ONLINE TENDER
FOR PROCUREMENT OF CONTRACEPTIVES FOR FAMILY PLANNING (FP)

Tender No: CMSS/PROC/2025-26/FP/017
(National Competitive Bidding)
(FOR CLASS-I 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: www.cmss.gov.in, email- dgceocmss@cmss.gov.in, anujprakash@cmss.gov.in, agmproc4@cmss.gov.in

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Notice Inviting Tender (NIT)

CENTRAL MEDICAL SERVICES SOCIETY

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NOTICE INVITING E-TENDER
(E-PROCUREMENT)
Tender No- CMSS/PROC/2025-26/FP/017, Dated 04th July 2025

1. The Central Medical Services Society, an autonomous body under Ministry of Health and Family welfare, Government of India, invites online tenders in prescribed format on GeM Portal, from eligible and qualified tenderers for supply of following goods for Family Planning Program:

Schedule No.	Name of Item	Quantity to be Procured	Unit of Measurement	EMD in Rs. for 100% quoted quantity	EMD in Rs. for 50% quoted quantity
I	Condoms (Free Supply)	19,76,98,750	Pieces	74,73,013	37,36,506
II	OCP (Free Supply)	3,05,35,200	Packet	48,73,418	24,36,709
III	Emergency Contraceptives Pills (ECP)	46,09,350	Packet	2,47,983	1,23,992
IV	Pregnancy Test Kit	1,50,50,700	Pack	10,32,478	5,16,239
V	Injectable Contraceptive (Antara)	39,82,000	Doses	28,11,292	14,05,646
VI	IUCD 380A	26,52,750	Pieces	19,44,996	9,72,498
VII	IUCD 375	20,10,150	Pieces	13,22,679	6,61,339
VIII	Tubal Rings	9,52,200	Pairs	4,10,779	2,05,390

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 19th July, 2024). 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 GeM portal for download	04/07/2025
(b)	Last date and time for receipt of pre-bid queries, if any	09/07/2025 till 05:00 PM
(c)	Pre-bid meeting date, time and venue	09/07/2025 at 11:00 AM Venue- Conference Hall, CMSS HQ New Delhi
(d)	Last date and time for bid submission	28/07/2025 at 03:00 PM
(e)	Last date and time for submission of original documents	28/07/2025 at 03:00 PM
(f)	Date and time for tender opening (technical bid)	28/07/2025 at 03:30 PM

3. Further details of the NIT along with the terms and conditions, tender document, other specification and Corrigendum (if any) can be published and downloaded from the GeM portal www.gem.gov.in.

04/07/2025 **DG&CEO**

SECTION II: INSTRUCTIONS TO BIDDERS (ITB)

1. Scope of Bid	**1.1 Scope of Bid** Purchaser as defined in Bid Data Sheet invites bid for supply of goods as stipulated in "Schedule of Requirement" conforming to specification as indicated in the "Technical Specification and Quality Assurance" and as per terms and conditions as indicated in GCC (General Condition of contract) read with SCC (Special Condition of Contract). The Bids should be submitted as per instruction given below and in the prescribed bidding forms. **1.2 Interpretations, Definitions, Abbreviations and Document Conventions** General Conditions of Contract (GCC), details Tenets of interpretation (GCC-clause 1.1), Definitions (GCC-clause 1.2), Document conventions (GCC-clause 1.3) and Abbreviations (GCC-clause 1.4), which shall also apply to the rest of the Tender Document.
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 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 fulfill the eligibility criteria detailed in this bid document. Bidder should meet (as on the date of his bid submission and should continue to meet till the award of the contract) the 'Eligibility Criteria' detailed in this bid document. Bidder shall submit a declaration about the 'Eligibility Criteria' compliance in Form 1.2 – Eligibility Declarations. **3.2 Eligibility of bidders from specified countries** Entities having beneficial ownership in land border sharing countries, as defined in Department of Expenditure Order No. F.7/10/2021-PPD dated 23.02.2023, as amended from time to time, shall be eligible to bid only if they are registered with competent authority in accordance with the provisions of the Order. **3.3 Conflict of Interest -** Any bidder having a conflict of interest, which substantially affects fair competition, shall not be eligible to bid in this tender. Bids found to have a conflict of interest shall be rejected as nonresponsive. Bidder shall be required to declare the absence of such conflict of interest in Form 1.2 - Eligibility Declarations. A bidder in this Tender Process shall be considered to have a conflict of interest if the bidder:

	1. directly or indirectly controls, is controlled by or is under common control with another Bidder; or 2. receives or have received any direct or indirect subsidy/ financial stake from another bidder; or 3. has the same legal representative as another bidder for purposes of this bid; or 4. has a relationship with another bidder, directly or through common third parties, that puts it in a position to have access to information about or influence the bid of another Bidder or influence the decisions of the Procuring Entity regarding this Tender process; or 5. Participates in more than one bid in this tender process. Participation in any capacity by a Bidder (including the participation of a Bidder as sub-contractor in another bid or vice-versa) in more than one bid shall result in the disqualification of all bids in which he is a party. However, this does not limit the participation of a non-bidder firm as a sub-contractor in more than one bid; or 6. would be providing goods, works, or non-consulting services resulting from or directly related to consulting services that it provided (or were provided by any affiliate that directly or indirectly controls, is controlled by, or is under common control with that firm), for the procurement planning (inter-alia preparation of feasibility/ cost estimates/ Detailed Project Report (DPR), design/ technical specifications, terms of reference (ToR) / Activity Schedule/ schedule of requirements or the Tender Document etc) of this Tender process; or 7. has a close business or family relationship with a staff of the Procuring Organization who: (i) are directly or indirectly involved in the preparation of the Tender document or specifications of the Tender Process, and/or the evaluation of bids; or (ii) would be involved in the implementation or supervision of resulting Contract unless the conflict stemming from such relationship has been resolved in a manner acceptable to the Procuring Entity throughout the Tender process and execution of the Contract. 3.4 **Eligibility of Distributors/ Agents/ Resellers –** Unless otherwise stipulated in Bid Data Sheet, only manufacturers of the quoted items are authorized to participate in this bid. Distributors/ Agents/ Resellers are not eligible to bid **3.5 Eligibility of Class-I/ Class-II/ Non-local Suppliers -** As detailed in Bid Data Sheet.

	1. **Minimum local content requirement for bidder's** classification as Class-I/ Class-II local Suppliers shall be as detailed in Bid Data Sheet. 2. The 'Class-I local Supplier'/ 'Class-II local Supplier' at the time of tender, bidding, or solicitation are required to indicate the percentage of local content and provide self-certification that the item offered meets the local content requirement for 'Class-I local Supplier'/ 'Class-II local Supplier' as the case may be. In cases of procurement for a tender value above Rs. 10 crores, the 'Class-I local Supplier'/ 'Class-II local Supplier' shall be required to provide a certificate, in the prescribed format, from the statutory auditor or cost auditor of the company (in the case of companies) OR from a practicing cost accountant or practicing chartered accountant (in respect of suppliers other than companies) giving the percentage of local content. Bids with false declarations regarding Local contents shall be rejected as responsive, in addition to punitive actions under the MII orders and for violating the Code of Integrity as per the Tender Document. 3. Failure to comply with declared local content shall attract penalty as prescribed in GCC 10.1.7 **3.6 Eligibility of Non-MSE entities** (MSE means Micro and Small Enterprises) **-** As detailed in Bid Data Sheet. **3.7 Debarred/ black listed bidders –** In accordance with DoE guidelines vide OM No F.1/20/2018/PPD dt. 02.11.2021, the bidder should not be debarred, in general or for the goods tendered, by CMSS, MoH&FW and DoE on the date of tender opening and on the date of award of contract. Aforesaid debarred bidders are not eligible to bid. **3.8 Qualification Criteria** – Only the bidders, who meet the qualification criteria as detailed in Section IV of the bid document shall be considered for award of contract. Bidders are required to submit supporting documents, as indicated in Section IV "Qualification Criteria".
4. Purchase Preference Policies of the Government	**4.1 Support to local manufacturers** Policies of the Government to support local manufacturers shall apply to this procurement. Accordingly, the provisions of Public Procurement (Preference to Make in India) Order 2017 dated 19.07.2024, as amended from time to time, shall apply to this procurement. In accordance with aforesaid provisions: 1. If the nodal Ministry has notified the item as having sufficient local capacity and competition, and to be procured exclusively from Class-

I local suppliers, under Para 3(a) of PPP-MII Order, only Class-I local suppliers shall be eligible to submit a bid and be considered.

2. If the item is not reserved for procurement exclusively from Class-I local suppliers and if Class-II/ Non-local suppliers are also eligible to participate in the tender, as per ITB 3.5, purchase preference shall be given to Class-I local suppliers over Class-II/ Non-local suppliers provided its quoted rates fall within 20% margin of purchase preference, in accordance with PPP-MII Order dated 19.07.2024.

   The 'Class-I local Supplier'/ 'Class-II local Supplier' availing aforesaid benefit are required to indicate at the time of tender, bidding, or solicitation the percentage of local content and provide self-certification that the item offered meets the local content requirement for 'Class-I local Supplier'/ 'Class-II local Supplier', as the case may be. In cases of procurement for a tender value above Rs. 10 crores, the 'Class-I local Supplier'/ 'Class-II local Supplier' shall be required to provide a certificate, in the prescribed format, from the statutory auditor or cost auditor of the company (in the case of companies) OR from a practicing cost accountant or practicing chartered accountant (in respect of suppliers other than companies) giving the percentage of local content. Bids with false declarations regarding Local contents shall be rejected as responsive, in addition to punitive actions under the MII orders and for violating the Code of Integrity as per the Tender Document.

4.2 Support to MSEs

Policies of the Government to support Micro and Small Industries shall apply to this procurement. Accordingly, the provisions of M/o MSME Public Procurement Policy for the Micro and Small Enterprises (MSEs) Order, 2012, as amended from time to time shall apply to this procurement. In accordance with aforesaid provisions:

1. MSEs shall be exempted from payment of Earnest Money. They shall be required only to submit Bid Securing Declaration.
2. If the item is reserved for exclusive purchase from Micro and Small Enterprises (MSEs) as per the Public Procurement Policy for the Micro and Small Enterprises Order, 2012, only MSEs shall be eligible to submit a bid and be considered.
3. If the item is not reserved for procurement exclusively from MSEs and if Medium/ Large enterprises are also eligible to participate in the tender, purchase preference shall be given to MSEs over Medium/ Large enterprises provided its quoted

	rates fall within 15% margin of purchase preference, in accordance with Public Procurement Policy for the Micro and Small Enterprises (MSEs) Order, 2012. 4. Relaxation in Prior Turnover and Experience: The prior turnover and prior experience requirement for MSEs enterprises shall be as indicated in Qualification Criteria/ Section IV. 5. In accordance with M/o MSME Gazette Notification No S.O. 2119 (E) dt. 26th June 2020, " In case of reverse-graduation of an enterprise, whether as a result of re-classification or due to actual changes in investment in plant and machinery or equipment or turnover or both, and whether the enterprise is registered under the Act or not, the enterprise will continue in its present category till the closure of the financial year and it will be given the benefit of the changed status only with effect from 1st April of the financial year following the year in which such change took place." 6. In accordance with M/o MSME Gazette Notification No S.O. 4926 (E) dt. 18th October 2022, "In case of an upward change in terms of investment in plant and machinery or equipment or turnover or both, and consequent re-classification, an enterprise shall continue to avail of all non - tax benefits of the category (micro or small or medium) it was in before the re-classification, for a period of three years from the date of such upward change." MSEs interested in availing aforesaid benefits must enclose in Form 1.2 with their offer the Udhyam Registration Certificate with the Udhyam Registration Number as proof of their being MSE registered on the Udhyam Registration Portal. The certificate should be valid on the date of bid submission. **4.3 Support to Start-up Enterprises** - Policies of the Government to support Start-ups shall apply to this procurement. Accordingly, in accordance with Department of Expenditure OM No F.20\212014-PPD dated 25.07.2016 and its subsequent clarifications: 1. **Exemption from submission of Bid Security:** DPIIT registered Start-ups shall be exempted from payment of Earnest Money. They shall be required only to submit Bid Securing Declaration.

	2. Relaxation in Prior Turnover and Experience: The prior turnover and prior experience requirement for DPIIT registered start-up enterprises shall be as indicated in Qualification Criteria/ Section IV. **4.4** The guidelines regarding concurrent applicability of "Public Procurement (Preference to Make in India) Order 2017" and "Public Procurement Policy for the Micro and Small Enterprises (MSEs) Order, 2012" for simultaneous purchase preference to both Class-I local suppliers and MSE suppliers are detailed as under: 1. The applicability of "Public Procurement Policy for MSEs Order 2012" (PPP MSE Order) and "Public Procurement (Preference to Make in India) Order 2017" (PPP-MII Order) in various scenarios, involving simultaneous purchase preference to MSEs and Class-I local suppliers respectively, shall be in accordance with Department of Expenditure OM No. F.1/4/2021-PPD dated 18.05.2023 read with "Public Procurement (Preference to Make in India) Order 2017" and "Public Procurement Policy for the Micro and Small Enterprises (MSEs) Order, 2012", as amended till date.
5. The Goods, Eligible Goods and Basis of Evaluation	**5.1 Eligible Goods –Origin and Minimum Local Content** Unless otherwise stipulated in the Tender Document, all 'Goods' and 'incidental Works/ Service' to be supplied under the contract must conform to i) restrictions on certain countries with land-borders with India (ITB-clause 3.2; ii) minimum local content (Make in India Policy (ITB-clause 3.5 and 4.1); iii) Procurement Policy for the Micro and Small Enterprises (MSEs) Order, 2012 (ITB-clause 3.6 and 4.2). If Bidder avails benefits under any preferential policy as Class-I Local Supplier or as MSE or Start-up enterprise, the Goods must not circumvent the provisions relating to such benefits. **5.2 Basis of Evaluation for Schedules** 5.2.1 Unless otherwise stipulated in Bid data sheet, if there is more than one schedule in Section V: Schedule of Requirements, evaluation of financial ranking of bids shall be done separately for each schedule, and Bidder has the option to submit its quotation for any one or more schedules. 5.2.2 Bidder shall submit bid for minimum 50% of the scheduled quantity, unless otherwise defined in the bid data sheet.

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

2. The prices in the corresponding price schedule shall be entered separately in the following manner:

a. The price of the Goods quoted ex-factory, ex-showroom, ex-warehouse or off-the-shelf, as applicable, shall be assumed to include all taxes and duties like GST, customs duty, etc. already paid or payable on the components and raw material used in the manufacture or assembly of the Goods.

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

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

6.1.4 Price Schedule

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

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

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

6.1.5 Provisions of GST

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

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

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

6.1.6 Currencies of Bid and Payment

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

6.1.7 Non-compliance

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

6.2.2 Firm/ Variable Price

1. Firm Price

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

6.2.3 Exchange Rate Variation- Deleted

6.3 Goods and Services Tax (GST)

6.3.1 GST Registration Status:

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

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

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

3. Composition scheme:

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

4. Exemption from Registration:

If a bidder is not liable to take GST registration, i.e., having turnover below threshold, he shall submit undertaking/ indemnification against tax liability. Bidder claiming exemption in this respect shall submit a valid certificate from practising Chartered Accountant (CA)/ Cost Accountant with Unique Document Identification Number (DIN) to the effect that Bidder fulfils all conditions prescribed in notification exempting him from registration. Such bidder/ dealer shall not charge any GST and/ or GST Cess in the bill/ invoice. In such case, applicable GST shall be deposited under Reverse Charge

Mechanism (RCM) or otherwise as per GST Act by the Procuring Entity directly to concerned authorities. Bidder should note that his offer would be loaded with the payable GST under the RCM. Further, Bidder should notify and submit to the Procuring Entity within 15 days from the date of becoming liable to registration under GST.

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

S No.	LOCATION	STATE	GSTIN	Address
1	AGARTALA	TRIPURA	16AABAC6275F1ZV	CMSS, CWC Complex, Hapania, Near ONGC complex, Opposite of Satsangha Ashram, Agartala, Tripura Pin-799014
2	AHMEDABAD	GUJRAT	24AABAC6275F1ZY	CMSS, Central warehousing corporation premises, Opposite P&T Colony, Teen Batti Road, Near Shahalam Gate, Shahalam, Ahmedabad, Gujarat Pin- 380028
3	BANGLORE	KARNATAKA	29AABAC6275F1ZO	CMSS, Ministry of Health &

					Family Welfare, Central warehousing corporation premises, APMC Yard, Yeshwanthapur, Bangalore, Pin- 560 022
	4	BHOPAL	MADHYA PRADESH	23AABAC6275F1Z0	CMSS, Central warehousing corporation premises, Godown no. 1A, Near railway cabin no. 3, Chhola road, Nishatpura, District: Bhopal Pin-462 010. Landline No. 0755-2508050
	5	BHUBANESWAR-JAJPUR	ODISHA	21AABAC6275F1Z4	CMSS, 326, Khata No-456/948 Mouza-Johal, PO/PS-PAHALA, District – Khurda, Bhubanesw

					ar, 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- 781031
	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 Warehousin

					g Corporation, GN. 01, Regional Office Mumbai, Sector-20, NR, Turbe RLY Station, Vashi - Navi Mumbai-400703 Landline No. 022-27830009.
	14	PATNA	BIHAR	10AABAC6275F1Z7	CMSS C/O-Central Warehousing Corporation, Katra Bazar, Bazar Samiti, Patna City Pin - 800008.
	15	RAIPUR	CHHATISGARH	22AABAC6275F1Z2	CMSS, C/O-Central Warehousing Corporation, Near Harish Petrol Pump, Rauabhata, Birgaon, Raipur, Pin-493221

	16	RANCHI	JHARKHAND	20AABAC6275F1Z6	CMSS C/O-Central Warehousing Corporation, Near OTC ground, Ranchi, Pin no. 834005
	17	TRIVANDRUM	KERAL	32AABAC6275F1Z1	CMSS C/O-Central Warehousing Corporation Kinfra Aplarel Park Menamkulam, Trivandrum Kerala Pin-695586 Landline No. 0471-2704470
	18	ZIRAKHPUR	PUNJAB	03AABAC6275F1Z2	CMSS, Ground Floor, Warehouse No. B014/3433, Godown Area. 35 Feet Road, Village Bhabat, Thana Zirakpur, SAS NAGAR, Punjab Pin-140603

