should be fabricated from virgin quality 'A' grade kraft paper. The overall dimension of the carton should be such that the product does not get damaged during transportation and storage.
Each shipping carton when packed should weigh not more than 50 kg.

K. Markings

All containers and invoices must bear the name of the product, expiry dates of and appropriate storage conditions.

Millboard/Greyboard Box:
The Boxes shall be marked with the following information in a clearly legible manner which is acceptable to the Purchaser:

- Manufacturer's name and registered address
- Manufacturer's License number
- Batch number of the drug
- Number of Tablets/strips contained in the box
- Date of manufacture (month and year) of the drug
- Expiration date (month and year) of the drug
- Instructions for storage and handling
- Logo of DOTS
- Place of manufacture (Made in_____)

5 – Ply Shipper:

The following information shall be stenciled or labeled on 5 – Ply Shippers on all four sides in bold letters of at least **Arial font size 18** with waterproof indelible ink in a clearly legible manner which is acceptable to the Purchaser:

- Generic name of the product
- Batch number of the drug
- Date of manufacture of the drug (month and year)

- Expiration date of the drug (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 (if any)
- Contract number
- Number of Millboard/Greyboard Boxes contained in the carton (5 Ply Shipper)
- Gross weight of each carton (in kg)
- Instructions for storage and handling
- Logo of DOTS
- Place of manufacture (Made in____)

L. Documentation

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

M. Dimensions of the logos

MILLBOARD/GREYBOARD BOX

3.5x3cm 	**3.5x3cm** 

5 – Ply Shipper

5.5x4.7 cm 	**5.5x4.7 cm** 

Product Code 23: Pyrazinamide-750mg

A. Specific requirements

Product Code 23 (PC-23) is for Pyrazinamide -750mg. The drug contained in the product shall have valid registration in the country of manufacture and shall meet all requirements of the licensing authority of the country of manufacture. The drug contained in the product shall also have valid registration in India and shall meet all the requirements of the licensing authority in India.

Description:

Pyrazinamide Tablets contained in blisters of the strip shall conform to the general requirements of Tablets and the requirements under individual monograph given in IP or any other International Pharmacopoeia of equivalent accuracy.

Pyrazinamide Tablets contain Pyrazinamide.

Each tablet shall contain– Pyrazinamide-750mg, Pharmacopeia* (IP/ BP/USP/Other International Pharmacopeia

The quality of Pyrazinamide should conform to the requirements of the individual monograph given in IP or any other International Pharmacopoeia of equivalent accuracy.

Protocols and Testing:

For manufacturer outside India:

Complete test protocols along with the samples of all the batches should be sent to the Head of a Testing laboratory identified and specified by the purchaser.

For Indian manufacturer:

Complete Test Protocol and samples are taken and sent to the laboratory (identified by the purchaser) by the Inspecting Officer duly sealed and signed by him or his authorized representative.
Protocols of tests should include the requirements given for Tablets and those included under individual monograph given in IP or any other International Pharmacopoeia, besides the following tests.

**Only one of the selected pharmacopeia to be indicated.*

Package Integrity Test:

Check 10 strips. Bundle up the strips and submerge them under water in a vacuum desiccator or equivalent device. Draw a vacuum of about 18k Pa and hold for a minute. Examine for the air leakage indicated by a fine stream of bubbles. Reestablish normal pressure and open strips to examine for water penetration.

Microbial Count:

When the test is conducted as per IP
-Total viable aerobic count- Not more than 10^3 bacteria and not more than 10^2 fungi per gram
-Absence of Escherichia coli.

The drug should be dispatched to the consignee only on clearance from the Testing Laboratory. The drug shall be released on the basis of Protocol scrutiny by the authorized representative of the Purchaser and testing of the drugs by authorized laboratory.
Each batch should be accompanied with a certificate from the manufacturer that the drugs meet the specified requirements.