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

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

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

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

6.3.2 HSN Code and GST Rate:

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. No, separate communication shall be sent by procuring entity to the bidders regarding corrigendum/addendum. Any corrigendum or addendum thus issued shall be considered a part of the Tender Document. To give reasonable time to the prospective bidders to take such corrigendum/ addendum into account in preparing their bids, the Procuring Entity may suitably extend the deadline for the bid submission, as necessary. After the procuring entity makes such modifications, any Bidder who has submitted his bid in response to the original invitation shall have the opportunity to either withdraw his bid or re-submit his bid superseding the original bid within the extended time of submission as per ITB-clause 10.4.1 below. **7.3 Clarification on the Tender Document** A Bidder may seek clarification of the Tender Document from Office/ Contact Person/ e-procurement Help Desk as mentioned in BDS, provided

	the clarifications are raised before the clarification end date mentioned in BDS (or if not mentioned, within 7 days before the deadline for the bid submission). The Procuring Entity shall respond within 5 working days of receipt of such a request for clarification. The query and clarification shall be shared on the portal with all the prospective bidders. No separate communication shall be sent to the bidders. Accordingly, bidders are advised to regularly visit the portal for any update. Any modification of the Tender Document that may become necessary due to the clarification shall be made by the Procuring Entity through an Addendum/ Corrigendum issue under the sub-clause above.
8. Pre-bid Conference	1. Prospective bidders interested in participating in this tender may attend a Pre-bid conference to clarify techno-commercial conditions of the Tenders at the venue, date and time specified in Bid Data Sheet. Participation in the Pre-bid conference is restricted to prospective bidders who have downloaded the Tender Document. 2. Participation is not mandatory. However, if a bidder chooses not to (or fails to) participate in the Pre-bid conference or does not submit a written query, it shall be assumed that they have no issues regarding the techno/ commercial conditions. 3. The date and time by which the written queries for the Pre-bid must reach the authority and the last date for registration for participation in the Pre-bid conference are also mentioned in the Bid Data Sheet. If the dates are not mentioned, such date and time shall be 7 days before the date and time of the pre-bid conference. 4. Delegates participating in the Pre-bid conference must provide a photo identity and an "Authorization for attending a Pre-bid Conference" from their Company/ principals; else, they shall not be allowed to participate. The pre-bid conference may also be held online at the discretion of the Procuring Entity. 5. After the Pre-bid conference, Minutes of the Pre-bid conference shall be published on the Procuring Entity's portal. If required, a clarification letter and corrigendum to Tender Document shall be issued, containing amendments of various provisions of the Tender Document, which shall form part of the Tender Document. As per ITB-clause para under 7.2 above, to give reasonable time to the prospective bidders to take such clarifications into account in preparing their bids, the Procuring Entity may suitably extend, as necessary, the deadline for the bid submission. 6. No separate communication shall be sent to the prospective bidders regarding their pre-bid queries/ any other clarification. Purchaser's response to the queries/ clarifications shall be uploaded only on the

	portal. Accordingly, bidders are advised to regularly visit the portal for any update.
9. Preparation of Bids	**9.1 The bid** **9.1.1 Language of the bid** The bid submitted by Bidder and all subsequent correspondence and documents relating to the bid exchanged between Bidder and the Procuring Entity shall be written in English Language. However, the language of any printed literature furnished by Bidder in connection with its bid may be written in any other language provided a translation accompanies the same in the bid language. For purposes of interpretation of the bid, translation in the language of the bid shall prevail. **9.1.2 Acquaintance with Local Conditions and Factors** The Bidder, at his own cost, responsibility, and risk, is encouraged to visit, examine, and familiarize himself with all the site/ local conditions and factors. The Bidder acknowledges that before the submission of the bid, he has, after a complete and careful examination, made an independent evaluation of the Site/ local conditions, the legal, environmental, infrastructure, logistics, communications and any other conditions or factors of which would have any effect on the price to be quoted by him or affecting performance/ completion of the contract. Bidders shall themselves be responsible for compliance with Rules, Regulations, Laws and Acts in force from time to time at relevant places. On such matters, the Procuring Entity shall have no responsibility and shall not entertain any request from the bidders in these regards. **9.1.3 Cost of Bidding** The Bidder(s) shall bear all direct or consequential costs, losses and expenditure associated with or relating to the preparation, submission, and subsequent processing of their Bids, including but not limited to preparation, copying, postage, delivery fees, expenses associated with any submission of samples, demonstrations, or presentations which the Procuring Entity may require, or any other costs incurred in connection with or relating to their Bids. All such costs, losses and expenses shall remain with the Bidder(s), and the Procuring Entity shall not be liable in any manner whatsoever for the same or any other costs, losses and expenses incurred by a Bidder(s) for participation in the Tender Process, regardless of the conduct or outcome of the Tender Process. **9.1.4 Interpretation of Provisions of the Tender Document** The provisions in the Tender Document must be interpreted in the context in which these appear. Any interpretation of these provisions far removed from such context or other contrived or in between-the-lines interpretation is unacceptable.

9.1.5 Quote Quantities/ Prices in both Numerals and Words

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

9.1.6 Alternative Bids not Allowed

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

9.2 Documents comprising the bid:

9.2.1 Techno-commercial bid/ Cover

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

1. Form 7: Documents relating to Bid Security: Scanned copy of Bid Securing Declaration (applicable for MSEs and Startups)/ EMD (applicable for all other bidders i.e. other than MSEs and Startups), as applicable, is to be uploaded along with electronic bid. Also, the original EMD documents (if applicable) are to be deposited with the Tender Inviting Authority within timelines as prescribed in the Bid Data Sheet. Failure to upload scanned copy of bid securing declaration / EMD and/or to deposit the original EMD document by the specified date and time shall result in summarily rejection of bid. Format of Bid Security Declaration and EMD Bank Guarantee shall be as under;
   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 Auditor or Cost Auditor for Companies/ Cost or Chartered Accountant for others for purchases above Rs. 10 Crore. d. Form 1.4: Integrity Pact duly signed by the bidder. **3.** Form 4: 'Qualification Criteria – Compliance and Deviations': Unless otherwise stipulated in Bid Data Sheet; Following documentary evidence to establish the Bidder's qualifications as stipulated in Section IV: Qualification Criteria, apart from any other document listed explicitly in the bid document may also be attached. a. Valid Manufacturing license b. Valid WHO GMP Certificate c. Valid COPP Certificate d. Market Standing Certificate for last 02 years e. Non-Conviction Certificate for last 02 years f. Certificate of Annual Production Capacity g. Performance Statement in support of having supplied same or similar items in the past in the Form 4.1 h. Annual Turnover Statement of previous years in the Form 4.2 i. Audited Annual Reports of previous years j. Any other document stipulated in Section -IV: "Qualification Criteria"/ Bid document. **4.** Form 2: Schedule of Requirements – Compliance and Deviation: Bidders should fill this form to detail the Schedules of Goods offered by them, maintaining the same numbering and structure. They may add additional details not covered elsewhere in their bid. They should highlight here any deviations/ exceptions/ reservations regarding Section V: 'Schedule of Requirements' in tabular format. Even in case of no deviation, please fill in confirmations and nil deviation statements. If mentioned

	elsewhere in the bid, such deviations shall not be recognized and shall be null and void. **5.** Form 3 - Technical Specifications and Quality Assurance – Compliance and Deviation: Bidder is required to provide clause by clause compliance/ deviation Statement in a tabular form relating to all parameters of Technical Specifications, Quality Assurance. Even in case of no deviation, please fill in confirmations and nil deviation statements. If mentioned elsewhere in the bid, such deviations shall not be recognized and shall be null and void. Unless otherwise stipulated in Bid Data Sheet; Bidder shall upload following documents with the compliance statement, along with any other supporting documents explicitly stipulated in bid documents: i. Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life as per technical specification requirement and it should be for the same manufacturing premises from which quoted goods have been offered for supply. However, for the drugs recently introduced in the county (i.e. if the time period from the date of introduction of drug in the country to the tender opening date is less than shelf life of the drug), the requirement for Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life shall be waived off. Point no (iii) shall be applicable. ii. Only for the drugs introduced in Indian Pharmacopoeia in the recent past (i.e. if the time period from the date of introduction of drug in Indian Pharmacopoeia to the tender opening date is less than shelf life of the drug), Long Term (Real Time) Stability Data for previously approved Pharmacopoeia or In-house Standards shall be accepted, as the case may be. iii. Accelerated Stability data for a period of 6 months in specified packing for at least 3 batches and available long term (Real Time) stability data as available for the quoted product shall be submitted. iv. Certificate of Analysis of one batch of the quoted product should be submitted. Latest version of IP (2022) shall be referred. a. Any other document as stipulated in the Section VI: "Technical Specifications and Quality Assurance"/ Bid document.

	6. Form 5 - Terms and Conditions – Compliance and Deviation: Bidder must comply with the entire commercial and other clauses of this Tender Document. Any deviations should be listed in a tabular form without ambiguity or conditionality. Even in case of no deviation, please fill in confirmations and nil deviation statements. If mentioned elsewhere in the bid, such deviations shall not be recognized and shall be null and void. **7.** Form 6- Bidder must upload the Bid Summary in the format as prescribed in Form 6 of the bid document to confirm that he has complied with all the instructions in the Tender Document, and nothing is inadvertently left out. This summary is only for general guidance and may not be comprehensive, and does not absolve Bidder from complying with all the requirements stipulated elsewhere in the Tender Document. **8.** Any other format/ form, not covered above but part of bid document/ considered relevant by the bidder **9.2.2 Financial bid/ Cover** "Financial bid" shall comprise the Price Schedule (To be submitted separately as an excel sheet) considering all financially relevant details, including Taxes and Duties as per ITB-clause 6.3. No additional technical details, which have not been brought out in the Technical bid shall be brought out in the Financial bid. **9.3 Bid Validity** 1. Unless specified to the contrary in the BDS, Bids shall remain valid for a period not less than 150 days from the deadline for the bid Opening stipulated in BDS. A bid valid for a shorter period shall be rejected as nonresponsive. 2. In case the day upto which the bids are to remain valid falls on/ subsequently declared a holiday or closed day for the Procuring Entity, the bid validity shall automatically be deemed to be extended upto the next working day. 3. In exceptional circumstances, before the expiry of the original time limit, the Procuring Entity may request the bidders to extend the validity period for a specified additional period. The request and the bidders' responses shall be made in writing or electronically. A bidder may agree to or reject the request. A bidder who has agreed to the Procuring Entity's request for extension of bid validity, in no case, he shall be permitted to modify his bid.

9.4 Bid Security - Related Documents

1. Bidders shall submit Earnest Money Deposit (EMD) for the amount as indicated in **Bid Data Sheet**.

2. The EMD shall be paid by Account payee Demand Draft/ Fixed Deposit Receipt/ Banker's Cheque /Bank Guarantee or RTGS/NEFT/Insurance Surety Bonds.

3. For EMD fund transfer, purchaser's bank account details are as under:
   Beneficiary Name: Central Medical Services Society
   A/C No. : 50100729160644
   Bank Name: HDFC Bank
   Branch: SAFDARJUNG ENCLAVE-DEER PARK, New Delhi
   IFSC Code: HDFC0000503

4. EMD Bank Guarantee format is given in **Section – IX/ Form: 7A**. The name of beneficiary in Bank Guarantee shall be **Central Medical Services Society**.EMD shall remain valid for 45 days beyond the validity period for the bid and will be extended accordingly beyond any extension subsequently requested by purchaser. The Bank guarantee shall be issued by a Commercial bank in India to make it enforceable and acceptable to the purchaser.

5. Offers of the firms submitted without EMD / EMD for a shorter period/EMD for an amount lesser than the amount as demanded will summarily rejected.

6. The EMD will be forfeited, if the bidder withdraws or amends, impairs or derogates from the tender in any respect within the period of validity of his Tender

7. The EMD will be refunded to the successful bidder/s within 30 days from the date of signing the contract agreement and on the deposit of the Performance Security.

8. The EMD furnished by all unsuccessful tenderers will be returned as early as possible after the expiration of the period of

	tender validity but not later than 30 days of the award of the contract. 9. For bidders falling in the category of MSEs and Startup, EMD requirement has been waived off as detailed in ITB Section 4.2 and 4.3 respectively. In lieu of Bid Security, such Bidders shall furnish Bid Securing Declaration (BSD) as Form 7: The BSD is required to protect the Procuring Entity against the risk of the Bidder's unwarranted conduct as amplified under the sub-clause below. a) The BSD provides for automatic suspension of the Bidder from being eligible for bidding in any tender in Ministry/ Department of Procuring Organisation for 2 years from the date of such enforcement. This declaration shall stand enforced if Bidder breaches the following obligation(s) under the tender conditions: i. withdraws or amends his bid or impairs or derogates from the bid in any respect within the period of validity of its bid; or ii. after having been notified within the period of bid validity of the acceptance of his bid by the Procuring Entity: iii. refuses to or fails to submit the original documents for scrutiny or the required Performance Security within the stipulated time as per the conditions of the Tender Document. iv. fails or refuses to sign the contract. 10. Unsuccessful Bidders' Bid-Securing Declaration shall expire, if the contract is not awarded to them, upon: a) receipt by Bidder of the Procuring Entity's notification i. of cancellation of the entire tender process or rejection of all bids or ii. of the name of the successful bidder or b) forty-five days after the expiration of the bid validity or any extension thereof 11. The bid-Securing Declaration of the successful bidder shall stand expired only when Bidder has furnished the required Performance Security and signed the Agreement. **9.5 Non-compliance with these provisions** Bids are liable to be rejected as nonresponsive if a Bidder:

	1. fails to provide and/ or comply with the required information, instructions etc., incorporated in the Tender Document or gives evasive information/ reply against any such stipulations. 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 6 below). In the case of downloaded documents, Bidder must not make any changes to the contents of the documents while uploading, except for filling the required information – otherwise, the bid shall be rejected as nonresponsive. 2. Bids shall be received only *Online* on or before the deadline for the bid submission as notified in BDS. 3. Only one copy of the bid can be uploaded, and Bidder shall digitally sign all statements, documents, certificates uploaded by him, owning sole and complete responsibility for their correctness/ authenticity as per the provisions of the IT Act 2000 as amended from time to time. 4. Bidder need not sign or up-load the Bid documents above while uploading his bid unless otherwise instructed in the Tender Document. It is assumed that Bidder commits itself to comply with all the Sections and documents uploaded by the Tender Inviting Officer. 5. Bidder must upload scanned copies of originals (or self-attested copies of originals – as specified). Uploaded Pdf documents should not be password protected. Bidder should ensure the clarity/ legibility of the scanned documents uploaded by him. 6. If stipulated in the BDS, copies/ originals of such specified uploaded scanned documents must also be physically submitted

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

	12. Bid submitted through modalities other than those stipulated in BDS shall be liable to be rejected as nonresponsive. **10.3.2 Implied acceptance of procedures by Bidders** Submission of bid in response to the Tender Document is deemed to be acceptance of the e-Procurement and tender procedures and conditions of the Tender Document. **10.3.3 Late Bids** The bidder shall not be able to submit his bid after the expiry of the deadline for the bid submission (as per server time). Therefore, in eProcurement, a situation of Late Tender does not arise. **10.4 Modification, Resubmission and Withdrawal of Bids** **10.4.1 Modification & Resubmission** Once submitted in e-Procurement, Bidder cannot view or modify his bid since it is locked by encryption. However, resubmission of the bid by the bidders for any number of times superseding earlier bid(s) before the date and time of submission is allowed. Resubmission of a bid shall require uploading of all documents, including financial bid afresh. The system shall consider only the last bid submitted as the valid bid. **10.4.2 Withdrawal** 1. The bidder may withdraw his bid before the bid submission deadline, and it shall be marked as withdrawn and shall not get opened during the Bid opening. 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, as applicable, in addition to other punitive actions provided in the Tender Document for such misdemeanor.

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

12. Evaluation of Bids and Award of Contract	**12.1 General norms** **12.1.1 Evaluation based only on declared criteria.** The evaluation shall be based upon scrutiny and examination of all relevant data and details submitted by Bidder in its/ his bid and other allied information deemed appropriate by Procuring Entity. Evaluation of bids shall be based only on the criteria/ conditions included in the Tender Document. **12.1.2 Deviations/ Reservations / Omissions - Substantive or Minor** 1. During the evaluation of Bids, the following definitions apply: a. "Deviation" is a departure from the requirements specified in the Tender Document; b. "Reservation" is the setting of limiting conditions or withholding from complete acceptance of the requirements specified in the Tender Document; and c. "Omission" is the failure to submit part or all of the information or documentation required in the Tender Document. **2** A deviation/ reservation/ omission from the requirements of the Tender Document shall be considered as a substantive deviation as per the following norm, and the rest shall be considered as Minor deviation: **a.** which affects in any substantive way the scope, quality, or performance of the product; **b.** which limits in any substantive way, inconsistent with the Tender Document, the Procuring Entity's rights or the Bidder's obligations under the contract; or **c.** Whose rectification would unfairly affect the competitive position of other Bidders presenting substantively responsive Bids. **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 be summarily rejected.
4. Bidder is not eligible to participate in the bid as per laid down eligibility criteria;
5. The Goods offered are not eligible as per the provision of this tender.
6. Bidder has quoted conditional bids or more than one bid or alternative bids unless permitted explicitly in the BDS.
7. The bid validity is shorter than the required period.
8. The bid departs from the essential requirements stipulated in the bidding document;
9. Against a schedule in Section V: Schedule of Requirement, Bidder has not quoted the entire Goods as stipulated in that schedule.
10. Non-submission or submission of illegible scanned copies of stipulated documents/ declarations.

12.2.2 The evaluation process

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

12.3 Techno-commercial Evaluation

Only substantively responsive bids shall be evaluated for techno-commercial evaluation. In evaluating the techno-commercial bid, conformity to the eligibility/ qualification criteria, technical specifications, and Quality Assurance; and commercial conditions of the offered Goods to those in the Tender Document is ascertained. Additional

	factors incorporated in the Tender Document shall also be considered in the manner indicated therein. Bids with substantive techno-commercial deviations shall be rejected as nonresponsive. Procuring entity reserves its right to consider and allow minor deviations in technical and Commercial Conditions as per ITB-clause 12.1.2. **12.3.1 Evaluation of eligibility** Procuring Entity shall determine, to its satisfaction, whether the Bidders are eligible as per ITB-clause 3 above to participate in the Tender Process as per submission in Form 1.2: Eligibility Declarations in Form 1: bid Form. Tenders that do not meet the required eligibility criteria prescribed shall be rejected as nonresponsive. **12.3.2 Evaluation of Qualification Criteria** Procuring Entity shall determine, to its satisfaction, whether the Bidders are qualified and capable in all respects to perform the contract satisfactorily as per submission in Form 4. This determination shall, inter-alia, consider the Bidder's financial, technical and production or other prescribed capabilities for satisfying requirements incorporated in the Tender Document. The determination shall not consider the qualifications of other firms such as the Bidder's subsidiaries, parent entities, affiliates, subcontractors (other than specialized subcontractors if permitted in the bidding document), or any other firm(s) different from the Bidder. **12.3.3 Evaluation of Conformity to Schedule of Requirements and Technical Specifications/ Quality Assurance** Procuring Entity shall evaluate schedule-wise conformity of the description, scope of supply, quantity, delivery schedules, terms of delivery, transportation of the offered goods to Section V- Schedule of requirements as per submissions in Form 2: 'Schedule of Requirements - Compliance'. Technical specifications, drawings, quality assurance and other technical terms and conditions of the Bids shall be examined, as per Form 3: 'Technical Specifications and Quality Assurance - Compliance'. Unless otherwise stated in the BDS, alternative offers/ makes/ models shall not be considered. **12.3.4 Evaluation of Conformity to Commercial and Other Clauses** Bidder must comply with all the Commercial and other clauses of the Tender Document as per submissions in Form 5. The Procuring Entity shall also evaluate the commercial conditions quoted by Bidder to confirm that all terms and conditions stipulated in the Tender Document have been accepted without substantive omissions/ reservations/ exception/ deviation by the Bidder. Deviations from or objections or reservations to critical provisions such as those concerning Governing laws and Jurisdiction (GCC Clause 3), Contractor's Obligations and Restrictions of its Rights (GCC Clause 5), Performance Bond/ Security (GCC Clause

	5.8), Warranty/ Guarantee (GCC Clause 6.7), Force Majeure (GCC Clause 9.13), Taxes & Duties (GCC Clause 10.2) and Code of Integrity (GCC Clause 13) will be deemed to be a material deviation. **12.3.5 Declaration of Techno-commercially Suitable Bidders and Opening of Financial Bids** Bids that succeed in the above techno-commercial evaluation shall be considered techno-commercially suitable, and financial evaluation shall be done only of such Bids. The list of such techno-commercially suitable bidders and date/time and venue for the opening of their financial bids shall be declared on the Portal in accordance with ITB-clause 12.2.2 as per the type of Tender Processes. **12.4 Evaluation of Financial Bids and Ranking of Bids** **12.4.1 Ranking of Financial Bids** 1. Unless otherwise stipulated, evaluation of the financial bids shall be on the price criteria only. Financial Bids of all Techno-commercially suitable bids are evaluated and ranked to determine the lowest priced bidder. 2. Unless otherwise stipulated, the comparison of the responsive Bids shall be on total outgo from the Procuring Entity's pocket, to be paid to the contractor or any third party, including all elements of costs as per the terms of the proposed contract, duly delivered, commissioned, etc. as the case may be, including any taxes, duties, levies etc., freight, transit Insurance, loading/ unloading/ stacking, insurance etc. 3. The bid for a schedule shall not be considered if the complete requirements prescribed in that schedule are not included in the bid; 4. If any bidder offers conditional discounts/ rebates in his bid or suo motu discounts and rebates after the Bid Opening (techno-commercial or financial), such rebates/ discounts shall not be considered for ranking the offer. But if such a bidder does become L-1 without discounts/ rebates, such discounts/ rebates shall be availed and incorporated in the contracts; 5. Unless announced beforehand, the quoted price shall not be loaded based on deviations in the techno-commercial conditions. If it is so declared, such loading of the financial bid shall be done as per the relevant provisions; 6. As per policies of the Government, from time to time, the Procuring Entity reserves its option to give purchase preferences to eligible categories of Bidders as indicated in the Tender Document. 7. evaluation of Bids shall include and consider the following taxes/ duties, as per ITB-clause 6.3 above:

a. GST & other similar duties, which shall be contractually payable, on the Goods if a contract is awarded on the bidder;
b. The offers shall be evaluated based on the GST rate quoted by each bidder, and the same shall be used for determining the inter-se ranking. The Procuring Entity shall not be responsible for any misclassification of HSN Number or incorrect GST rate if quoted by the bidder. Any increase in GST rate due to misclassification of HSN number shall have to be absorbed by the supplier; and
c. If GST is quoted extra, but with the provision that it shall be charged as applicable at the time of delivery, the offer shall be evaluated for comparison purposes by loading the maximum existing rate of GST for the product/ HSN code.

8. **Price Variation:** Deleted

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

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

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

12.4.4 Cartel Formation/ Pool Rates

1. If Procuring Entity decides this to be a case of Cartel/ Pool Rates, leading to "Appreciable Adverse Effect on Competition" (AAEC) as identified in Competition Act, 2002, as amended from time to time, it reserves its rights to:
    a) order any quantity on any one or more bidders without assigning any reason thereof.
    And/ or
    b) consider it as a violation of the Code of Integrity and reject the bid(s) as nonresponsive in addition to other punitive actions provided in this regard in the Tender Document. In addition to such remedies, the Procuring Entity also reserves the right to refer the matter to the Competition Commission of India (CCI) for obtaining necessary relief. In addition, the attention of the bidders is drawn to Chapter VI of the "The

	Competition Act 2002", which deals with Penalties. Such actions shall be in addition to other rights and remedies available to the Procuring Entity under the contract and Law. **12.4.5 Reasonableness of Rates Received** Procuring Entity shall evaluate whether the rates received in the Bids in the zone of consideration are reasonable. If the rates received are considered abnormally low or unreasonably high, it reserves its right to take action as per the following sub-clauses, or as per ITB-clause 2.3, reject any or all Bids; abandon/ cancel the Tender process and issue another tender for the identical or similar Goods. **12.4.6 Consideration of Abnormally Low Bids** An Abnormally Low bid is one in which the bid price, in combination with other elements of the bid, appears so low that it raises substantive concerns as to the Bidder's capability to perform the contract at the offered price. Procuring Entity shall in such cases seek written clarifications from the Bidder, including detailed price analyses of its bid price concerning scope, schedule, allocation of risks and responsibilities, and any other requirements of the Tender Document. If, after evaluating the price analyses, procuring entity determines that Bidder has substantively failed to demonstrate its capability to deliver the contract at the offered price, the Procuring Entity shall reject the bid/ proposal, and evaluation shall proceed with the next ranked bidder. **12.4.7 Price Negotiation** Usually, there shall be no price negotiations. However, the Procuring Entity reserves its right to negotiate with the lowest acceptable bidder (L-1), who is techno-commercially suitable for supplying bulk quantity and on whom the contract would have been placed but for the decision to negotiate.

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

	13.2 Letter of Award (Acceptance - LoA) and Signing of Contract **13.2.1 Selection of Successful Bidder(s)** The Procuring Entity shall award the contract to the Bidder(s) whose bid(s) is Techno-commercially suitable and bid price(s) is lowest and reasonable, as per evaluation criteria detailed in the Tender Document. **13.2.2 Verification of Original Documents** The Procuring Entity may, at its discretion, ask Bidder to submit for verification the originals of all such documents whose scanned copies were submitted online along with the technical bid. If so decided, the photocopies of such self-certified documents shall be verified and signed by the competent officer and kept in the records as part of the contract agreement. If the Bidder fails to provide such originals or in case of substantive discrepancies in such documents, it shall be construed as a violation of the Code of Integrity. Such bid shall be liable to be rejected as nonresponsive in addition to other punitive actions in the Tender Document. **13.2.3 Letter of Award (LoA)** **1.** The Bidder, whose bid has been accepted, shall be notified of the award by the Procuring Entity before the expiration of the Bid-Validity period by written or electronic means. This notification (hereinafter and in the Conditions of Contract called the "Letter of Award - LoA") shall state the sum (hereinafter and in the contract called the "Contract Price") that the Procuring Entity shall pay the contractor in consideration of the supply of the Goods. The Letter of Award (LoA) shall constitute the legal formation of the contract, subject only to the furnishing of performance security as per the provisions of the sub-clause below. **2.** It shall be mandatory for the successful bidder to be registered on GeM and obtain a unique GeM Seller ID before the placement of LoA or the contract. This ID shall be incorporated in the contract. **13.2.4 Performance Security** 1. Within 14 days of receipt of the Letter of Award (LoA, or the contract if LoA has been skipped), performance Security as per details in GCC-5.8 shall be submitted by the contractor to the Procuring Entity. 2. If the contractor, having been called upon by the Procuring Entity to furnish Performance Security, fails to do so within the specified period, it shall be lawful for the Procuring Entity at its discretion to annul the award, besides taking any other administrative punitive action.

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

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

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

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

	documents/records of the tender for which a complaint or issue is raised before them, as and when warranted. c) The role of IEM is advisory, and the advice of IEM is non-binding on the Organization; however, their advice would help properly implement the Integrity Pact. 7. In case of any dispute between the management and the contractor relating to those contracts where an Integrity Pact is applicable, in case both the parties are agreeable, they may try to settle the dispute through mediation before the panel of IEMs in a time-bound manner. If required, the organisations may adopt any mediation rules for this purpose. However, no more than five meetings shall be held for dispute resolution. Both parties shall equally share the fees/expenses on dispute resolution. If the dispute remains unresolved even after mediation by the panel of IEMs, the organisation may take further action as per the terms & conditions of the contract.

SECTION III: BID DATA SHEET (BDS)

Reference ITB Section	Description.
ITB 1.1	Purchaser- The Central Medical Services Society, an autonomous body under Ministry of Health and Family welfare, Government of India.
ITB 2.1	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
ITB 3.4	Only manufacturers of the quoted items are authorized to participate in this bid. Distributors/ Agents/ Resellers are not eligible to bid
ITB 3.5	**For item Schedule no. I (Condoms Free Supply), VI (IUCD 380A), VII (IUCD 375) & VIII (Tubal Rings):** In accordance with DPIIT Public Procurement (Preference to Make in India) Order, 2017 dated 19.07.2024 read with DOP Circular F.No.31026/36/2016-MD dated 16.02.2021 as amended till date, only Class-I and Class II local suppliers, as defined in aforesaid notifications are eligible to bid. **For item Schedule no. IV (Pregnancy Test Kits):** In accordance with DPIIT Public Procurement (Preference to Make in India) Order, 2017 dated 19.07.2024 read with DOP order no. 31026/36/2016-MD Circular dated 16.02.2021 as amended till date, only Class-I 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.31026/36/2016-MD dated 16.02.2021 as amended till date. Accordingly, **Class I Local Supplier** means a supplier or service provider, whose goods, services or works offered for procurement, has local content equal to or more than 50%. **Class II Local Supplier** means a supplier or service provider, whose goods, services or works offered for procurement, has local content more than 25% but less than 50%. **For item Schedule no. II (OCP-Free Supply), III Emergency Contraceptives Pills & V (Injectable Contraceptive (Antara)):** In accordance with DPIIT Public Procurement (Preference to Make in India) Order, 2017 dated 19.07.2024 read with DOP Circular F.No.31026/65/2020-

<table>
<tr><td></td><td>MD dated 30.12.2020 as amended till date, only Class-I and Class II local suppliers, as defined in aforesaid notifications are eligible to bid.

Minimum local content requirement for bidders- classification as Class-I/ Class-II local Suppliers shall be as per the DOP Circular F.No.31026/65/2020-MD dated 30.12.2020 as amended till date. Accordingly, Class I Local Supplier means a supplier or service provider, whose goods, services or works offered for procurement, has local content equal to or more than 80%. Class II Local Supplier means a supplier or service provider, whose goods, services or works offered for procurement, has local content more than 50% but less than 80%.

Special treatment for items covered under PLI Scheme- In accordance with Department of Pharmaceuticals Order No. 31026/83/2021-MD dated 17.10.2024, bidders manufacturing the quoted item under PLI scheme as notified vide aforesaid order, shall be treated as deemed “Class II Suppliers” under PPP-MII order. It is further clarified that the deemed class II supplier status does not preclude their qualification as Class I supplier, if they fulfil the criteria as Class I supplier.</td></tr>
<tr><td>ITB 3.6</td><td>MSEs (Micro & Small Enterprises) and Non- MSEs entities are eligible to bid.</td></tr>
<tr><td>ITB 5.2.1</td><td>No change</td></tr>
<tr><td>ITB 5.2.2</td><td>No change</td></tr>
<tr><td>ITB 7.3</td><td>All clarifications to the tender document should be addressed to Tender Inviting Authority. An email, seeking clarification to the bid document, should be sent at email id. agmproc4@cmss.gov.in; with copy to anujprakash@cmss.gov.in and dgceocmss@cmss.gov.ins</td></tr>
<tr><td>ITB 8</td><td>Tender timelines are as under:
<table>
<tr><td>Sr. No.</td><td>Descriptions</td><td>Scheduled date</td></tr>
<tr><td>(a)</td><td>Availability of tender documents on GeM portal for download</td><td>04/07/2025</td></tr>
<tr><td>(b)</td><td>Last date and time for receipt of pre-bid queries, if any</td><td>09/07/2025 till 05:00 PM

The pre-bid queries should be addressed to Tender Inviting Authority at email Id agmproc4@cmss.gov.in with copy to anujprakash@cmss.gov.in</td></tr>
</table></td></tr>
</table>

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<tr><td></td><td>
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<tr><td></td><td></td><td>and
dgceocmss@cmss.gov.in</td></tr>
<tr><td>(c)</td><td>Pre-bid meeting date, time and venue</td><td>09/07/2025 at 11.00 AM at CMSS, Conference Hall, New Delhi</td></tr>
<tr><td>(d)</td><td>Last date and time for online bid submission</td><td>28/07/2025 at 03:00 PM</td></tr>
<tr><td>(e)</td><td>Last date and time for submission of Original EMD</td><td>28/07/2025 at 03:00 PM</td></tr>
<tr><td>(f)</td><td>Date and time for tender opening (technical bid)</td><td>28/07/2025 at 03:30 PM</td></tr>
</table>
</td></tr>
<tr><td>ITB 9.4</td><td>Schedule wise EMD shall be as under:
<table>
<tr><th>Sr. No.</th><th>Schedule No.</th><th>EMD Amount in INR for 100% quantity quoted</th><th>EMD Amount in INR for 50% quantity quoted</th></tr>
<tr><td>(a)</td><td>Schedule I</td><td>74,73,013</td><td>37,36,506</td></tr>
<tr><td>(b)</td><td>Schedule II</td><td>48,73,418</td><td>24,36,709</td></tr>
<tr><td>(c)</td><td>Schedule III</td><td>2,47,983</td><td>1,23,992</td></tr>
<tr><td>(d)</td><td>Schedule IV</td><td>10,32,478</td><td>5,16,239</td></tr>
<tr><td>(e)</td><td>Schedule V</td><td>28,11,292</td><td>14,05,646</td></tr>
<tr><td>(f)</td><td>Schedule VI</td><td>19,44,996</td><td>9,72,498</td></tr>
<tr><td>(g)</td><td>Schedule VII</td><td>13,22,679</td><td>6,61,339</td></tr>
<tr><td>(h)</td><td>Schedule VIII</td><td>4,10,779</td><td>2,05,390</td></tr>
<tr><td colspan="4">Note: The applicable EMD has been indicated in above table and is for 100% and 50% quantity of the schedule. If quoted quantity is anywhere between 50% to 100% of the quantity of schedule, the applicable EMD may be calculated by the tenderer proportionately.</td></tr>
</table>
</td></tr>
<tr><td>“ITB 9.2.1 Sub-para 1” and “10.3.1 Sub-para 6”</td><td>Original copies of Earnest Money Deposit (if applicable), is to be submitted in a sealed cover. The envelope should be superscribed as Earnest Money Deposit against Tender No CMSS/PROC/2025-26/FP/017, Dated 04/07/2025 Scheduled to be opened on 28/07/2025 at 03:30 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.</td></tr>
<tr><td>ITB 9.2.1.3</td><td><u>For Sch I, IV, VI, VII & VIII only:</u>
The requirement of Valid WHO GMP Certificate and Valid COPP Certificate is deleted and bidder will submit valid ISO 13485 certificate in compliance with tender clause no. (c) of Section IV.</td></tr>
<tr><td>ITB 9.2.1.5</td><td>No Change</td></tr>
</table>

ITB 10	**The bid is published on GeM Portal. Accordingly, bidders are requested to submit their bid online on GeM Portal. In case of any contradiction in terms and conditions stipulated in this bid document and the terms of and conditions of GeM portal, the clauses of this tender document shall prevail.**
ITB 13.1.2 (2)	Deleted
ITB 13.1.2 (3)	No Change
ITB 16.1	No Change
ITB 16.3	IEM's : Name and Contact Details are as under: a) Sh. B. Siddhartha Kumar, Email Id : bsiddharthak_66@rediffmail.com b) Sh. Arun Kumar Sinha Email Id: aksinha2@yahoo.com

SECTION-IV -QUALIFICATION CRITERIA

a) Tenderer must be a manufacturer of quoted product.

b) **For Sch I, IV, VI, VII & VIII only:**

Tenderer shall be a domestic manufacturer of the quoted item having valid own manufacturing license for the offered product issued by Central Licensing Authority. The Manufacturing License should be valid on the date of tender opening packet 1. In case of failure to submit the same, the bid shall not be considered any further.

For Sch II, III & V only:

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.

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

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

For Sch I, II, III, IV, V, VI, VII & VIII:

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) **For Sch I, IV, VI, VII & VIII only:**

Tenderer must submit ISO 13485 certificate issued by an independent recognized certification body for the factory where the specific goods are manufactured and are being offered for supply. Certificate should be valid on the date of tender opening.

For Sch II, III & V only:

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

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).

d) Tenderer must submit Market standing certificate issued by the Licensing Authority, as a Manufacturer of the item quoted, for any two out of last three financial years i.e. 2023-24, 2024-25 and 2025-26. However, this would not apply to products which have been licensed by DCG (I) less than two years ago.

Note:

1. Unless or until Market standing certificate explicitly state that the bidder has manufacturing and marketing experience for more than one financial year, the said certificate issued on a particular date shall be treated as valid certificate for the financial year in which it has been issued. For example, Market Standing Certificate issued on 15.07.2022 shall be treated as Market Standing Certificate for the FY 22-23 only.

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 (last 2yrs), Market standing certificate for previously approved Pharmacopoeia or In-house Standards shall be accepted, as the case may be.
4. For the drugs recently introduced drugs in the county (introduced in the last two financial years), the requirement for Market standing certificate shall be waived off.

e) The tenderer should not have been convicted by the Licensing Authority in the past three years prior to the date of bid submission. Bidder shall give explicit undertaking for the same in Form 4 of the Bid Document. Also, 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 for the last three financial years i.e. 2023-24, 2024-25 and 2025-26.
Note:

1. Unless or until Non-Conviction Certificate explicitly state that the bidder has not been convicted for more than one financial year, the said certificate issued on a particular date shall be treated as valid certificate for the financial year in which it has been issued. For example, Non-Conviction Certificate issued on 15.07.2022 shall be treated as Non-Conviction Certificate for the FY 22-23 only.

2. Non-Conviction Certificate should be for the same manufacturing premises from which quoted goods have been offered for supply.

3. In case, the tenderer stands convicted by the Licensing Authority in due course of time, i.e. after submission of bid but before award of contract, tenderer should promptly intimate the same to the Tender Inviting Authority.

f) **For Sch I, IV, VI, VII & VIII only:**
Tenderer must submit long term stability data and CoA (Certificate of Analysis) in accordance

with ITB 9.2.1 (5) along with copy of License Certificate authorizing bidder to manufacture stability batches.

For Sch II, III & V only:

Tenderer must submit long term stability data and CoA (Certificate of Analysis) in accordance with ITB 9.2.1 (5) along with copy of License Certificate authorizing bidder to manufacture stability batches. Long term stability data & COA should mandatorily include parameters like Assay Dissolution, "Uniformity of Weight" or "Content Uniformity" (whichever is applicable) and "Related Substance Parameters".

g) The tenderer must have supplied at least the following quantity of the same or similar item during the last two financial years:

Schedule No.	**Minimum Quantity of the same or similar item during the last two financial years including the period of current F.Y. till the date of Tender Opening**	
	Qty for 100% quantity Quoted against the tender	**Qty for 50% quantity Quoted against the tender**
I	7,90,79,500 Pieces	3,95,39,750 Pieces
II	1,22,14,080 Packet	61,07,040 Packet
III	18,43,740 Packet	9,21,870 Packet
IV	60,20,280 Pack	30,10,140 Pack
V	15,92,800 Doses	7,96,400 Doses
VI	10,61,100 Pieces	5,30,550 Pieces
VII	8,04,060 Pieces	4,02,030 Pieces
VIII	3,80,880 Pairs	1,90,440 Pairs

Note: The applicable quantity has been indicated in above table and is for 100% and 50% quantity of the schedule. If quoted quantity is anywhere between 50% to 100% of the quantity of schedule, the applicable quantity may be calculated by the tenderer proportionately.

In support of above, the tenderer shall submit details of past purchase orders executed by them along with the copy of GST invoice and E-way bill against the proof of execution of order for every submitted Purchase Order. If GST invoice is not applicable for any Purchase Order, the affidavit to that effect on stamp paper of Rs. 100/- should be submitted. For the supply of export, bidder should submit the copy of invoice, bill of lading/airway bill/any other document issued by custom authority against the proof of execution of order for every submitted Purchase Order. The details shall be duly certified by the practicing Chartered Accountant in the form 4.1. The certifying Chartered Accountant must indicate the details

along with its UDIN.

Note: Similar item means will be as follows:

Schedule No.	Similar Items means
I	Any type of Condoms
II	Any type of OCP or ECP
III	Any type of OCP or ECP
IV	Pregnancy Test Kits
V	Any Injectable Contraceptive
VI	Any type of IUCDs
VII	Any type of IUCDs
VIII	Tubal Rings

h) The tenderer must have annual production capacity at least 1.5 times the quoted quantity. **For Sch I, IV, VI, VII & VIII only:** Annual capacity certificate, issued by the licensing authority/ practicing chartered accountant, must be submitted along with the bid.