B. Labelling:

General requirements of the labels:

- Shall meet WHO GMP standards.
- All the labels should be peel proof.
- **"NTEP- Central Government Supply- NOT FOR SALE"** to be imprinted on the labels of strips, Millboard/Greyboard Boxes & 5 Ply Shippers.
- **"Schedule H1 Drug"** to be imprinted on label of strips, Millboard/Greyboard Boxes & 5 Ply Shippers.

Labelling on Strip of Blisters:

The label shall indicate the content of Pyrazinamide in each tablet.
All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact.
The label shall incorporate manufacturing license no., batch no., date of mfg., date of expiry of the individual drug and storage requirements.

The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

Labelling on Millboard/Greyboard Box:

The label shall indicate the content of Pyrazinamide in each tablet.

The label shall incorporate manufacturing license no., batch no., date of mfg., date of expiry of the drug and storage requirements along with the number of the strips. The label shall include Bar Code and be tear proof, to be pasted on smooth surface to enable it to be read by Bar Code reader / Hand held device (Tablet computer / Smartphone).

The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

National Tuberculosis Elimination Program (NTEP)

TB TREATMENT DRUG CONTAINS PRODUCT CODE 23

PYRAZINAMIDE 750 mg (10 x10 TABLET)

Each Blister Strip contains 10 Tablets of Pyrazinamide-750mg

राष्ट्रीय क्षय उन्मूलन कार्यक्रम
टीबी मुक्त भारत
टीबी हारेगा देश जीतेगा

NATIONAL TUBERCULOSIS ELIMINATION PROGRAMME
TB MUKT BHARAT
TB Harega Desh Jeetega

Batch No.:
Mfg. Date:
Exp. Date:

SCHEDULE H1 PRESCRIPTION DRUG – CAUTION
It is dangerous to take this preparation except in accordance with the medical advice.
Not to be sold by retail without the prescription of a Registered Medical Practitioner.

"NTEP Central Government Supply
NOT FOR SALE"

Manufacturer's Name
Manufacturing Lic. No.

Labelling on 5-Ply Shipper:

The labels on shipper package must be attached to at least two sides. The label should include the name of the product, the number of Millboard/Greyboard Boxes, the number of strips, the name of the manufacturer, batch number, Mfg. date & Expiry date of the drug. The label shall also include storage handling instructions. The label shall include Bar Code and be tear proof, to be pasted on smooth surface to enable it to be read by Bar Code reader / Hand held device (Tablet computer / Smartphone). The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

Labelling for 5 – Ply Shipper packaging:

5 – Ply Shipper

National Tuberculosis Elimination Program (NTEP)

TB TREATMENT DRUG CONTAINS PRODUCT CODE 23
PYRAZINAMIDE TABLETS 750 mg

20 Millboard/Greyboard Boxes

Batch No:
Mfg. Date:
Exp. Date:

SCHEDULE H1 PRESCRIPTION DRUG – CAUTION
It is dangerous to take this preparation except in accordance with the medical advice.
Not to be sold by retail without the prescription of a Registered Medical Practitioner.

"NTEP Central Government Supply
NOT FOR SALE"

Manufacturer's Name
Manufacturing Lic. No.

4

Numbering of shipper packaging:

All 5 Ply Shippers should be numbered consecutively. Shipping documents should be included in the shipper numbered first (consignee wise).

C. 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 the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller; (d) meet the requirements of manufacturing legislation and regulation of pharmaceuticals in the country of origin; (e) are free from defects in workmanship and in materials and (f)) the product has been manufactured as per WHO GMP requirements.

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 records with regards to process validation demonstrating batch to batch consistency.
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 provide evidence of basis for expiration dating and stability data concerning the commercial final package upon request.

The test data for raw materials, in-process, finished product and packaging material testing must be on record for each lot shipped and must be made available to Purchaser's representatives when requested.
Details of samples lifted for testing (such as quantity of strips, Millboard/Greyboard boxes, batch no. etc.) should be pasted on packing of 5 Ply Shipper and records to this effect be also made available to the purchaser.