For Sch II, III & V only: 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 last three FY i.e. 2021-22, 2022-23 and 2023-24 OR 2022-23, 2023-24 and 2024-25 more than the followings:

Schedule No.	Amount (in Rs)	
	Turnover for 100% quantity quoted against the tender	**Turnover for 50% quantity quoted against the tender**
I	14,94,60,255	7,47,30,128
II	9,74,68,358	4,87,34,179
III	49,59,661	24,79,830
IV	2,06,49,560	1,03,24,780
V	5,62,25,840	2,81,12,920
VI	3,88,99,926	1,94,49,963
VII	2,64,53,574	1,32,26,787
VIII	82,15,582	41,07,791

Note: The applicable annual turnover has been indicated in above table and is for 100% and 50% quantity of the schedule. If quoted quantity is anywhere between 50% to 100% of the quantity of schedule, the applicable annual turnover may be calculated by the tenderer proportionately.

Annual turnover statement for last three financial years i.e. 2021-22, 2022-23 and 2023-24 OR 2022-23, 2023-24 and 2024-25 should be furnished in the format given in Section IX Form 4.2 duly certified by the practicing Chartered Accountant. The certifying Chartered

Accountant must indicate the details along with its UDIN. The MSEs and Startups bidders are exempted from aforesaid minimum turnover requirement.

j) Copies of the audited Annual reports including the Balance Sheet and Profit and Loss Account for the last three years i.e. 2021-22, 2022-23 and 2023-24 OR 2022-23, 2023-24 and 2024-25 duly certified by a practicing Chartered Accountant, where ever applicable.

k) **For Schedule I: Condoms (Free Supply): -**

The tenderer must have manufactured & supplied in their brand name (s) in the domestic market or have export sales of their own brand name(s) of at least the following quantity during the last two financial years i.e. 2023-24 & 2024-25: -
46,31,250 Pieces

This should be supported by Brand Registration Certificate, copy of Purchase Order, copy of invoices, copy of E-way bill and a certificate by the Chartered Accountant certifying the correctness of the claim based on the audited Balance Sheet.

l) **For Schedule V (Injectable Contraceptive-Antara) only: -**
The tenderer should manufacture the product in a dedicated sex hormonal facility in compliance with schedule M of the drug and cosmetics act. ***(Certificate for the same will be submitted by the tenderer).***

m) **For Schedule V (Injectable Contraceptive-Antara) only: -**
Tenderer should enclose Test Reports for Injectable Contraceptive (Medroxyprogesterone Acetate) manufactured by them duly tested from Accredited laboratory of NABL or Accredited laboratory of the foreign country authorized for conducting tests of Injectable contraceptives.

n) **<u>For Sch I, IV, VI, VII & VIII only:</u>**
In case a bidder is successful past supplier of the item for CMSS/MoH&FW in last 02 years (last consignment supplied in last 02 years) from the date of tender opening but do not meet some of the qualification criteria requirements, the bidder shall be considered to be qualified in view of their proven credentials provided they meet essential tender enquiry requirement viz. Valid manufacturing license and ISO 13485 certificate (all valid on the date of tender opening). Also, bidder should not have been convicted in last 02 years.

<u>For Sch II & III only:</u>
In case a bidder is successful past supplier of the item for CMSS/MoH&FW in last 02 years (last consignment supplied in last 02 years) from the date of tender opening but do not meet some of the qualification criteria requirements, the bidder shall be considered to be qualified in view of their proven credentials provided they meet essential tender enquiry requirement viz. Valid manufacturing license, WHO GMP and COPP (all valid on the date of tender opening). Also, bidder should not have been convicted in last 02 years.

For Sch V only:

In case a bidder is successful past supplier of the item for CMSS/MoH&FW in last 02 years (last consignment supplied in last 02 years) from the date of tender opening but do not meet some of the qualification criteria requirements, the bidder shall be considered to be qualified in view of their proven credentials provided they meet essential tender enquiry requirement viz. Valid manufacturing license, certificate required as per requirement of Section IV (l & m), WHO GMP and COPP (all valid on the date of tender opening). Also, bidder should not have been convicted in last 02 years.

SECTION V

SCHEDULE OF REQUIREMENTS

LIST OF PRODUCTS & THEIR TECHNICAL SPECIFICATIONS

Sch. No.	Item Name	Total Tentative Quantity	Unit	Detailed Technical Specifications of the Goods/Drugs	Order Distribution Criteria	Inspection Methodology (PDI/Non-PDI)	Consignee Location
I	Condoms (Free Supply)	19,76,98,750	Pieces	Section VI	Refer ITB clause no. 13.1.2	Refer GCC clause no. 7.1.7	Direct to State Consignee (DTC)
II	OCP (Free Supply)	3,05,35,200	Packet				CMSS Warehouses
III	Emergency Contraceptives Pills (ECP)	46,09,350	Packet				
IV	Pregnancy Test Kit	1,50,50,700	Pack				
V	Injectable Contraceptive (Antara)	39,82,000	Doses				
VI	IUCD 380A	26,52,750	Pieces				
VII	IUCD 375	20,10,150	Pieces				
VIII	Tubal Rings	9,52,200	Pairs				

(Please refer Technical specifications attached in SECTION VI)

Delivery Terms:

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

(b) Delivery Schedule

Tranche I: 25% quantity to be delivered within 90 days from the date of issue of LOA.

Tranche II: 25% quantity to be delivered within 91-180 days from the date of issue of LOA.

Tranche III: 50% quantity to be delivered within 181-270 days from the date of issue of LOA.

A. Delivery Locations:

The details of CMSS warehouses are indicated in ITB clause no. 6.3.1 (5).

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

SECTION VI
TECHNICAL SPECIFICATIONS AND QUALITY ASSURANCE

Schedule-I

TECHNICAL SPECIFICATIONS OF LATEX RUBBER CONDOM UNDER FREE SUPPLY OF CONTRACEPTIVES SCHEME

(As per the provision of Rule 7 of Medical Device Rule 2017)

1. Condom (Brand Name: Nirodh) with teat end, lubricated for single use with shelf life of 3 years.

2. Details of lubrication and lubricant (as per IS 17810:2022 / ISO 19671:2018 enclosed-Annexure-I)

a. Quantity of lubricant - 250mg minimum
b. Details of lubricant - Silicon Iol (Dimethyl Poly Siloxane)
c. Viscosity - 200-350 CTSK
d. Properties - Non-toxic and non-irritant to skin

3. **Dimensions:**

   i. **Length**: the length of condom when unrolled (excluding teat) shall not be less than 170mm.
   ii. **Width**: the width of a condom when laid flat and measured at any point within 85mm from the open end shall be 49±2mm
   iii. **Single wall thickness**: the single wall thickness of a condom when measured at three points, one at 30±2mm from open end, 30±5mm from the closed and excluding the reservoir tip and at the mid distance between these two points shall be from 0.045mm to 0.075mm.

4. Product should be licensed by competent authority for import or manufacture for sale and distribution in the country as defined under Drugs & Cosmetic Act 1940 and Medical Device Rules 2017. The Latex Rubber Condoms should be confirm requirement as prescribed by Bureau of Indian Standards (BIS)- IS 17692:2021 / ISO 16038:2017 (Annexure II).

5. Each condom (Brand Name: Nirodh) under Free Supply of Contraceptive scheme is to be strip packed individually and one strip of each 5 squire foiled condoms are to be placed in one wallet, duly printed with the various instructions required under Standards of Weights and Measures Act 1976 and rules made under the law.

6. The design and drawing of the strip, wallet, dispenser box and master carton should be in conformity with the artwork attached. **"Government of India, FREE SUPPLY. Not for Sale"** will be printed in indelible ink across each wallet, carton and master carton.

7. The label of the condom shall conform the requirements as prescribed in Rule 44 of the Medical Device Rules 2017.

8. Condom width and length specification and that they comply to packaging instruction as well as A type must be mentioned on wallets and cartons.

9. **Packaging Specifications:**

#	Specifications			No. of Pieces
i.	Foil	Material:	Foil- Square Pack- Alumunium paper top foil Specification: 40-42 GSM GIP (GLASSINE) paper (similar paper)/18-20 micro polythene/9 micron Aluminium/ 6-8 GSM Heal Seal Coating (equivalent sealant) nor Nucrel	1 condom/ square strip
		Size of each strip A type:	Square pack of strips. **Size** 55 x 55 mm (L x B) No. of color: Two	
		Printing:	As per the artwork	
ii.	Wallet	Material:	Duplex board, matt UV varnish, **GSM** 250 **Dimension ID**- 65 x 65 x 25 mm (LxBxH) **No. of color**: four	5 square strips/ wallet
iii.	Carton	Material:	3 ply 'E' micro flute with top open (250 **GSM** Duplex board as the top layer and other inner layers are virgin kraft paper of 100 **GSM** each) **No. of color** : four **GSM** 450 **Dimension ID**- 205 x 135 x 110 mm (LxBxH)	5*24 =120 pieces.
iv.	Master Carton	Material:	5 ply narrow flute corrugated cardboard box of each ply of 150 **GSM** virgin kraft paper **No. of color**: two (Black and Red) **GSM** 850 **Dimension ID-** 630 x 570 x 425 mm (LxBxH) Bursting Strength: 19 kg/cm2(min) Others: The minimum burst factor of the 5 layers are 40,24,40,24,40 stapled	5*24*45 =5400 pieces.
v.	Leaflet	Material:	Creamover paper GSM: 81 min. **Dimensions (ID):** 55x55 mm (L x B) **No. of color** : One (Black)	1 piece leaflet/ wallet
		Printing:	Leaflet illustrating how to use condoms must be enclosed in each wallet of condoms.	
		Language:	English on one side and Hindi on other side	

10. Specification for packing material for outer box

Narrow flue corrugated card board boxes of 7 ply, each ply of 150 gsm virgin Kraft paper of which outer ply to be alkali resistant (chemically treated of bituminsed against white ants and other insects). Outer layer will be 60 + 40 + 60 gsm and corners reinforced with 3" wide gummed cloth tapes in dark tan colour as per write up as in previous supplies. Inside to be lined with polythene liner.

As per above specification the total GSM is as follows:

Out of 7 piles 6 inner piles (1 to 6 piles)		
150 gsm each	-	900
7th out ply 160gsm x 1	-	160
Total	**-**	**1060**
Extra GSM for	-	158
Corrugation of 3 piles (@35%)		
G.Total	**-**	**1218**

Bursting strength not less than 19 KGs/sq.cm.

Note:

i. Name of the firm should be printed on the tape pasted on the cardboard for sealing purpose.
ii. The Batch No. would also be indicated in bar-code on the outer packaging in addition to its indication in the alpha numeric form.

SPECIFICATION FOR LATEX RUBER CONDOMS - IS/ISO 4074:2015

(Relevant IS/ISO attached)

1. **Dimensions:**
   i. Length: the length when unrolled (excluding teat) shall be net less than 170mm with width 49±2mm measured as per details in part 2 below.
   ii. Width: the width of a condom when laid flat and measured at any point within 85mm from the open end shall be 49±2mm.
   iii. Single wall thickness: the single wall thickness of a condom when measured at three points, one at 30±2mm from open end, 30±5mm from the closed and excluding the reservoir tip and at the mid distance between these two points shall be from 0.045mm to 0.075mm.

2. **Freedom from Holes:**

Statistical sampling from quality control assessment of the finished product in respect of water leakage test shall be done in accordance with the plan set out in Appendix I. Condom shall show no evidence of water leakage when tested as follows:-

Unroll the condom and fit the open end on a suitable mount. The condom is thus suspended open end upwards. Fill it with 300ml water at room temperature and inspect it after a period of atleast 1 minute for leakage upto25mm from the open end. If, because of distension of the condom, the water does not extend to 25mm from the open end, raise the closed end until water level reaches the distance. After atleast 1 minute, inspect the newly-wetted part of the condom for leakage.

Note: Air leakage test is deleted from requirements.

3. **Bursting Volume and Pressure Test:**

Sample condoms shall be tested for bursting volume and pressure test. Statistical sampling for this test shall be done in accordance with the plan set out in Appendix-II.

Condom shall not leak or burst at a volume of less than that specified or pressure less than 1.0kpa(gauge), when test as in Appendix-IIA both before and after oven conditioning as specified in Appendix-III. Bursting volume minimum limit in litres shall be equal to

$$= \frac{(\text{Mean condom width in mm})^2}{151.8} \text{ rounded to the nearest 0.5 litres.}$$

Note: Tensile test is deleted from requirements.

4. **Integrity of Individual Package Seals:**

Sample condoms in individual packages shall be placed in a sealed, transparent container (such as laboratory bell jar) and subjected to a vacuum of 50±10kpa(gauge) for a period of one minute.

Condom packages that do not inflate and remain inflated for the period of the test shall be deemed non-compliers. In doubtful cases, the test may be repeated and both the inflation and deflation of packages may be observed on application and removal of vacuum.

An AQL of 2.5 will be applied in assessing the results of this test. 50 samples of condoms shall be tested for integrity test of individual package seals. The compliance limit or acceptance number shall be not more than 3 condoms.

Appendix-I

Sampling plan for Quality Control of Condoms at Manufacturer's Level/Purchaser's level

Batch Size :35001 to 1.50 lakhs

Single Sampling Plan

Sample Size: 200	AQL	-	0.25
	AC	-	1
	R	-	2

Batch Size : 1.50 lakhs to 5 lakhs

Sample Size: 315	AQL	-	0.25
	AC	-	2
	R	-	3

Batch Size : Over 5 lakhs

Single Sampling Plan

Sample Size: 500	AQL	-	0.25
	AC	-	3
	R	-	4

Note: AQL means Acceptance Quality Level.

AC means Acceptance Number i.e. the maximum allowable number of defectives for acceptance of the Batch.

R Means Rejection Number i.e. the minimum number of defectives for rejection of the Batch

Appendix-II

Sampling plan for Bursting Volume and Pressure Test

Batch Size : 35001 to 1.50 lakhs

Single Sampling Plan

Sample Size: 200	AQL	-	1.5
	AC	-	7
	R	-	8

Batch Size : 1.50 lakhs to 5 lakhs

Single Sampling Plan

Sample Size: 315	AQL	-	1.5
	AC	-	10
	R	-	11

Batch Size : Over 5 lakhs

Single Sampling Plan

Sample Size: 500	AQL	-	1.5
	AC	-	14
	R	-	15

Note: AQL means Acceptance Quality Level.

AC means Acceptance Number i.e. the maximum allowable number of defectives for acceptance of the Batch.

R Means Rejection Number i.e. the minimum number of defectives for rejection of the Batch

Appendix-IIA

Determination of Bursting Volume and Pressure

1. **Principle**
Inflation of a constant length of the condoms with air and recording the volume and pressure at the moment of bursting.

2. **Apparatus:**
2.1 Apparatus suitable for inflating the condom with clean air at a specified rate and provided with equipment for measuring volume and pressure.
2.2 Suitable mount for fitting the condoms to the apparatus.
2.3 Rod, 140mm in length having a smooth sphere 20mm in diameter at its top for hanging the unrolled condom when fixed to the apparatus.

3. **Procedure:**
3.1 Unroll the condom, hang it on the rod (2.3), affix to the mount (2.2) and inflate with air at a rate of 0.4 to 0.5 litre/sec (24 to 30 litres/min.)
3.2 Measure and note the bursting volume, in litres rounded to he nearest 0.5 litre and the bursting pressure, in kilopascals rounded to the nearest 0.1kpa.

Appendix-III

Oven Conditioning

1. Principle of the method:
The test consists in subjecting test samples to control deterioration by air at an elevated temperature and a atmospheric pressure after which Burst Volume and Pressure limits are measured.

2. Apparatus:
The air oven shall be of such a size that the total volume of the test samples does not exceed 10% of the free air space of the oven. Provision shall be made for slow circulation of air in the oven of not less than three changes and not more than ten changes per hour. The temperature of the oven shall be thermostatically controlled so that the test samples are kept with±20C of the specified ageing temperature. A thermometer shall be placed near the centre of the ageing test samples to record the actual ageing temperature.

Note: Copper or Copper alloys shall not be used for the material of construction of the oven prescribed.

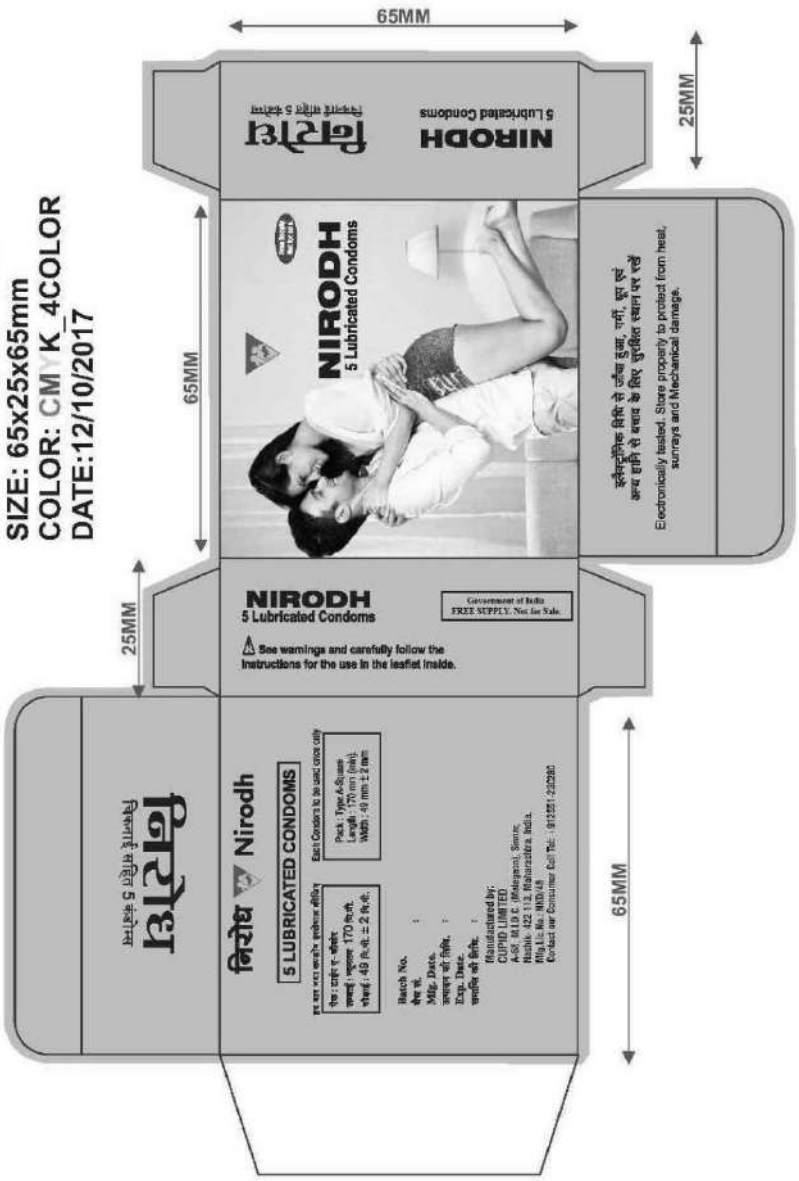
3. Test Samples:
The foil limitations of individual packages should remain in tact throughout all laboratories handling including oven conditioning.

4. Test Reports:
The test report shall include the following particulars;

a. The identification of the sample.
b. The bursting volume and bursting pressure of each test condom.
c. The date of testing.

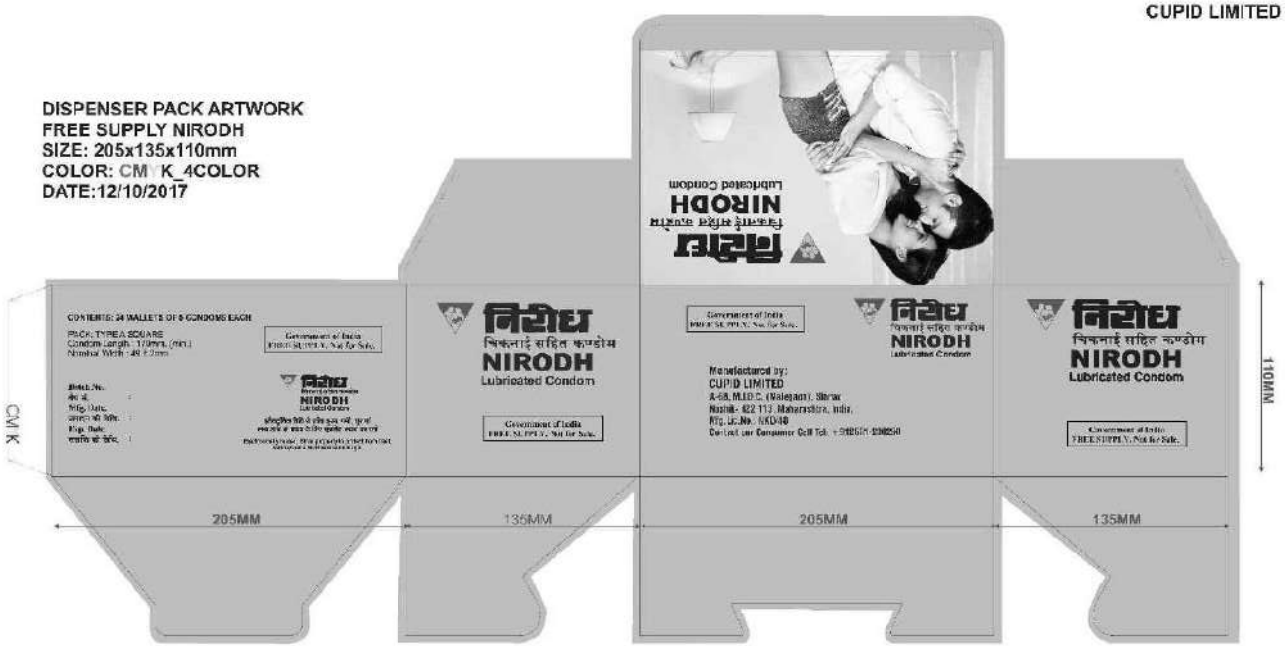
Annexure-3 a

CONSUMER PACK ARTWORK
FREE SUPPLY NIRODH
SIZE: 65x25x65mm
COLOR: CMYK_4COLOR
DATE:12/10/2017



CUPID LIMITED

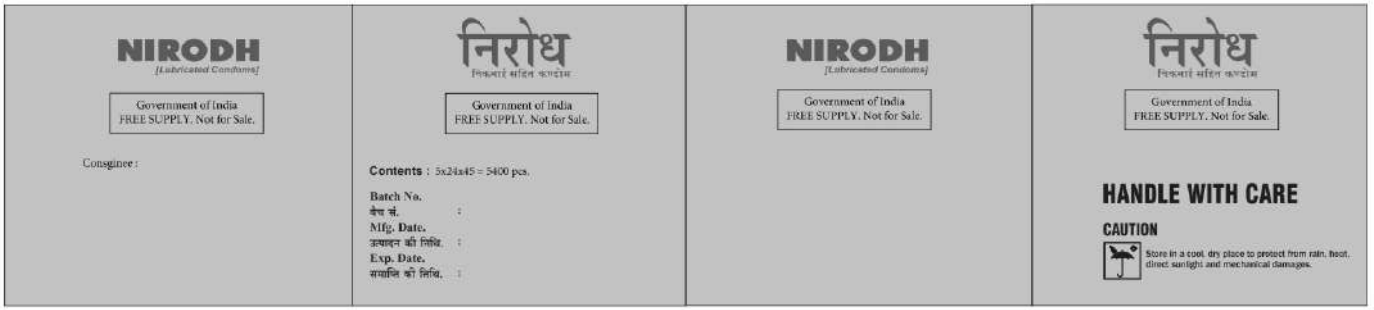
DISPENSER PACK ARTWORK
FREE SUPPLY NIRODH
SIZE: 205x135x110mm
COLOR: CM Y K_4COLOR
DATE:12/10/2017



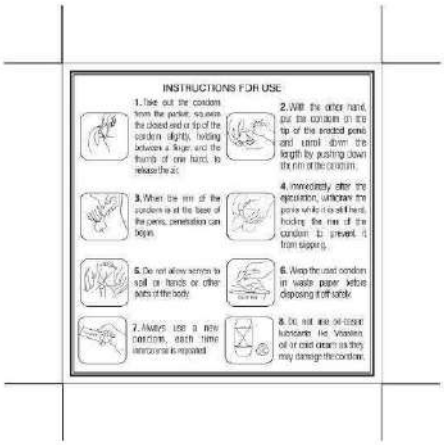
FOIL ARTWORK
FREE SUPPLY NIRODH
COLOR: PANTONE 427 C , BLACK
DATE:12/10/2017

CUPID LIMITED

Shipper Box Artwork
Nirodh (FREE supply)
Size: 630x570x425mm



5.5cm x 5.5cm


INSTRUCTIONS FOR USE
1. Take out the condom from the packet, squeeze the closed end or tip of the condom slightly, holding between a finger and the thumb of one hand, to release the air.
2. With the other hand, put the condom on the tip of the erected penis and unroll down the length by pushing down the rim of the condom.
3. When the rim of the condom is at the base of the penis, penetration can begin.
4. Immediately after the ejaculation, withdraw the penis while it is still hard, holding the rim of the condom to prevent it from slipping.
5. Do not allow semen to spill on hands or other parts of the body.
6. Wrap the used condom in waste paper before disposing it off safely.
7. Always use a new condom, each time intercourse is repeated.
8. Do not use oil-based lubricants like Vaseline, oil or cold cream as they may damage the condom.


उपयोग के निर्देश

Schedule-II

DESCRIPTION AND SPECIFICATION

1. Product Formulation (each tablet)

i. Free Distribution Programme: Mala-N-Packed as per 2 below

a) 21 tablets containing Harmones as under:-

Levonorgestrel I.P.	0.15 mg
Ethinyloestradiol I.P.	0.03 mg

b) 7 tablets containing Ferrous Fumerate as per I.P. – 60 mg

ii. Social Marketing Programme: Mala-D-Packed as per 2 below

a) 21 tablets containing Harmones as under :-

Levonorgestrel I.P.	0.15 mg
Ethinyloestradiol I.P.	0.03 mg

b) 7 tablets containing Ferrous Fumerate as per I.P. -60 mg

iii. Other private Brands of Marketing Companies:- Packed upto strip stage

a) 21 tablets containing Harmones as under :-

Levonorgestrel I.P.	0.15 mg
Ethinyloestradiol I.P.	0.03 mg

b) 7 tablets containing Ferrous Fumerate as per I.P. -60 mg

Tablet in all the three packing as above should conform to IP standards (Disintegration time as per IP)

2. Packaging insert, Logo Brand Name-Mala etc. will be same for both the products under the two schemes except for colour scheme and printing of 'Free Supply-Not for Sale' both on the catch cover and on the strip of pills under the Free-Distribution Scheme. To distinguish the two brands Mala-N or Mala-D will be printed on both the strip and the catch cover respectively. A sample of each is enclosed.

3. Tableting: The OCP strip will have 28 tablets constituting of twenty-one Oral Pills with active ingredients as mentioned above and seven Ferrous Fumerate tablets. The tablets will be coated and packed in 'Blister packs' only.

4. Colour Scheme:

As per sample attached-but actual printing material and colour scheme has to be got approved by the supplier as per clause 10.

Catch Cover

a) Free Scheme- The paper of Mala-N catch cover will Meplitho 95 dimension will be 110x65+65+40mm. The paper will be of 120 GSM.

b) Social Marketing Scheme:- The paper of Mala-D catch cover will be Chemo-art of good quality. Its dimension will be 110x65+65+40mm. The paper will be of 140 GSM. For physician samples, the strip bear Inscription Physician Sample – Not for Sale' and the same will be inscribed on the catch cover also.

5. Packaging insert/instructions leaflets:

It should be both in English and Hindi and four Regional Languages. The size of leaflet should be 290x220+-5mm on good quality white prints paper of 48 GSM.

6. Carton

i) Free Distribution (Mala-N) 100 cycles each (in plain carton) and ten such cartons in a corrugated box to fit in the Outer box. The paper of the inner box will be the same as of the outer box. The outer box should be conforming to specifications indicated in the attached Annexure 'A'. The size of inner box will be 350x225x70mm.

ii) Social Marketing: 10 cycles in a carton with five sides marking as on catch cover and bottom plain and 100 such cartons in a outer corrugated box.

iii) The size and specification of the Outer box will be as per Annexure 'B'.

7. Paper for wallet/catch cover/carton:

i) Both for wallet/catch cover for free Scheme (Mala-N)-Mplitho.,
ii) Paper for carton for Social Marketing-GSM 25 Duplex Board
iii) The size of Carton will be 115x75x70mm.

8. Brand Name i.e. Mala-N or Mala-D Name of Manufacturer, date of Manufacturing etc., and batch number should be indicated on both the catch covers and strip.

9. Approval of packaging materials
Samples of strips, catch cover, carton etc. will have to be approved in advance.

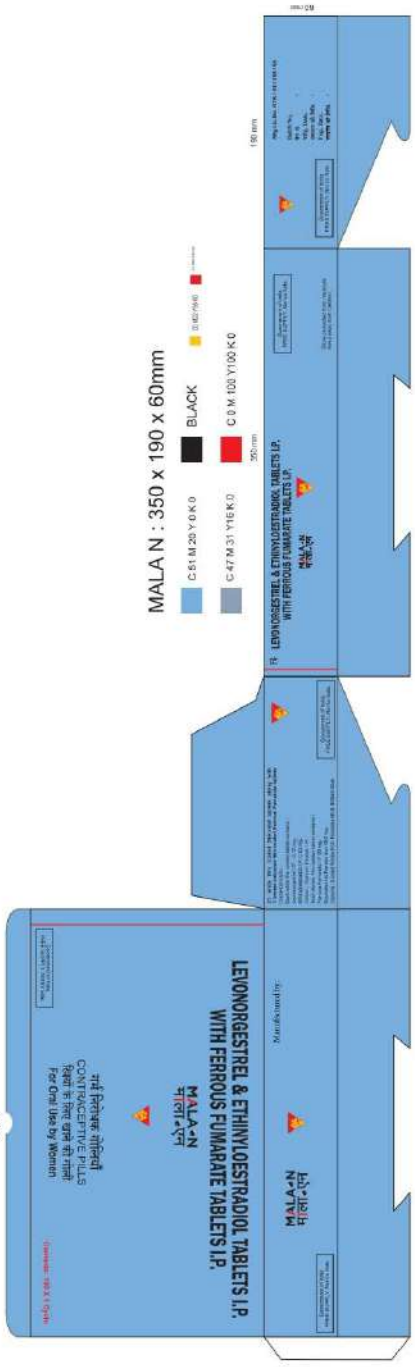
SIZE OF PACKAGING MATERIAL OF MALA-'N'

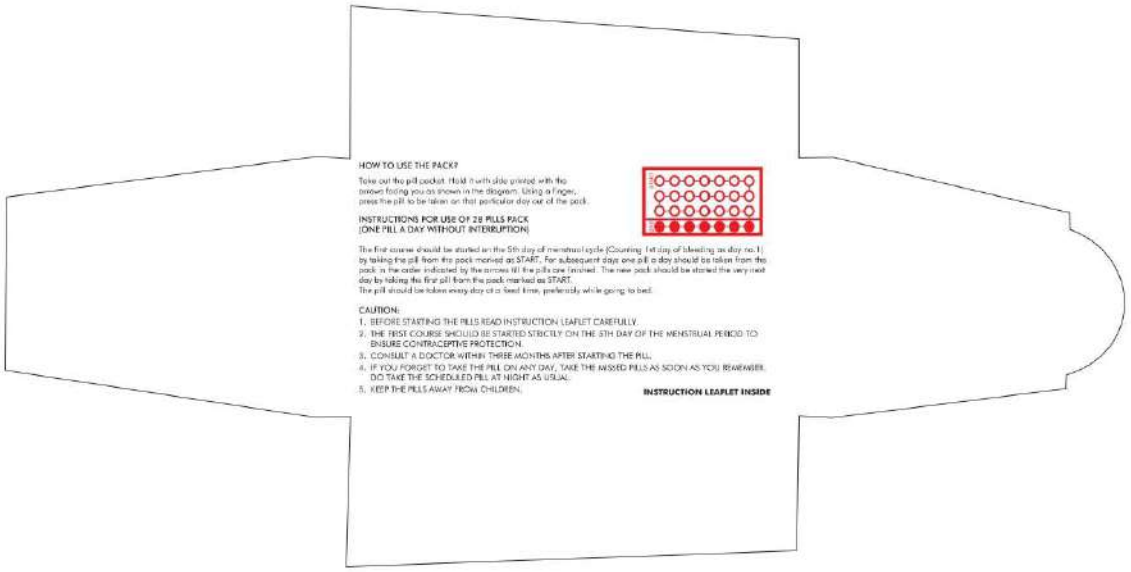
MALA – N

Sl. No.	Name of material	Size		
I	Leaflet	290 x 220mm		
II	Catch Cover	110 x 65 + 65 + 40mm		
III	Inner Box	115x75x70mm		
IV	Outer Box	470 x	370 x	390mm
		L	B	H

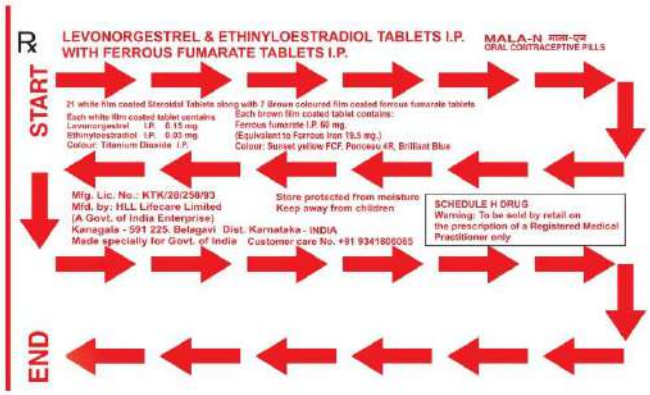
Annexure- 5 a


53 cm
67 mm
98 cm
71 mm
MALA•N
Contraceptive Pills
For Oral use by Women
Free Supply. Not for sale.
LEVONORGESTREL & ETHINYLOESTRADIOL TABLETS I.P. WITH FERROUS FUMARATE TABLETS I.P.
MALA•N
माला•एन
Contraceptive Pills
गर्भ निरोधक गोलियाँ
For Oral use by Women
One Cycle / pack
माला•एन गर्भ निरोधक गोलियाँ
Store protected from moisture
Keep away from children
Manufactured by:
Government of India
FREE SUPPLY. Not for Sale.
C 51 M 20 Y 0 K 0
BLACK
C 47 M 31 Y16 K 0
C 0 M 100 Y100 K 0
C0 M22 Y98 K0
C4 M99 Y98 K0
A3496 AW HLL Mala-N-(catch cover)-(Free Supply) / 15 09 15


MALA N : 350 x 190 x 60mm
BLACK
C 0 M 100 Y100 K 0
C 47 M 31 Y16 K 0
LEVONORGESTREL & ETHINYLOESTRADIOL TABLETS I.P.
WITH FERROUS FUMARATE TABLETS I.P.
MALA-N
माला-एन
नार्ई निरोधक गोलियाँ
CONTRACEPTIVE PILLS
सिर्फ महिलाओं के लिए मुखी की गोली
For Oral Use by Women



BLACK C 0 M 100 Y100 K 0


℞
LEVONORGESTREL & ETHINYLOESTRADIOL TABLETS I.P.
WITH FERROUS FUMARATE TABLETS I.P.
MALA-N माला-एन
ORAL CONTRACEPTIVE PILLS
START
21 white film coated Steroidal Tablets along with 7 Brown coloured film coated ferrous fumarate tablets
Each white film coated tablet contains:
Levonorgestrel I.P. 0.15 mg
Ethinyloestradiol I.P. 0.03 mg
Colour: Titanium Dioxide I.P.
Each brown film coated tablet contains:
Ferrous fumarate I.P. 60 mg.
(Equivalent to Ferrous Iron 19.5 mg.)
Colour: Sunset yellow FCF, Ponceau 4R, Brilliant Blue
Mfg. Lic. No.: KTK/28/258/93
Mfd. by: HLL Lifecare Limited
(A Govt. of India Enterprise)
Kanagala - 591 225. Belagavi Dist. Karnataka - INDIA
Made specially for Govt. of India
Store protected from moisture
Keep away from children
Customer care No. +91 9341808085
SCHEDULE H DRUG
Warning: To be sold by retail on
the prescription of a Registered Medical
Practitioner only
END


LEVOMEPROMAZINE & ETHINYLOESTRADIOL TABLETS I.P.
WITH FERROUS FUMARATE TABLETS I.P.
MALA • N
Government of India
FREE SUPPLY. Not for Sale.
Manufactured by
मला • एन
Government of India
FREE SUPPLY. Not for Sale.
HANDLE WITH CARE
Store protected from moisture
Keep away from children
LEVOMEPROMAZINE & ETHINYLOESTRADIOL TABLETS I.P.
WITH FERROUS FUMARATE TABLETS I.P.
MALA • N
Government of India
FREE SUPPLY. Not for Sale.
Consignee
मला • एन
Government of India
FREE SUPPLY. Not for Sale.
CONTENTS
395 mm
365 mm
395 mm
365 mm
320 mm

HLL LIFECARE LIMITED
KANAGALA, BELGAUM- DIST. KARNATAKA

FINAL APPROVED ARTWORK FORMAT
(HLL/KFB/QA-022R01)

Artwork Name: INST LEAFLET MALA-N GMPS

Item code number: 1110322075 **Mode: Domestic**

Effective Date: 23.07.2016 **Revision No.:01**

Reason:change in size

SIZE:276X200 MM

Prepared By:
(Lab Dept.)
Date:

Checked By:
(Lab Dept.)
Date:

Reviewed By:
Executive (QA)
Date:

Approved by:
Head of QA
Date:

HLL LIFECARE LIMITED
KANAGALA, BELGAUM- DIST. KARNATAKA

FINAL APPROVED ARTWORK FORMAT

Artwork Name: INST LEAFLET MALA-N GMPS (HLL/KFB/QA-022R 01)

Item code number: 1110322075 **Mode: Domestic**

Effective Date: 23.07.2016 **Revision No.:01**

Reason:change in size

SIZE:270X200 MM

Prepared By:
(Lab Dept.)
Date:

Checked By:
(Lab Dept.)
Date:

Reviewed By:
Executive (QA)
Date:

Approved by:
Head of QA
Date:

HLL LIFECARE LIMITED
KANAGALA, BELGAUM- DIST. KARNATAKA

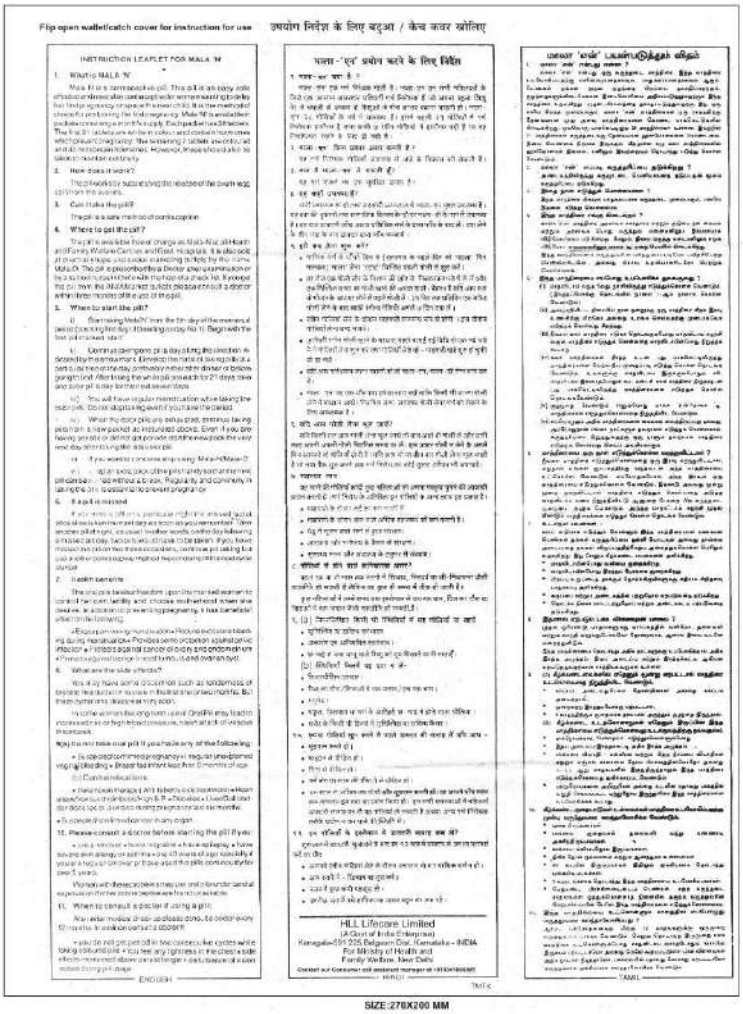
Artwork Name: INST LEAFLET MALA-N TMTK

FINAL APPROVED ARTWORK FORMAT
(HLL/KFB/QA-022R01)