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.
The successful Bidder will also be required to provide the Purchaser with access to its manufacturing facilities to inspect its facilities, quality control procedures for raw materials, test methods, in-process tests, and finished dosage forms.

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 the product.

D. Storage:

As per applicable Pharmacopoeia.

E. Shelf Life:

Shelf life should be minimum 36 months from the date of manufacture.

At least 5/6th of the total stipulated shelf life must remain at the time of arrival at the consignee's warehouse. The supplier will provide manufacturer's stability test data substantiating the claimed shelf life in the proposed package. Not only the pharmaceuticals, but also the packaging components should also conform to specifications suitable for use in a climate prevailing in India. The product supplied should have been subjected to long term stability conditions as per below requirements:

Study	Storage condition
Long Term Stability	25 °C ± 2 °C/60% RH ± 5% RH or 30 °C ± 2 °C/65% RH ± 5% RH

F. Qualification of the Manufacturer:

The Bidder shall furnish a certificate from the competent Regulatory Authority that the manufacturer of the pharmaceutical product is licensed to manufacture these products. The manufacturing facility must conform to WHO-GMP standards.

G. Recalls:

If products must be recalled because of problems with product quality or adverse reactions to the drug, the Supplier will be obliged to notify the purchaser providing full details about the reason leading to the recall and shall take steps to replace the product in question at its own cost with a fresh batch of acceptable quality, or withdraw and give a full refund if the product has been taken off the market due to safety problems.

H. Colour Coding:

The labels on Blisters, Millboard/Greyboard Boxes and 5 Ply Shipper package shall be identified by white background.

I. Bar Coding

Bar coding shall be used for better inventory management. It shall be printed on the labels of Millboard / Greyboard Boxes and 5 Ply Shippers containing all requisite information as per the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, New Delhi orders pertaining to Bar Code labeling in drugs, vide letter dated 14 January 2019 or as modified from time to time by the competent / regulatory authority.

The important information which shall be incorporated in bar code is:

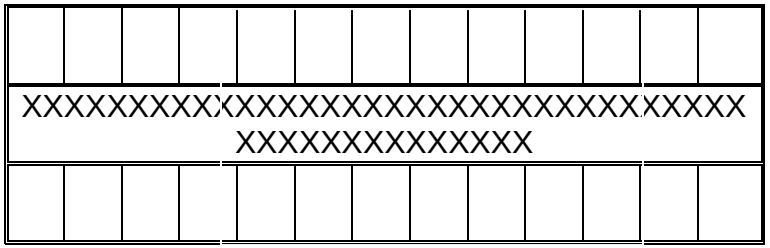
1) Product Name/content
2) Product Strength
3) Batch Number
4) Date of Manufacturing
5) Date of Expiry
6) Manufacturer Address
7) Manufacturer License number
8) Storage conditions requirement
9) Number of Tablets in a Blister Strip/ Millboard/Greyboard Boxes and 5 Ply Shipper

J. Packaging

The drug is initially packed in a Blister Strip each containing 10 tablets. 10 such strips would be further packed in white coloured Millboard/Grey board boxes and 20 such Boxes are ultimately packed in 5-Ply Shipper.
A strip consisting of individual blister of the drugs duly identified should be packed in an Aluminium-PVC blister pack. The blister should be tropicalized with regard to moisture barrier properties for drug stability under field conditions. Quality Assurance is according to Norm ISO 9001 for all the packaging material.
Aluminium-PVC Blister:

PVC Film: Transparent, clear /amber, food grade, blister forming PVC film, film gauge- 200microns, PE coating: 25 microns, PVdC coating: 60gsm.
Aluminium foil: Hard tempered Blister foil, VMCH coated,Thickness: 0.025mm.
Spacing between tablets should be enough so as to allow removal by patients with finger deformities.

Complex Constructions with PVC Films



TECHNICAL DATA FOR THE STANDARD COMPLEXES

Complex:

Rigid PVC film gauge (microns)	200	
PE coating (microns)		25
PVdC coating (gsm)	60	
Total weight (gsm)	356	
Complex gauge (mm)		0.280

Water Vapour Transmission Rate (W V T R):

Temperature	**Relative Humidity**	**gsm/24h**	**Vapour Transmission rate**	
			Thermoformed	**Not thermoformed**
(^{0}C)	**% RH**			
20	85	gsm/24 h	0.15	0.06
38	90	gsm/24 h	0.7	0.4

Shrinkage longitudinally

T = 140^{o}C, t = 20 min. (%)	5 – 6
Application temperature (^{0}C)	68 – 74

Millboard/ Grey board Box:

Each box shall contain 10 strips. The boxes shall be labelled and fabricated from 3 mm corrugated cardboard surrounded on inside and outside by tightly affixed millboard of at least 400 gsm. The style of top and bottom shall be tuck-in-flap.

5-Ply Shipper Package:

Each 5 Ply Shipper shall contain 20 millboard/greyboard boxes. The boxes shall be packed in weather resistant, triple walled, insulated, corrugated, RSC (Universal) type 5-ply Shippers, each ply having strength of minimum 150gsm. It should be fabricated from virgin quality 'A' grade kraft paper. The overall dimension of the carton should be such that the product does not get damaged during transportation and storage.
Each shipping carton when packed should weigh not more than 50 kg.

K. Markings

All containers and invoices must bear the name of the product, expiry dates of and appropriate storage conditions.

Millboard/Greyboard Box:
The Boxes shall be marked with the following information in a clearly legible manner which is acceptable to the Purchaser:

- Manufacturer's name and registered address
- Manufacturer's License number
- Batch number of the drug
- Number of Tablets/strips contained in the box
- Date of manufacture (month and year) of the drug
- Expiration date (month and year) of the drug
- Instructions for storage and handling
- Logo of DOTS
- Place of manufacture (Made in_____)

5 – Ply Shipper:

The following information shall be stenciled or labeled on 5 – Ply Shippers on all four sides in bold letters of at least **Arial font size 18** with waterproof indelible ink in a clearly legible manner which is acceptable to the Purchaser:

- Generic name of the product
- Batch number of the drug
- Date of manufacture of the drug (month and year)

- Expiration date of the drug (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 (if any)
- Contract number
- Number of Millboard/Greyboard Boxes contained in the carton (5 Ply Shipper)
- Gross weight of each carton (in kg)
- Instructions for storage and handling
- Logo of DOTS
- Place of manufacture (Made in____)

L. Documentation

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

M. Dimensions of the logos

MILLBOARD/GREYBOARD BOX

3.5x3cm 	**3.5x3cm** 

5 – Ply Shipper

5.5x4.7 cm 	**5.5x4.7 cm** 

Section VI: 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 despatch 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 'Capitalised 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 Contract	**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 **5.3 Change in its qualification criteria submitted in its bid in Form 4: Qualification Criteria - Compliance and its sub-form(s). 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. (b) The sale by the Procuring Entity in any country of the products produced by the Goods supplied by the contractor, and (c) 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, valid for the period as specified in SCC (for sixty days after the date of completion of all contractual obligations by the contractor including the shelf life/ warranty obligations). 2) The amount of Performance security shall be for an amount as indicated in SCC (@ 3% of the contract Price) 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 is drawn on any commercial bank in India, favouring the authority mentioned in SCC (b) Bank Guarantee issued by a commercial bank in India, in the prescribed form provided in Format 1.3. 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 availing 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 V 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** Deleted **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 Additional Conditions for Rate Contracts** If SCC/ Contracts stipulates explicitly that this is a "Rate Contract" for the supply of the Goods outlined in the Contract during the period therein specified, then the following additional Contract Conditions shall be applicable: **6.8.1 Quantity Contracted-for** 1) The Rate Contract is only a standing offer from the Contractor. Subject as hereinafter mentioned, no guarantee is given as to the number or quantity of the Goods which shall be ordered during the period of the rate contract.