Item code number: 1110322074 **Mode: Domestic**

Effective Date: 23.07.2016 **Revision No.:01**

Reason:change in size



SIZE:270X200 MM

■ PANTONE BLACK 6C

Prepared By:
(Lab Dept.)
Date:

Checked By:
(Lab Dept.)
Date:

Reviewed By:
Executive (QA)
Date:

Approved by:
Head of QA
Date:

HLL LIFECARE LIMITED
KANAGALA, BELGAUM- DIST. KARNATAKA

Artwork Name: INST LEAFLET MALA-N TMTK

FINAL APPROVED ARTWORK FORMAT
(HLL/KFB/QA-022R01)

Item code number: 1110322074

Mode: Domestic

Effective Date: 23.07.2016

Revision No.:01

Reason:change in size

MALAYALAM — TELUGU — KANNADA

SIZE:270X200 MM

Prepared By:
(Lab Dept.)
Date:

Checked By:
(Lab Dept.)
Date:

Reviewed By:
Executive (QA)
Date:

Approved by:
Head of QA
Date:

HLL LIFECARE LIMITED
KANAGALA, BELGAUM- DIST. KARNATAKA

Artwork Name: INST LEAFLET MALA-N BAOU

FINAL APPROVED ARTWORK FORMAT
(HLL/KFB/QA-022R 01)

Item code number: 1110322073

Mode: Domestic

Effective Date: 23.07.2016

Revision No.:01

Reason:change in size

ASSAMESE

ORIYA

URDU

SIZE:270X200 MM

Prepared By:
(Lab Dept.)
Date:

PANTONE BLACK 6C

Checked By:
(Lab Dept.)
Date:

Reviewed By:
Executive (QA)
Date:

Approved by:
Head of QA
Date:

HLL LIFECARE LIMITED
KANAGALA, BELGAUM- DIST. KARNATAKA

Artwork Name: INST LEAFLET MALA-N BAOU

FINAL APPROVED ARTWORK FORMAT
(HLL/KFB/QA-022R 01)

Item code number: 1110322073 | **Mode: Domestic**

Effective Date: 23.07.2016 | **Revision No.:01**

Reason:change in size

PAGE 1 OF 2


Flip open wallet/catch cover for instruction for use

उपयोग निर्देश के लिए बटुआ / कैच कवर खोलिए

INSTRUCTION LEAFLET FOR MALA 'N'

1. What is MALA 'N'

2. How does it work?

3. Can I take the pill?

4. Where to get the pill?

5. When to start the pill?

HLL Lifecare Limited

ENGLISH

BENGALI

Prepared By:
(Lab Dept.)
Date:

Checked By:
(Lab Dept.)
Date:

Reviewed By:
Executive (QA)
Date:

Approved by:
Head of QA
Date:

Schedule-III

Specification for Emergency Contraceptives Pills (ECP)

Specifications : I.P. 2014 (Indian Pharmacopoeia)

Against this enquiry, the procurement decision as well as the subsequent supply in pursuance to such decision shall be on the condition that Emergency Contraceptive Pills are manufactured out of the material of Levonorgestrel 1.5 mg with three years shelf life as specified in the IP. 2014. The supplier shall furnish a certification from the Drug Authority in the country of origin that the material offered by him meets the requisite standard of quality. Such certificate shall also be furnished with each batch supply for inspection by successful tenderer.

1. Product Formulation (each tablet)

Name of the Pill	"Ezy Pill"
Packing	1 pill per strip.
Composition	Each film coated tablet contains Levonorgestrel 1.5 mg
Colour	Titanium Dioxide I.P
Shelf life	3 years

2. Packing and Marking:

The store should be packed as per details given in the relevant specifications. Each pack will have the following printed in indelible ink across each label. For Free Supply: "**Government of India. FREE SUPPLY, Not for Sale**". The packing will also be marked as under

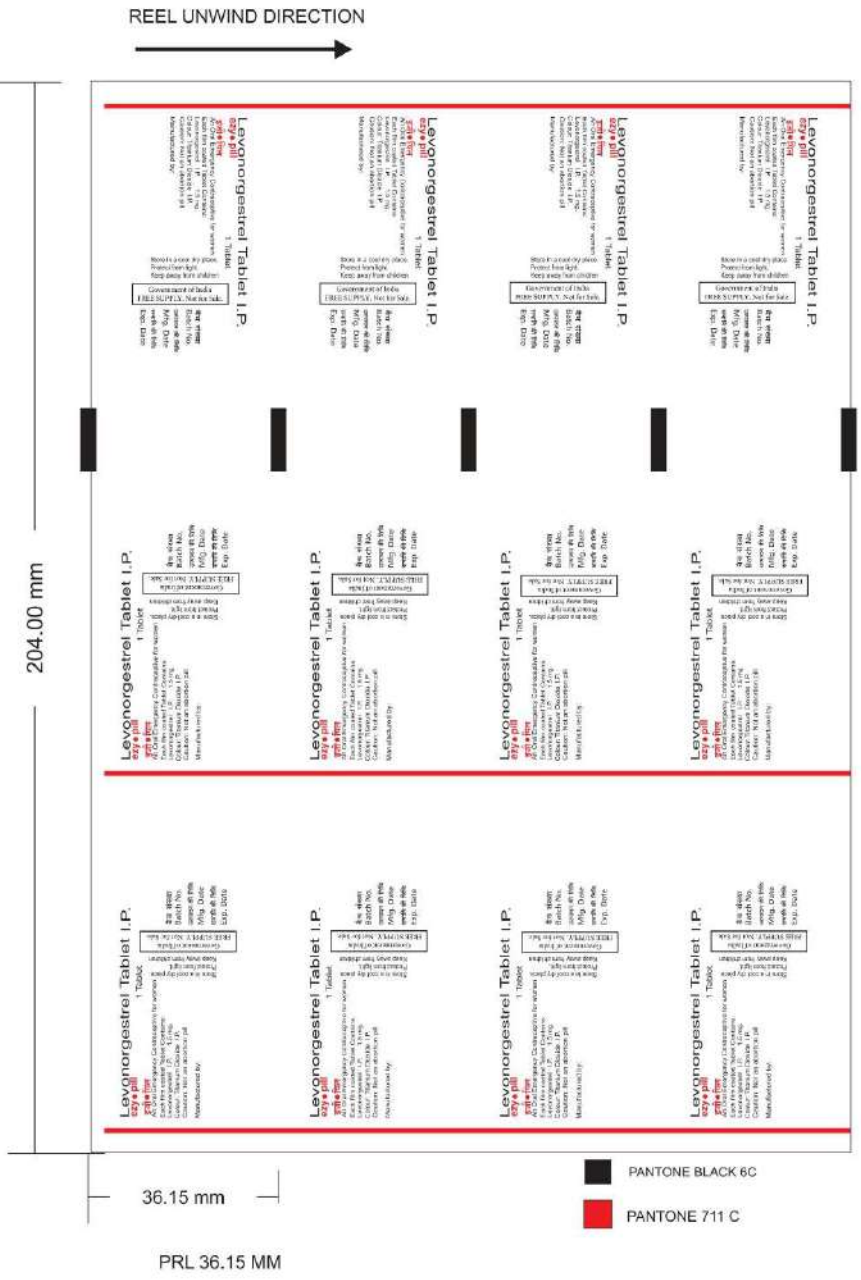
i. Nomenclature of the stores.
ii. Manufacturers name , Address and Licence No.
iii. Date of Manufacture, Expiry and Batch No.
iv. Quantity contained therein.
v. Inspection Note No. and Date.
vi. Any other particulars required under the Drugs and Cosmetics Act of India and theRules framed there under.
vii. Artwork of the EC Pills for Free Supply should be approved by theMinistry before manufacturing the tablets.

Special Note:

i	The identification mark "initial" for Emergency Contraceptive Pills should be embossed on the tablet itself.
ii	The packing of the outer cases of Emergency Contraceptive Pills should bear batch numbers indicated prominently both in "Alphanumeric characters" and in Bar-code.

MATERIAL SPECIFICATION & DIMENSION OF PACKING MATERIAL - EC PILL
(Free Supply)

	SPECIFICATION	NO.OF PIECES
Catch cover	1.SIZE : 23 X 11.5 CM (OPEN WALLET) 2. GSM : 250 MIN 3.WHITE BACK DUPLEX BOARD, with "Matt UV - Varnish" after printing. PRINTED IN FIVE COLOURS ON FRONT SIDE AS PER ARTWORK. 4,CUT, CREASED, & SUPPLIED FLAT, Supply in bundles of 100	One tab / Catch Cover
CARTON	Size:165(L) X 190 W X 57 (H) mm GSM:300 (min) Grey back duplex board with "Matt UV-Varnish " after printing with locked bottom . Partition plate of size :155 X 50 mm Thick:2 mm . Printed in 05 colours. Punched, creased & pasted with resin glue and supplied. mode of packing : Supply in bundles of 100	50 Strip/Carton
CORRUGATED BOX	*INTERNAL DIMENSIONS L:395MM,'W:345MM, 'H:300 MM' *NARROW FLUTE 7 PLY BOXES WITH INNER & OUTER PLY VIRGIN KRAFT PAPER OF WHICH OUTER PLY TO BE ALKALI RESISTANT WITH BITUMIN *THE BOX SHALL BE IN SINGLE PIECE WITH DOUBLE STAPPLING AS PER ISI 10066-1981*TOTAL GSM COMPRISING OF 1) OUTER LINING 160(BIT.) I 2) LINING 120X3 I>L1147 3) FLUTING 150x3 I DIRECTION OF FLUTE:VERTICAL PUNCTURE RESISTANCE NOT LESS THAN 45 C' OZS INCH PER TEAR INCH NATURE OF GUM:STARCH BASED BURSTING STRENGTH : 15KG/SQ'CM(MIN) STYLE: UNIVERSAL BURST FACTOR : NLT 20 STAPPLING : NLT 20 NO OF COLOURS FOR PRINTING: 02	20 Cartons/Master Carton


REEL UNWIND DIRECTION
204.00 mm
36.15 mm
PRL 36.15 MM
PANTONE BLACK 6C
PANTONE 711 C

LEVONORGESTREL TABLET I.P.
ezy • pill
AN ORAL EMERGENCY CONTRACEPTIVE FOR WOMEN
STORE IN A COOL AND DRY PLACE
PROTECT FROM LIGHT
LEVONORGESTREL TABLET I.P.
ईज़ी • पिल
Manufactured by:
LEVONORGESTREL TABLET I.P.
ezy • pill
AN ORAL EMERGENCY CONTRACEPTIVE FOR WOMEN
Consignee:
LEVONORGESTREL TABLET I.P.
ईज़ी • पिल
Contents
Batch No.
Mfg. Date
Exp. Date
390 mm
345 mm
396 mm
345 mm

HLL LIFECARE LIMITED
KANAGALA, BELGAUM- DIST. KARNATAKA

FINAL APPROVED ARTWORK FORMAT
(HLL/KFB/QA-022R 01)

Artwork Name:Wallet for EZY-PILL(Ministry)

Item code number:1110210748

Effective Date: 01.06.2016

Reason:New Logo added

Mode: Domestic

Revision No.:01

C 16 M 11 Y 10 K 0 BLACK C 6 M 97 Y 1 K 4 C0 M22 Y98 K0 C4 M99 Y98 K0

Prepared By:
(Lab Dept.)
Date:

Checked By:
(Lab Dept.)
Date:

Reviewed By:
Executive (QA)
Date:

Approved by:
Head of QA
Date:

HLL LIFECARE LIMITED
KANAGALA, BELGAUM- DIST. KARNATAKA

Annexure- 9 a

FINAL APPROVED ARTWORK FORMAT
(HLL/KFB/QA-022R 01)

Artwork Name:Carton for EZY-PILL(Ministry)

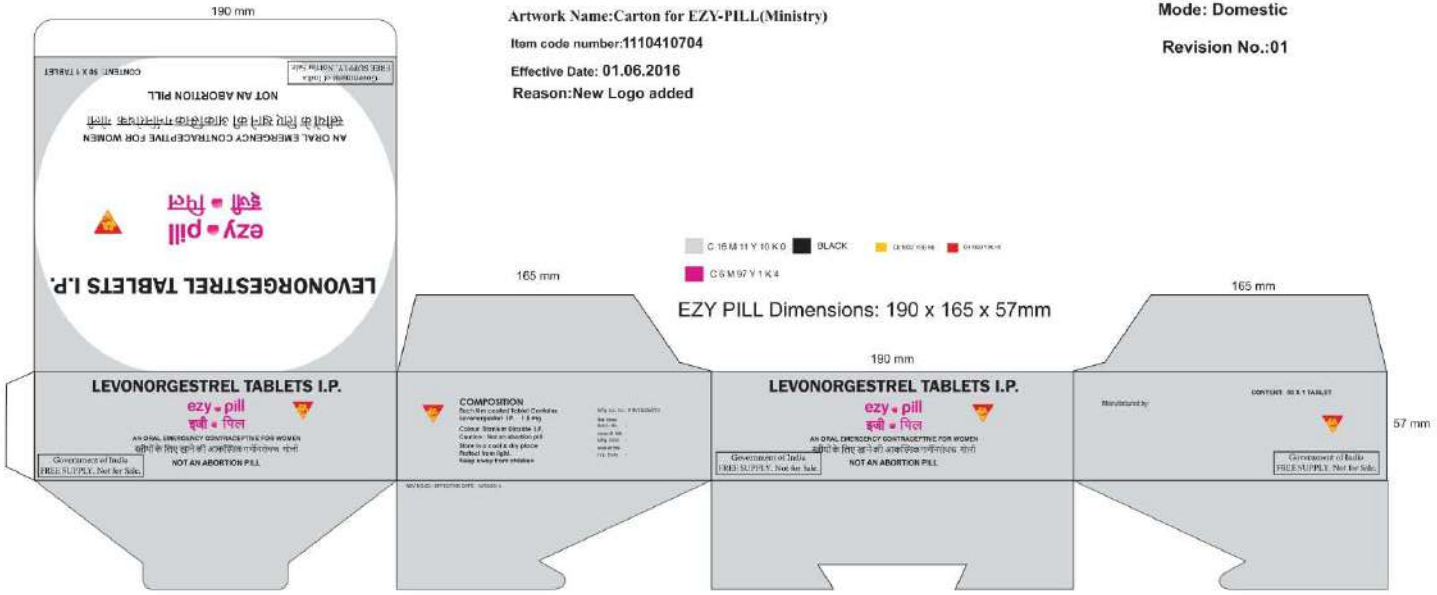
Item code number:1110410704

Effective Date: 01.06.2016

Reason:New Logo added

Mode: Domestic

Revision No.:01



Prepared By:
(Lab Dept.)
Date:

Checked By:
(Lab Dept.)
Date:

Reviewed By:
Executive (QA)
Date:

Approved by:
Head of QA
Date:

ARTWORK OF EZY PILL (LEVONORGESTREL 1.5 MG TABLETS I.P.) LEAFLET

160 mm

110 mm

ईजी - पिल लेने के लिए सूचनाएँ

ईजी - पिल महिलाओं के लिए मौखिक आकस्मिक गर्भनिरोधक है. यह एक हार्मोनल दवा है जो असुरक्षित संभोग के 72 घंटो के अंदर लेने से गर्भधारण को रोकती है.

ईजी - पिल का प्रयोग कब किया जाता है ?

- ईजी - पिल का इस्तेमाल केवल आकस्मिक परिस्थितियों में किया जाना चाहिए, जैसे असुरक्षित संभोग
- दंपति द्वारा अपनाए गर्भनिरोधक के इस्तेमाल में गलती होने पर (जिससे उसके विफल हो जाने की संभावना हो)
- बलात्कार या जबरदस्ती किए गए संभोग में

ईजी - पिल खुराक

1.5 मि. ग्रा. लिओनार्जेस्ट्रल की एक गोली

कैसी लेनी है ?

यह गोली असरक्षित संभोग के 72 घंटों के अंदर लेनी है (बेहतर है 12 घंटों के अंदर). अगर गोली लेने के 2 घंटे के अंदर महिला को उल्टी होती है तो दूसरी गोली, उल्टी रोकने की दवा के साथ लेनी चाहिए (स्वास्थ्य कार्यकर्ता / डाक्टर की सलाह लें). अगर उल्टी, गोली लेने के 2-घंटे पश्चात होती है, तो दूसरी गोली लेने की आवश्यकता नहीं है.

प्रभावशीलता

ईजी - पिल असुरक्षित लैंगिक संबंध से होनेवाली गर्भधारणा की जोखिम को 85 प्रतिशत से कम करती हैं.

गर्भधारणा एवं दुग्धस्त्रवण

ईजी - पिल लेने पर गर्भधारण अथवा दुग्धस्त्रवण पर कोई हानिकर परिणाम के कोई प्रमाण प्राप्त नहीं है.

साईड इफेक्ट्स

कुछ मामलों में उबकाई, पेट में दर्द एवं उल्टी संभावित है. कम सामान्य साईड इफेक्ट्स - सिरदर्द, स्तन में नरमी एवं चक्कर आना.

विपक्ष / प्रतिकलतः

- लिओनार्जेस्ट्रल अतिसंवेदनशील
- ज्ञात अथवा संदिग्ध गर्भधारणा

महत्वपूर्ण :

- ईजी - पिल नियमित गर्भनिरोध का विकल्प नहीं है, इसलिये ईजी - पिल लेने के बाद जितनी जल्दी हो सके अपने निकटतम स्वास्थ्य केन्द्र से परिवार नियोजन के नियमित तरीकों की सलाह लें.
- ईजी - पिल बाह्य गर्भधारणा (गर्भाशय के बाहर - या तो ट्यूब में या अन्य कहीं) को न तो रोकती है और न ही उसके होने की संभावना बढाती है.
- यह गर्भपात गोली नहीं है.

विनिर्माणकर्ता :
एचएलएल लाइफकेयर लिमिटेड
(भारत सरकार का उद्यम)
कणगला - 591 225, जिला - बेलगावि, कर्नाटक राज्य
स्वास्थ्य एवं परिवार कल्याण मंत्रालय, नई दिल्ली के लिए
हमारे उपभोक्ता कक्ष सहा. प्रबंधक से संपर्क करें - 919341806085

ARTWORK NO.	: AL-A2A-00
ITEM CODE	: 1110310161
EFFECTIVE DATE	: MAY 2019
REFERENCE	: OCP ARTWORK

REVISION HISTORY:
00 - New Artwork

REMARKS:

PREPARED BY:	CHECKED BY:	VERIFIED BY:	APPROVED BY:
(RA)	(QA)	(Production)	(Head of QA)

ARTWORK OF EZY PILL (LEVONORGESTREL 1.5 MG TABLETS I.P.) LEAFLET

160 mm

110 mm

INSTRUCTIONS FOR EZY-PILL USE

What is EZY-PILL ?
EZY-PILL is an Oral Emergency Contraceptive for women. It is a hormonal which can prevent pregnancy if used within 72 hours of unprotected intercourse.