	2) The Procuring Entity undertakes to place the supply orders for Goods detailed in the Contract at the terms and prices mentioned therein. 3) However, they reserve the right to obtain from any source any Goods referred to in the Contract to meet an emergency or for values less than the threshold specified in the Contract (Rs 1.5 - one and a half - Lakhs, if not specified) if the Procuring Entity is satisfied that the Contractor is not in a position to supply specific quantities of Goods within the period in which these are required. **6.8.2 Applicability of Fall Clause** GCC-clause 10.1.6 shall be expressly applicable to Rate Contracts. **6.8.3 Supply Orders and Deliveries** 1) Supply orders for obtaining supplies through the rate contract, incorporating a definite quantity of Goods along with all other required conditions following the rate contract terms, shall be issued by the Procuring Entity during the validity period of Rate Contract. 2) The Contract shall deliver the quantities thus ordered as per the terms and conditions of the Supply Order and the Rate Contract. 3) Procuring Entity is entitled to place supply orders up to the last day of the validity of the rate contract and, though supplies against such supply orders shall be affected beyond the validity period of the rate contract, all such supply shall be guided by the terms & conditions of the rate contract. **6.8.4** Deleted **6.8.5** Right to repeat competitive bidding 1) Procuring Entity reserves the right to undertake repeat competitive bidding through open/ advertised tenders on the same terms & conditions, including specifications during the validity period of existing valid R/Cs.

	2) In such cases, the existing R/C holders can bid, apart from the new eligible bidders, and equal and fair opportunity would be provided. 3) If the prices received are found lower than the existing R.C. prices, new R/Cs may be awarded at reduced prices. 4) Existing R/Cs at higher prices may be short-closed, giving adequate notice if they do not match such reduction in prices under the fall clause (GCC-clause 10.1.6). **6.8.6 Short-closing or Renegotiation of the Rate Contract** During the currency of the Rate Contract, the Procuring Entity can short-close the rate contract or renegotiate the price by serving a suitable notice of thirty days. **6.8.7 Renewal of Rate Contracts** In case it is not possible to conclude new rate contracts before the expiry of existing ones, due to some exceptional reasons, the existing rate contracts would be extended with identical terms, conditions etc., for a suitable period, with the consent of the rate contract holders. Rate contracts of the firms, who do not agree to such extension, shall be left out. The period of such extension would generally not be more than three months.
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 V 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) **At Pre-Dispatch stage:** 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 despatch 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. (b) **At Delivery Stage:** 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 consignees location. The samples will be collected from the consignees 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. 4) 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. 5) 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. 6) 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 prejudice to the Purchaser's right for alter Inspection at any other stage for whole/ part of supplies. The purchaser's decision in this regard shall be final. 7) 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: (i) Short Close the Purchase Order for entire quantity of batch (localised/ 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 (ii) Ask the supplier to replace the entire quantity of relevant batches (localised/ widespread, as the case may be), under its warranty obligation. or (iii) 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. (iv) 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. (iv) In addition, the FDA/ Drugs Control Authority of concerned State will be informed for initiating necessary action on the Tenderer in their state. (v) 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. 8) In case, supplier is asked to make replacement of rejected batches under its warranty obligations 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. 9) 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. 10) 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 would be claimed from the defaulting vendor. **7.2 Consequence of Rejection** 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: 1) 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.

	2) 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. 3) 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. 4) Deleted. **7.3 Inspections at the last moment** 1) If the contract stipulates pre-despatch 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. **7.4 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.
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 upto 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 V 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 despatch 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 despatch 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 despatch 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 procedure. **8.4.1 Distribution of Despatch Documents for Clearance/ Receipt of Goods** 3) The contractor shall send all the relevant despatch 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. Unless otherwise stipulated in the contract, the usual documents involved and the drill to be followed in general for this purpose are as follows: 4) Supplier will integrate with e- aushdhi 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. Bidders 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. 5) The contractor shall notify the Procuring Entity, consignee, and others concerned, if mentioned in the contract, the complete details of despatch 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) Generic name of the product b) Batch No. c) Pharmacopeial Reference and/ or In-house method d) Batch quantity

			e) Date of manufacture f) Expiry date g) Date of test h) Description 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) Product name b) Lot/Batch Number c) Date of manufacture d) Date of Expiry e) Manufacturer's name f) Number of samples tested g) Testing principle h) Information about reference used i) TESTING PROCEDURE-Sensitivity, Specificity etc j) Results k) report number l) Date of Analysis m) Designation and signature of analyst n) Authorized signatory of lab	

		The above mentioned batch shall be manufactured in accordance with the applicable GMP/QMS regulations.
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.	

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 5/6th (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 it has been signed by the Procuring Entity or the effective date mentioned in the contract, whichever is later. 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 IV – Schedule of Requirements. **9.4 Terms of Delivery** 1) Terms of delivery Is DDP Consignee site unless otherwise stipulated differently in Section IV – 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 despatch. If the contractor despatches 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 despatch regarding every instalment shall be made to the consignee and to the Procuring Entity immediately on despatch 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 instalment 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. **9.12 Liquidated 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 2½ % 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 subject to a maximum deduction of the 10% (or any other percentage if prescribed in the contract) of the delayed Goods' or incidental Works/ Services' 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** **10.1.1 Charged 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:-"* **10.2 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.

	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 GST rate during the original and extended delivery period.* *We certify that there has been reduction in the GST rate during the original and extended delivery period. Details of which are as under:* *We further confirm that we are passing the benefit of statutory reduction in duties to the purchaser. Accordingly, we have charged reduced GST rates of ..... %, as against GST rate of ....% mentioned in the contract."* *(Strike out which ever is not applicable)* 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) Unless otherwise stipulated in the SCC, payments to Contractors shall be made through EFT only. 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.

	2) The usual payment term is 100% on receipt 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) Undertaking for Statutory reduction in duties and taxes as per GCC 10.2.4 j) Undertaking that the contractor is agreeable to receive payment of goods by recovering liquidated damages for delayed supplies in accordance with the conditions of the contract. k) Such other documents as indicated in SCC 3) 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 have to mention e- aushadhi PO No. and tranche/ lot on the invoice. 4) 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. 5) 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. 6) 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. 7) 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. 8) Supplier will integrate with e- aushdhi 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. Bidders 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.

	9) No advance payments towards costs of items will be made to the Tenderer. **10.3.2 – Deleted.** **10.3.3 General Payment condition for payment** 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) Deleted. 5) 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 Organisation. Since conciliation is a voluntary process, within 30 days of receipt of "Notice of Conciliation", the Head of the Procuring Organisation 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 Organisation 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 years 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; Misdemeanours 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 Organisation from participation in Tender Processes. Failure to do so shall amount to a violation of this code of integrity. **13.3 Misdemeanours and Penalties** The following shall be considered misdemeanours - 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 misdemeanours: (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 misdemeanour, 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 misdemeanours: (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 Misdemeanours** 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 misdemeanour 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 misdemeanours 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 misdemeanours 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 VII: Special Conditions of Contract

Reference GCC Section	Description
GCC 2.4	The details of Procuring Entity and Contractor are as under: Procuring Entity - Contractor -
GCC 5.8	1. 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 INR 10 Crores of Rupees valid till expiry of Rate Contract Period i.e. till …… for its commitment to honour the purchase order issued under the Rate Contract. 2. Additionally, for each of the purchase order placed against the Rate Contract, within fourteen days of issue of purchase order, the contractor shall furnish to the Procuring Entity performance security for an amount equivalent to 3% of the value of purchase order inclusive of duties and taxes. valid for the period of sixty days after the date of completion of all contractual obligations by the contractor including the shelf life/ warranty obligations of the goods supplied.
GCC 6.8	The purchaser shall enter into Rate Contract agreement with the contractor for supply of goods for a period of one year.
GCC 7.1.6	The goods supplied under the contract shall be subjected to PDI at manufacturer's manufacturing premises before despatch.
GCC 8.7.5	The contractor shall ensure that at least $5/6^{th}$ of shelf-life remains balance on delivery date.