When to use EZY-PILL ?
EZY-PILL should be used only in Emergency situations like:

- Any unprotected sex
- Contraceptive mistakes (Failure to use regular contraceptive method in a correct and consistent manner)
- Sex was forced (rape) or coerced.

Dosage
One Pill of Levonorgestrel 1.5 mg.

How to take?
The Pill must be taken within 72 hours of unprotected intercourse, preferably within 12 hours. If vomiting occurs within 2 hours after taking EZY-PILL, the dose should be repeated with anti-nausea medication (As per the direction of Health Care Provider)
If vomiting occurs after two hours of taking EZY-PILL, she need not take any extra Pill.

Effectiveness.
EZY-PILL reduces the risk of pregnancy from a single act of unprotected sexual intercourse by 85 percent.

Pregnancy and Lactation.
There is no evidence of harmful effects of EZY-PILL on pregnancy or lactation.

Side effects:
Nausea, pain in abdomen and vomiting may occur in some cases. Less common side effects are headache, breast tenderness, dizziness, irregular bleeding and effect on skin due to over sensitivity.

Contraindications:

- Hypersensitivity to Levonorgestrel.
- Known or suspected pregnancy.

Important:

- EZY-PILLs are not a substitute for regular contraception. Hence, after taking EZY-PILL it is advised to visit nearest health centre/health worker for regular contraception as soon as possible.
- EZY -PILLs neither prevent nor increase the chance of anectopic pregnancy.
- It is not an abortion Pill.

Manufactured by:
HLL Lifecare Limited
(A Govt. of India Enterprise)
Kanagala - 591 225, Dist. Belagavi Karnataka State, INDIA

For Ministry of Health & Family Welfare, New Delhi

Contact our consumer call assistant manager at +919341806085

ARTWORK NO.	: AL-A2A-00
ITEM CODE	: 1110310161
EFFECTIVE DATE	: MAY 2019
REFERENCE	: OCP ARTWORK

REVISION HISTORY:
00 - New Artwork

REMARKS:

PREPARED BY:	CHECKED BY:	VERIFIED BY:	APPROVED BY:
(RA)	(QA)	(Production)	(Head of QA)

Schedule-IV

Annexure-13

APPROVED SPECIFICATIONS FOR ONE STEP PREGNANCY TEST KIT (Card/Cassette Format)

1	TEST SPECIMEN	:	URINE
2	TEST PRINCIPLE	:	SINGLE STEP, SELF PERFORMING SANDWICHED IMMUNOSSAY USING COULLOINDAL GOLD & ANTI hCG ANTIBODIES IN LATERAL FLOWIMMUNOCHROMATOGRAPY FORMAT
3	SENSITIVITY	:	NOT LESS THAN 25 MILLI I.U PER ML. OF URINE
4	SPECIFICITY	:	100% (NO CROSS REACTIVITY WITH OTHER GONADOTROPIN HORMONES LIKE LH, FSH ETC.)
5	BUILT IN CONTROL	:	SHOULD HAVE BUILD IN CONTROL FOR CORRECTNESS OF THE TESTING PROCEDURE
6	NITROCELLULOSE PAPER	:	NITROCELLULOSE PAPER COATED WITH ANTI HCG ANITBODIES FOR TEST BAND & APPROPRIATE REAGENTS FOR CONTROL BAND
7	CASSESTTE	:	CASSETTE MADE OF ABS OR PP
8	POUCH	:	TRIPPLE LAYERED LAMINATED POUCH HAVING ALUMIMIUM FOIL IN THE MIDDLE LAYER
9	SILICA GEL	:	EVERY TEST PACK SHOULD HAVE MOISTURE INDICATING SLIICA GEL POUCH
10	DROPER	:	EVERY TEST POUCH SHOULD HAVE DISPOSABLE DROPER FOR URINE SPECIMEN ADDITION
11	SHELF LIFE	:	18-24 MONTH FROM THE DATE OF MANUFACTURING
12	PACK SIZE	:	10 TESTS PER BOX
13	STORAGE CONDITION	:	THE KIT SHOULD BE STABLE AT ROOM TEMPERATURE
14	PACKING	:	LAMINATED PRINTED CARTON, THE CARTONS SHOULD BE PACKED IN SUITABLE CORRUGATED SHIPPER BOX FOR DISPATCH.

Inspection

a) The mode of offering supply and procedure adopted for sampling will be governed as per specification.

b) A packing slip indicating the quantity of the contents in the box should invariably be kept in each box by the manufacturer / supplier. Quantities withdrawn from the boxes as samples for test should be indicated in the packing slip contained therein.

i) ISI specification is meant to be a reference to the latest issue of the said specification.

ISI specifications are priced publications and can be procured on payments from the Bureau of Standards, Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi – 2 or from any of the regional offices.

Size 110 x 65 mm

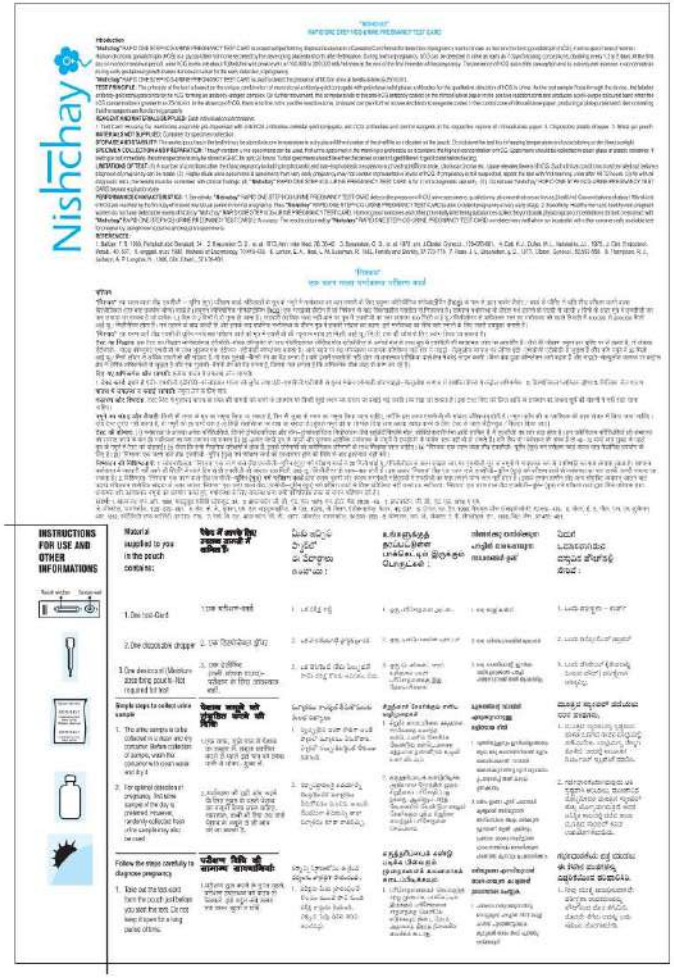
CMYK Blue

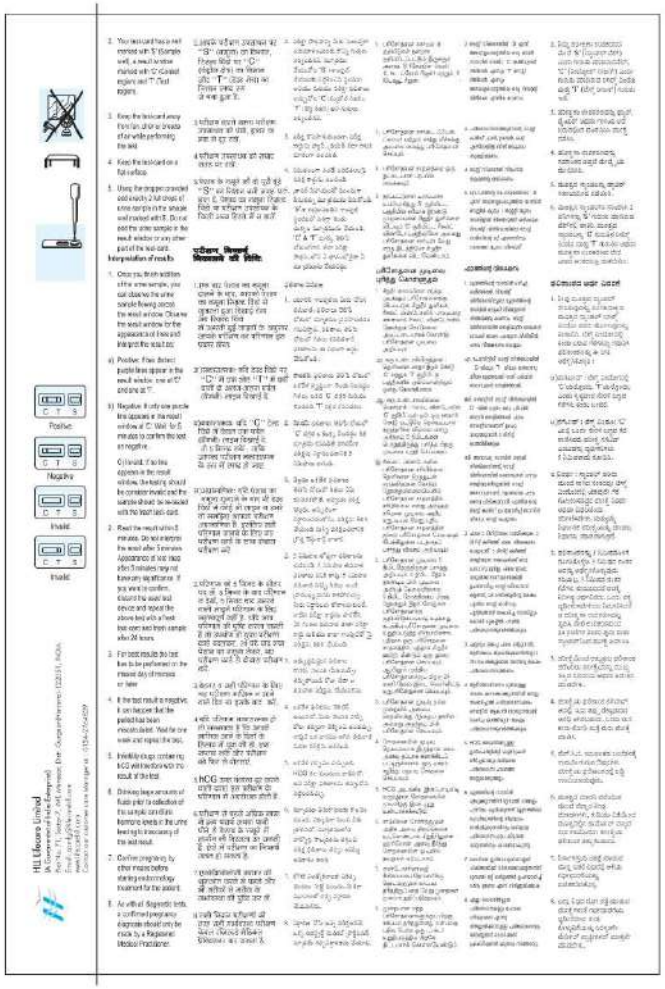

RSG 14.03.2018
Size: 110 x 60 x 60 mm
Nishchay
निश्चय
Nishchay
Rapid One Step hCG-Urine Pregnancy Test Card
(Anti hCG Anti Sera on membrane)
स्वस्थ मातृत्व, अब आपके हाथ
Healthy Motherhood, Now in your control
Government of India Free Supply, Not for sale.
Manufactured by:

RSG 29.11.12
SIZE:115x65x70mm

RSG 29.11.12

SIZE: 7.5" x 11"





Schedule-V

ANNEXURE-A

Technical Specifications

Approved Specifications for the Injectable Contraceptive (Medroxyprogesterone Acetate)

1	Name of Injection	:	Medroxyprogesterone Acetate Injection IP
2	Mode	:	IM vial with Sterile Disposable Syringe 2 ml & alcohol cotton swab.
3	Amount	:	1 ml. of Medroxyprogesterone Acetate injection vial+1 sterile single use syringe (2 ml) with needle+1 alcohol swab (containing isopropyl alcohol 70% v/v)
			Medroxyprogesterone Acetate I.P. 150 mg
11	SHELF LIFE	:	36 Months
12	PACK SIZE	:	Will be intimated later on
13	STORAGE CONDITION	:	Store at room temperature (**15^0** C to **30^0** C), Protect from light, do not freeze.
14	PACKING	:	**Pack Size** **Unit Pack:** 1 ml. Medroxyprogestrone acetate injection vial + 1 sterile single use syringe 2ml with needle + 1 alcohol swab + 1 patient information leaflet (all 4 components in one mono carton) **Outer Pack**: 8 x 1s (8 mono cartons each carrying one unit pack) **Shipper Pack:** 30 x 8s x 1s (30 outer packs of 8 unit packs. Shipper contains total 240 units packs) **Packaging Dimensions** **Unit Pack:** Length 12cm X Width 3.5 cm X Height 4.5 cm **Outer Pack**: Length 15cm X Width 9.5 cm X Height 12.5 cm **Shipper Pack:** Length 45cm x Width 49 cm x Height 32 cm


℞ Medroxyprogesterone Injection IP 150mg/ml
Contraceptive Injection
Antara Programme
अंतरा कार्यक्रम
Sterile Aqueous Suspension 1ml
For deep intramuscular use only.
Single Use Only
125X85X92
248-0618
Each ml contains:
Medroxyprogesterone acetate IP 150 mg
Sodium Chloride (tonicity regulator) IP 8.6 mg
Sodium Hydroxide (pH adjustment) IP q.s.
Hydrochloric Acid (pH adjustment) IP q.s.
Water for Injections IP q.s.
Excipients q.s.
Store at room temperature (15°C to 30°C)
Protect from light. Do not freeze.
Shake well before use
Keep out of reach of children.
Not for sale. For FREE SUPPLY under Antara Programme of Govt. of India
This pack contains 8 monocartons each containing 1 drug vial + 1 sterile single use syringe (2ml) with needle + 1 alcohol swab (containing isopropyl alcohol 70%v/v)
For information about use, dosage and administration please see package insert.
℞ Medroxyprogesterone Injection IP 150mg/ml
Contraceptive Injection
Antara Programme
अंतरा कार्यक्रम
STORE UPRIGHT
Sterile Aqueous Suspension 1ml
For deep intramuscular use only.
Single Use Only
Mfg. Lic. No.: MB/05/158
Batch No :
Mfg Date :
Expiry Date:
SCHEDULE H PRESCRIPTION
Manufactured in India by
Health Biotech Ltd.
(A WHO GMP Certified Company)
Nalagarh Road, Baddi,
Distt. Solan (H.P) India- 173205
For details of the syringe and alcohol swab, please refer to the individual labels of the syringe and alcohol swab.

45 X 20 X 120 MM

45 X18 MM

ENLARGE SIZE

℞

Medroxyprogesterone Injection IP 150mg/ml

Contraceptive Injection Sterile Aqueous Suspension 1ml
For deep intramuscular use only.
Single Use Only

Antara Programme अंतरा कार्यक्रम

STORE UPRIGHT

Each ml contains:

Medroxyprogesterone acetate	IP	150 mg
Sodium Chloride (tonicity regulator)	IP	8.6 mg
Sodium Hydroxide (pH adjustment)	IP	q.s.
Hydrochloric Acid (pH adjustment)	IP	q.s.
Water for Injections	IP	q.s.
Excipients		q.s.

Store at room temperature (15°C to 30°C)
Protect from light. Do not freeze.

Shake well before use

Keep out of reach of children.

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

For information about use, dosage and administration please see package insert.

This pack contains: 1 drug vial + 1 sterile single use syringe (2ml) with needle + 1 alcohol swab (containing isopropyl alcohol 70% v/v)

Mfg. Lic. No .: MB/05/158

Batch No :

Mfg Date :

Expiry Date:

Not for sale. For FREE SUPPLY under Antara Programme of Govt. of India

Manufactured in India by:
Health Biotech Ltd.
(A WHO GMP Certified Company)
Nalagarh Road, Baddi,
Distt: Solan (H.P) India- 173205

311-0716

145 x 110 mm

30 x 8 x 1 (Drug vial + Sterile single use syringe (2ml) with needle + Alcohol swab) each

℞ **Medroxyprogesterone Injection IP 150mg/ml**

Antara Programme
अंतरा कार्यक्रम

Store at room temperature (15°C to 30°C)
Protect from light. Do not freeze.

Shake well before use

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

Not for sale. For FREE SUPPLY under Antara Programme of Govt. of India

STORE UPRIGHT

Mfg. Lic. No .: MB/05/158
Batch No :
Mfg Date :
Expiry Date:
Case No.:

Manufactured in India by:
Health Biotech Ltd.
(A WHO GMP Certified Company)
Nalagarh Road, Baddi,
Distt: Solan (H.P) India- 173205

249-0616

For the use only of a registered medical practitioner, or a hospital or a laboratory

Medroxyprogesterone Injection I.P.

Antara

1. **NAME OF THE MEDICINAL PRODUCT**
Medroxyprogesterone Injection I.P.

2. **QUALITATIVE AND QUANTITATIVE COMPOSITION**
Each ml contains medroxyprogesterone acetate I.P. 150 mg.
For a full list of excipients, see section 6.1.

3. **PHARMACEUTICAL FORM**
Sterile aqueous suspension.

4. **CLINICAL PARTICULARS**

4.1 Therapeutic Indications
Medroxyprogesterone acetate (MPA) injectable suspension is indicated for:
- Contraception

Long-term Use
Since loss of bone mineral density (BMD) may occur in pre-menopausal women who use MPA injection long-term (see Section 4.4 - Special Warnings and Precautions for Use and Section 5.1 – Pharmacodynamic Properties), a risk/benefit assessment, which also takes into consideration the decrease in BMD that occurs during pregnancy and/or lactation, should be considered.

4.2 Posology and Method of Administration
Injectable suspensions should be shaken well before use.
Contraception
MPA intramuscular (IM) should be vigorously shaken just before use to ensure that the dose being administered represents a uniform suspension.
The recommended dose is 150 mg of MPA injectable suspension every 3 months (12-13 weeks) administered by intramuscular injection in the buttocks (gluteal muscle, upper outer portion), upper arm (deltoid muscle) or thigh (outer anterior). The preferred, easily accessible and acceptable site is deltoid muscle. Dosage does not need to be adjusted for body weight. The IM suspension is not formulated for subcutaneous injection.
First injection
The initial IM injection should be given during the first 7 days after the onset of a normal menstrual period. In post-partum women not breastfeeding and been less than 4 weeks after giving birth the IM injection can be started anytime. If it is more than 4 weeks after giving birth for a post-partum woman who is not breastfeeding and menses have not returned and if it is reasonably certain that the woman is not pregnant though the IM injection can still be given anytime she would need a back-up method for the first 7 days after the injection. In case of a woman who is exclusively breast feeding or, if exclusively breast-feeding, at or after 6 weeks postpartum.
Second and subsequent injections
If the time interval between IM injections is greater than 16 weeks, pregnancy should be ruled out before administering the next IM injection.
Switching from other methods of contraception
When switching from other contraceptive methods, (MPA IM) should be given in a manner that ensures continuous contraceptive coverage based upon the mechanism of action of both methods, (e.g., patients switching from oral contraceptives can start injectable IM immediately)
Hepatic insufficiency
No clinical studies have evaluated the effect of hepatic disease on the pharmacokinetics of MPA. However, MPA is almost exclusively eliminated by hepatic metabolism and steroid hormones may be poorly metabolized in patients with severe liver insufficiency (see Section 4.3 - Contraindications).
Renal insufficiency
No clinical studies have evaluated the effect of renal disease on the pharmacokinetics of MPA. However, since MPA is almost exclusively eliminated by hepatic metabolism, no dosage adjustment should be necessary in women with renal insufficiency.

4.3 Contraindications
MPA is contraindicated in patients with the following conditions:
- Known or suspected pregnancy
- Undiagnosed vaginal bleeding
- Severe liver dysfunction
- Known hypersensitivity to MPA or any component of the drug

Conditions with special precautions applying clinical judgement
- Known or suspected malignancy of the breast or genital organs
- Severe hepatic impairment
- Metabolic bone disease
- Active thromboembolic disease and in clients with current or past history of cerebrovascular disease

4.4 Special Warnings and Precautions for Use General
- Unexpected vaginal bleeding during therapy with MPA should be investigated.
- MPA may cause some degree of fluid retention; therefore, caution should be exercised in treating any patient with a pre-existing medical condition that might be adversely affected by fluid retention.
- Patients with a history of treatment for clinical depression should be carefully monitored while receiving MPA therapy.
- Some patients receiving MPA may exhibit a decreased glucose tolerance. Diabetic patients should be carefully observed while receiving such therapy.
- The pathologist (laboratory) should be informed of the patient's use of MPA if endometrial or endo-cervical tissue is submitted for examination.
- The physician/laboratory should be informed that use of MPA may decrease the levels of the following endocrine biomarkers:
  a. Plasma/urinary steroids (e.g., cortisol, estrogen, pregnanediol, progesterone, testosterone)
  b. Plasma/urinary gonadotrophins (e.g., LH and FSH)
  c. Sex-hormone-binding-globulin
- Medication should not be re-administered pending examination if there is a sudden partial or complete loss of vision or if there is a sudden onset of proptosis, diplopia, or migraine. If examination reveals papilledema or retinal vascular lesions, medication should not be re-administered.
- MPA has not been causally associated with the induction of thrombotic or thromboembolic disorders, however MPA is not recommended in any patient with a history of venous thromboembolism (VTE). Discontinuation of MPA is recommended in patients who develop VTE while undergoing therapy with MPA.