Section VIII- 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.'

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……. 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 16.09.2020 read with Department of Pharmaceutical Notification No. **31026/65/2020-MD dated 30.12.2020**. 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) **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 16.09.2020 read with Department of Pharmaceutical Notification No. **31026/65/2020-MD dated 30.12.2020**. 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 2: Schedule of Requirements – Compliance & Deviation

Schedule of Requirements

(Ref ITB-clause 9.2, Schedule VI: 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 IV: 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**	**Quantity**	**Units of Quantity**	**Local Content (%)**	**HSN Code**	**Bidder's GSTIN**
1	2	3	4	5	6	7
I						
II						
III						

We shall comply with, abide by, and accept without variation, deviation, or reservation all requirements detailed in Section IV: Schedule of 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 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]

□

Form 3: Technical Specifications and Quality Assurance – Compliance & Deviation

(Ref ITB-clause 9.2, Schedule VII: 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 VII: 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, 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 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: Relevant documents like technical data, literature, drawings, and other documents

Form 4: Qualification Criteria – Compliance & Deviation

(Ref ITB-clause 9.2, Schedule III 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 III: 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 3 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	2020-21						
Name of Purchaser with Contact Details	Purchase Order No and Date	Description of Goods	Unit	Qty.	Unit Price All Incl.	Total Value	Remarks
Financial Year	2021-22						
Name of Purchaser with Contact Details	Purchase Order No and Date	Description of Goods	Unit	Qty.	Unit Price All Incl.	Total Value	Remarks
Financial Year	2022-23						
Name of Purchaser with Contact Details	Purchase Order No and Date	Description of Goods	Unit	Qty.	Unit Price All Incl.	Total Value	Remarks

Copies of Purchase orders and e-way bills (Maximum 05 for each Purchase order- the ones pertaining to for large consignment) shall be submitted.

Note:

1. Proof for the manufacturing (BMR) / importing of the items quoted to be produced, if demanded.
2. Copies of purchase orders in support of performance statement may be uploaded along with this **Annexure-IV.**

Signature of Tenderer	Signature of Statutory Auditor
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.

Form 6: Check-List for Bidders

(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: This check-list is merely to help the bidders to prepare their bids, it does not over-ride or modify the requirement of the tender. Bidders must do their own due diligence also.

Sr	**Documents submitted, duly filled, signed**	**Yes/ No/ NA**
1.	Form 1.- bid Form (to serve as covering letter and declarations applicable for both the Techno-commercial bid and Financial bid)	
2.	Form 1.1: Bidder Information along with Power of attorney and Registration Certificates etc.	
2.a	Self-attested copy of Registration certificates etc. of the firm	
2.b	Self-attested copy of PAN	
2.c	Self-attested copy of GSTIN registration(s)	
2.d	Self-attested copy of Power of Attorney etc. authorizing signatories on stamp paper to sign the bid	
3.	Form 1.2: Eligibility Declarations, along with supporting documents	
3.a	Self-attested copy of Registration certificate for bidders/ subcontractors from restricted neighbouring countries	
3.b	Self-attested copy of MSME registration	
3.c	Self-attested copy of Start-up registration/ status	
3.d	Self-attested copy of the certificate of Local Supplier Status for Make in India policy, from auditors/ cost accountant in case of Tenders above Rs 10 Crore	
4.	Form 2: 'Schedule of Requirements - Compliance	
5.	Form 3: Technical Specifications and Quality Assurance - Compliance	
5.a	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	
6.	Form 4: Qualification Criteria – Compliance	

□

6.a	Documents Attached supporting the compliance to qualification criteria	
7.	Form 4.1: Performance Statement	
7.a	Documents/ contracts supporting the performance statement	
8.	Form 5: Terms and Conditions - Compliance	
9.	Form 6: This Checklist	
10.	Form 7/ 7A: Documents relating to Bid Security	
11.	Price Schedule (BOQ) Excel Sheet downloaded from the Portal filled and uploaded)	
12.	Any other requirements, if stipulated in bid document; or if considered relevant by the Bidder	

……..

(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, the bid must be supported by a Bid Securing Declaration in lieu of Bid Security.

We 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)**

[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……

Further more, 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: Contract Form

(Ref Clause 13.2.5 of ITB)

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

Contract No……. dated…….

To

Contractor [Write Name]

Unique GeM Supplier ID:…….

[Complete address of the contractor]

Subject: ----------

Ref: 1. *This office' Letter of Award (LoA) No…….. dated ……..*

2. This office Tender Document No. Tend No./ xxxx; Tender Title: GOODS, dated……. and subsequent Amendment No……., dated……. (If any). (Hereinafter referred to as 'the Tender Document')

3. Your Tender No…… dated…….. and subsequent communication(s)/ Revised Offer No…… dated …….. (If any), exchanged between you and this office in connection with this tender. (Hereinafter referred to as 'Your Offer')

Dear Sir/ Madam,

Your bid referred above, read with subsequent letters mentioned above, for the Goods stipulated in the Schedules annexed herewith, have been accepted. Terms and conditions in this Contract and the documents listed in the clause below shall apply.

2. Terms and conditions in the documents mentioned under Reference no: 1, 2 and 3 above (including General and Special Conditions of Contract) shall also be part of this contract.

Note: The words, expressions, definitions, and abbreviations used in this contract shall have the same meanings as are respectively assigned to them in the General Condition of Contract of 'the Tender Document'.

(Signature, name and address of [Procuring Entity]'s authorized official)

For and on behalf of…….

Received and accepted this contract ……..

(Signature, name, and address of the contractor's executive duly authorized to sign on behalf of the contractor)

For and on behalf of ……

(Name and address of the contractor)

…….

(Seal of the contractor)

Place:_____ Date:

□

Format 1.1: Bank Guarantee Format for Performance Security

(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 thereunder 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, 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:_____

□

Sample 1 of a BOQ (Item-rate BOQ from CPPP)

Validate Print Help tem Wise BoQ

Tender Inviting Authority: DG & CEO, CMSS

Name of Work:ONLINE TENDER FOR RATE CONTRACT FOR A PERIOD OF ONE YEAR FOR PROCUREMENT OF ANTI TB DRUGS FOR NTEP

Tender No: CMSS/PROC/2023-24/NTEP/003

Bidder Name :

PRICE SCHEDULE

(This BOQ template must not be modified/replaced by the bidder and the same should be uploaded after filling the relevent columns, else the bidder is liable to be rejected for this tender. Bidders are allowed to enter the Bidder Name and Values only)

NUMBER #	TEXT #	TEXT #	NUMBER #	TEXT #	TEXT	NUMBER #	NUMBER	NUMBER	NUMBER
Sl. No.	Name of the Item	Location	Tentative Quantity likely to be procured during RC period	Units	HSN Code	EX Works price per unit in Rs.	GST (In Rs.)	Transportation and any Other Charges in Rs. (Till Consignee Locations) on DDP basis, All Inclusive and firm & fixed	Total Unit Price With GST(In Rs.) (Col 7+ Col 8+Col 9)
1	2	3	4	5	6	7	8	9	10
1.01	Capsule Cycloserine 250mg	1. Section IV	15600400	Capsules					₹ 0.0000
1.02	Tablet Isoniazid 300mg	2. Section IV	6151700	Tablets					₹ 0.0000
1.03	Tablet Levofloxacin 250mg	3. Section IV	6589200	Tablets					₹ 0.0000
1.04	Tablet Levofloxacin 500mg	4. Section IV	6793900	Tablets					₹ 0.0000
1.05	Tablet Linezolid 600mg	5. Section IV	5299200	Tablets					₹ 0.0000
1.06	Tablet Pyrazinamide 500mg	6. Section IV	10194700	Tablets					₹ 0.0000
1.07	Tablet Pyrazinamide 750mg	7. Section IV	6494800	Tablets					₹ 0.0000