Additional Warnings & Precautions for Specific Use or Formulation:
Contraception/Endometriosis - Injectable Formulations
Loss of Bone Mineral Density
Use of MPA injection reduces serum estrogen levels in premenopausal women and is associated with loss of BMD as bone metabolism accommodates to a lower estrogen level. This loss of BMD is of particular concern during adolescence and early adulthood, a critical period of bone accretion. In both adult and adolescent females, the decrease in BMD during treatment appears to be substantially reversible after MPA injection is discontinued and ovarian estrogen production increases (see Section 5.1 – Pharmacodynamic Properties).
Other birth control methods or endometrial treatments should be considered in the risk/benefit analysis for the use of MPA injection in women with osteoporotic risk factors such as:
- Chronic alcohol and/or tobacco use
- Chronic use of drugs that can reduce bone mass, e.g, anticonvulsants or corticosteroids
- Low body mass index or eating disorder, e.g., anorexia nervosa or bulimia
- Metabolic bone disease
- Strong family history of osteoporosis

It is recommended that all patients have adequate calcium and Vitamin D intake.
Contraception
- Most women using MPA injectable suspension experience disruption of menstrual bleeding patterns (e.g., irregular or unpredictable bleeding/spotting, rarely, heavy or continuous bleeding). As women continue using MPA injectable suspension, fewer experience irregular bleeding and more experience amenorrhea.
- Long-term case-controlled surveillance of users of MPA injectable suspension found slight or no increased overall risk of breast cancer and no overall increased risk of ovarian, liver, or cervical cancer and a prolonged, protective effect of reducing the risk of endometrial cancer.
- MPA IM injectable suspension has a prolonged contraceptive effect. The average time to return of fertility is 7-10 months from date of last injection and is unrelated to duration to the duration of use. There was a tendency for women to gain weight while on therapy with MPA.
- If jaundice develops, consideration should be given to not re-administer the drug.
- Patients should be counseled that MPA injectable suspension does not protect against HIV infection (AIDS) or other sexually transmitted diseases.

Breast Cancer
The use of combined oral estrogen/progestin by post-menopausal women has been reported to increase the risk of breast cancer. Results from a randomized placebo-controlled trial, the WHI trial, and epidemiological studies (see Section 5.1 - Pharmacodynamic Properties) have reported an increased risk of breast cancer in women taking estrogen/progestin combinations for HT for several years. In the WHI conjugated equine estrogens (CEE) plus MPA trial and observational studies, the excess risk increased with duration of use (see Section 4.2 - Posology and Method of Administration). The use of estrogen plus progestin has also been reported to result in an increase in abnormal mammograms requiring further evaluation.
In several epidemiologic studies no overall increased risk for breast cancer was found among users of injectable depot progestogens in comparison to non-users. However, an increased relative risk (e.g. 2.0 in one study) was found for women who currently used injectable depot progestogens or had used them only a few years before. It is not possible to infer from these data whether this increased rate of breast cancer diagnosis among current users is due to increased surveillance among current users, the biological effects of injectable progestogens, or a combination of reasons.

Cardiovascular Disorders
Estrogens with or without progestins should not be used for the prevention of cardiovascular disease. Several randomized, prospective trials on the long-term effects (see Section 4.2 – Posology and Method of Administration), of a combined estrogen/progestin regimen in post-menopausal women have reported an little increased risk of cardiovascular events such as myocardial infarction, coronary heart disease, stroke, and venous thromboembolism.
- **Stroke and Venous thromboembolism/Pulmonary embolism**
In large trials, no substantial increase in the overall incidence of Venous thromboembolism (VTE) or stroke has been noted.

History and Physical Examination
- Menstrual - Date of Last Menstrual Period (LMP), menstrual cycle details including length of cycle, duration and amount of flow, any dysmenorrhoea, regularity of periods, any intermenstrual bleeding.
- Obstetric - number of pregnancies and living children and mode of delivery, date of last childbirth, number and date of abortion/MTP, current pregnancy status.
- Breast feeding - full, partial or not at all.
- Contraceptive - when and what was the last contraceptive used. If discontinued, when and why.
- Medical
  - History of illness and other medical conditions in the past or at present as mentioned under the screening checklist as adapted from WHO MEC 2015. Rule out any febrile illness or diabetes.
  - Known allergies especially to progesterone or to constituents of injection.
  - Current medications and reasons thereof.

Although a detailed examination is seldom necessary, it is a good practice to perform general physical examination, abdominal, pelvis and any other examination as indicated by the client's history.
- General Physical Examination: includes general condition, pulse, blood pressure, respiratory rate, temperature, body weight, pallor, nutritional status etc.
- A Routine Abdominal Examination should be done.
- Pelvic Examination: It is not mandatory but the opportunity may be used to rule out STIs/RTIs or other pelvic diseases.

Gynecology - *Injectable Formulations*
Prolonged anovulation with amenorrhea and/or erratic menstrual patterns may follow the administration of either a single or multiple injectable dose of MPA.

Pregnancy and Lactation
Pregnancy
MPA is contraindicated in women who are pregnant.
Studies have found no differences in the health, growth, sexual development, aggression, physical activity or sex role identity of teenage children exposed in utero to MPA as compared with no in utero exposure.
If the patient becomes pregnant while using this drug, the patient should be appraised of the potential hazard to the fetus.
Lactation
MPA and its metabolites are excreted in breast milk. There is no evidence to suggest that this presents any hazard to the nursing child (see Section 5.2 - Pharmacokinetic Properties).

4.6 Effects on Ability to Drive and Use Machines
The effect of medroxyprogesterone acetate on the ability to drive and use machinery has not been systematically evaluated.

4.7 Undesirable Effects
CONTRACEPTION Intramuscular (IM) Formulation:

MEDDRA SOC	EVENT
Infections and infestations	Vaginitis
Immune System disorders	Hypersensitivity reactions (e.g. anaphylaxis & anaphylactoid reactions, angioedema)
Endocrine disorders	Prolonged anovulation
Metabolism and nutritional disorders	Fluid retention, weight change
Psychiatric disorders	Depression, ,, nervousness
Nervous system disorders	dizziness, headache, somnolence
Vascular disorders	, hot flashes
Gastrointestinal disorders	Abdominal pain or discomfort, bloating, nausea
Hepato-biliary disorders	Jaundice
Skin and subcutaneous tissue disorders	Acne, alopecia, hirsutism, pruritus, rash, urticarial
Musculoskeletal and connective tissue and bone disorders	Arthralgia, backache, leg cramps
Reproductive system and breast disorders	Abnormal uterine bleeding (irregular, increase, decrease), amenorrhea, leukorrhea, pelvic pain, galactorrhea, mastodynia, breast tenderness
General disorders and administration site conditions	Fatigue, asthenia, injection-site reactions, pyrexia
Investigations	Decreased glucose tolerance, disturbed liver function, loss of bone mineral density

MEDDRA SOC	EVENT
Immune System disorders	Hypersensitivity reactions (e.g., anaphylaxis & anaphylactoid reactions, angioedema)
Endocrine disorders	Prolonged anovulation
Metabolism and nutritional disorders	Edema/fluid retention, weight change
Psychiatric disorders	Depression, insomnia, nervousness
Nervous system disorders	Dizziness, headache, somnolence
Vascular disorders	Thromboembolic disorders
Gastrointestinal disorders	Nausea
Hepatobiliary disorders	Cholestatic icterus/jaundice
Skin and subcutaneous tissue disorders	Acne, alopecia, hirsutism, pruritus, rash, urticaria
Reproductive system and breast disorders	Abnormal uterine bleeding (irregular, increase, decrease), amenorrhea, cervical erosions, galactorrhea, mastodynia, breast tenderness
General disorders and administration site conditions	Fatigue, injection-site reactions, pyrexia
Investigations	Alterations of cervical secretions, decreased glucose tolerance

4.8 Overdose
No positive action is required other than cessation of therapy.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties
Medroxyprogesterone acetate (17α-hydroxy-6α-methyl progesterone acetate) is a derivative of progesterone.

Mechanism of Action

MPA is a synthetic progestin (structurally related to the endogenous hormone progesterone) which has been demonstrated to possess several pharmacologic actions on the endocrine system:

- Inhibiting ovulation - by suppressing mid cycle peaks of LH and FSH
- Thickening of cervical mucus - due to depletion of oestrogen. The thick mucus prevents sperm penetration into the upper reproductive tract.
- Thinning of endometrial lining - due to high progesterone and depleted oestrogen, making it unfavourable for implantation of fertilized ovum.

All of these actions result in a number of pharmacological effects as described below.

Contraception

MPA, when administered parenterally at the recommended dose to women, inhibits the secretion of gonadotropins which, in turn, prevents follicular maturation and ovulation and results in endometrial thinning.

Medroxyprogesterone acetate (MPA), administered parenterally in the recommended doses to women with adequate endogenous estrogen, transforms proliferative into secretory endometrium. Androgenic and anabolic effects have been noted, but the drug is apparently devoid of significant estrogenic activity. Parenterally administered MPA inhibits gonadotropin production, which in turn prevents follicular maturation and ovulation.

Clinical Studies

Bone Mineral Density Studies

BMD Changes in Adult Women

In a controlled, clinical study adult women using MPA injection (150 mg IM) for up to 5 years for contraception showed spine and hip mean BMD decreases of 5%-6%, compared to no significant change in BMD in the control group. The decline in BMD was more pronounced during the first two years of use, with smaller declines in subsequent years. Mean changes in lumbar spine BMD of -2.86%, -4.11%, -4.89%, -4.93% and -5.38% after 1, 2, 3, 4 and 5 years, respectively, were observed. Mean decreases in BMD of the total hip and femoral neck were similar.

After stopping use of MPA injection (150 mg IM), there was progressive recovery of BMD toward baseline values during the 2-year post-therapy period. After 2 years off treatment, the BMD deficit had decreased to approximately 2.1% at the spine and hip. A longer duration of treatment was associated with a slower rate of BMD recovery (see Section 4.4 – Special Warnings and Precautions for Use).

BMD Changes in Adolescent Females (12-18 years)

An open-label non-randomized clinical study of MPA injectable (150 mg IM every 3 months for up to 240 weeks [4.6 years]) in adolescent females (12-18 years) for contraception also showed a decline in BMD from baseline. Among subjects who received ≥4 injections/60-week period, the mean decrease in lumbar spine BMD was -2.1% after 240 weeks; mean decreases for the total hip and femoral neck were -6.4% and -5.4%, respectively. Based on mean changes, post-treatment follow-up showed that lumbar spine BMD recovered to baseline levels approximately 1 year after treatment was discontinued and that hip BMD recovered to baseline levels approximately 3 years after treatment was discontinued. In contrast, unmatched, untreated subjects showed mean BMD increases at 240 weeks of 6.4%, 1.7% and 1.9% for lumbar spine, total hip and femoral neck, respectively (see Section 4.4 – Special Warnings and Precautions for Use).

Million Women Study

The MWS was a prospective cohort study enrolling 1,084,110 women in the UK aged 50-64 years of whom 828,923 with defined time since menopause were included in the main analyses of risk of breast cancer in relation to HT. Overall, 50% of the study population had used HT at some point. Most current users of HT at baseline reported using preparations containing estrogen only (41%) or estrogen-progestin combinations (50%). The average duration of follow-up was 2.6 years for analyses of cancer incidence and 4.1 years for analyses of mortality (see Section 4.4 - Special Warnings and Precautions for Use).

Heart and Estrogen/Progestin Replacement Studies

HERS and HERS II studies were two randomized, prospective secondary prevention trials on the long-term effects of oral continuous combined CEE/MPA (0.625 mg CEE plus 2.5 mg MPA) regimen in post-menopausal women with CHD (see Section 4.4 – Special Warnings and Precautions for Use). 2,763 post-menopausal women with a mean age of 66.7 years and with intact uteri were enrolled in this study. The average duration of follow-up was 4.1 years for HERS and 2.7 additional years (for a total of 6.8 years) for HERS II (see Section 4.4 - Special Warnings and Precautions for Use).

5.2 Pharmacokinetic Properties

Intramuscular Formulations

Absorption: Following intramuscular administration, MPA is slowly released, resulting in low, but persistent levels in the circulation. Immediately after intramuscular injection of 150 mg/ml MPA, plasma levels were 1.7 ± 0.3 nmol/L. Two weeks later, levels were 6.8 ± 0.8 nmol/L. Mean time to peak is approximately 4 to 20 days following an intramuscular dose. Serum medroxypro-gesterone acetate levels gradually decline and remain relatively constant at about 1 ng/ml for 2-3 months. Circulating levels can be detected for as long as 7 to 9 months following an intramuscular injection.

Distribution: MPA is approximately 90% to 95% protein bound. Volume of distribution is reported as 20 ± 3 litres. Medroxyprogesterone acetate crosses the blood-brain-barrier, and the placental barrier (see Section 4.6 - Pregnancy and Lactation). Low levels of medroxyprogesterone acetate have been detected in breast milk of lactating women (see Section 4.6 – Pregnancy and Lactation) administered 150 mg of medroxyprogesterone acetate by the IM route.

Metabolism: MPA is metabolized in the liver.

Elimination: The elimination half-life following single intramuscular injection is about 6 weeks. Medroxyprogesterone acetate is primarily excreted in the feces, via biliary secretion. Approximately 30% of an intramuscular dose is secreted in the urine after 4 days.

5.3 Preclinical Safety Data

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term intramuscular administration of medroxyprogesterone acetate (MPA) has been shown to produce mammary tumors in beagle dogs. There was no evidence of a carcinogenic effect associated with the oral administration of oral MPA to rats and mice. Medroxyprogesterone acetate was not mutagenic in a battery of *in vitro* or *in vivo* genetic toxicity assays. Medroxyprogesterone acetate at high doses is an antifertility drug and high doses would be expected to impair fertility until the cessation of treatment.

6 PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sodium Chloride
Methyl Parahydroxybenzoate
Propyl Parahydroxybenzoate
Polysorbate 80
Macrogol 3350 (Polyethylene Glycol 3350)
Water for Injections
Sodium Hydroxide and/or Hydrochloric Acid (when necessary to adjus pH)

6.2 Incompatibilities

MPA should not be mixed with any other agent.

6.3 Shelf Life

Please refer to the pack for the expiry date.

6.4 Special Precautions for Storage

Store at room temperature (15°C to 30°C). Protect from light. Do no freeze.

6.5 Nature and Contents of Container

1 ml glass vial (as 150 mg/ml) made up of hydrolytic glass class I and butyl rubber stopper + 1 sterile single use syringe (2ml) with needle + 1 alcohol swab (containing isopropyl alcohol 70% v/v).

6.6 Special Precautions for Disposal of a Used Medicinal Product or Waste Materials Derived From Such Medicinal Product and Other Handling of the Product

MPA injectable suspension should be vigorously shaken just before use to ensure that the dose being administered represent a uniform suspension.

Dispose off properly after use **as per biomedical waste management guidelines.**

Drug vial manufactured by:

Pack containing 1 drug vial + 1 sterile single use syringe (2ml) with needle + 1 alcohol swab (containing isopropyl alcohol 70% v/v)

Schedule-VI

Annexure-A

STANDARDS FOR COPPER-T 380 A

Definition: Copper-T 380A is a T shaped intrauterine device having a copper collar on each of the horizontal arms and a copper wire wound on to the vertical arm with dimensions as shown in figure l, with a plastic mono filament tied to the ball end of the vertical arm of the T. The T shall be dispensed with a plastic insertion tube and a solid rod having dimensions as shown in figure l, to facilitate insertion of the device in to the uterine cavity.

1.1 This standards, cover the shape dimensions, manufacturing specification and the finished product specifications required for intra uterine contraceptive device Copper-T 380 A and its components.

2. References:

2.1 The following standards contain provisions which through reference in this text, constitute provisions of this standards. At the time of publications, the edition indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent edition of the standards indicated below:

IS No.		Title
3395:1997	:	Low density, Poly Ethylene (LDPE) and Linear Low Density Poly Ethylene (LLDPE) – materials for moulding & extrusion (2nd Version)
13360 (part4/Secl): 1995	:	Plastics-methods of testing : part 4 Rheological properties: Section 1 determination of the melt mass flow rate (MFR) and the melt volume flow rate (MVR) of thermo plastics.

3. Procedure/specification for testing during manufacture:

3.1 Shape and dimensions

3.1.a The shape and dimensions of Copper-T 380A components are shown in Figure l.

3.1.b The flange as shown in figure shall be positioned so as to be at 70±5mm from T end on the insertion tube. The dimension of the flange given in the figure l are for guidance only.

3.2 Mass of Copper wire and collar

3.2.a Mass of Copper wire:

The mass of the copper wire wound on the vertical frame of the T shall be 176±11mgs – Sampling Plan: Single Plan General Inspections level II – AQL 1%

3.2.b Mass of Copper Collar-

The mass of each copper collar fitted on the horizontal arm shall be 68.7±3mgs – Sampling Plan General Inspections level II – AWL 1%

3.3 Materials for Copper-T components

3.3.a T

The T shall be made of a compound obtained by blending low density poly ethylene (see IS 3395) and barium sulphate (20-24%) quality of $BaSO_4$ shall be as per IP /USP/BP/EP. The low density poly ethylene shall pass the extractable test as per MethodA given in IS 12418(Part-4) and shall have melt mass flow rates between 1.8 to 2.2 g-per 10 minutes when tested according to the method in IS 13360 (part 4/Sec. 1). The blend of LDPE and $BaSO_4$ shall meet the requirements of the implantation test as per methodB given in IS 12418(Part-4).

3.3.a.1 The lower end of the vertical arm of the T shall not deviate by more than 3mm from the central axis.

3.3.b. Solid Rod

The solid rod shall be made of polypropylene with approximately 0.5% pharmaceuticals grade titanium dioxide.

3.3.b.1 The solid rods with following shape structures shall be accepted:

a. Rod without having ball or fin
b. Rod with ball
c. Rod with fin

3.3.c Insertion tube

The insertion tube shall made of high density poly ethylene which shall pass the extractable tests as per pharmacopoeia requirements. The polyethylene shall be tested at the manufacturing stage. It shall have a

melt mass flow rate between 0.6 to 0.8 g/10 minute when tested according to the method given in IS 13360(part4/Sec.1).

3.3.c.1 It is optional to have the marking on the scale in cm on the insertion tube with a pharmaceutical grade material so that it does not produce any toxic effects when in contract with the body fluids.

3.3.d. Flange

The flange shall be made of ply vinyl chloride containing approx. 1% titanium di oxide and pharmacopoeial grade "blue" or "yellow" (IP grade).

3.3.e. Tie (Thread)

The tie shall be made of high density polyethylene with approx. 1% titanium di oxide (IP grade) or iron oxide to give white or dark colour respectively. The material shall pass implantation test when tested as per Method B. The tie shall be monofilament.

3.3.f. Copper wire/Copper Collar

The material of copper wire and copper collar shall be 99.99% pure and no other individual element shall be more than 50ppm. The manufacturer shall ascertain the purity of copper wire and copper collar used.

3.4 Dimensions

		Specification	AQL	Sampling Plan
3.4.a	**T frame**			
	Horizontal arm length	31.6mm-32.3mm	4%	**Single plan General Inspection Level II**
	Horizontal arm diameter	1.5mm-1.7mm	1.5%	**- do -**
	Vertical arm length	35.7mm-36.2mm	4%	**- do -**
	Vertical arm diameter	1.4mm-1.6mm	1.5%	**- do -**
3.4.b	Suture			
	Diameter	0.25±0.05mm	4%	**- do -**
3.4.c	Copper Wire			
	Diameter of Copper Wire	0.25±0.005mm	2.5%	**- do -**
3.4.d	Copper Collar Length	4.9-5.15mm	4%	**- do -**
	Outer diameter	2.17-2.22mm	1.5%	**- do -**
	Inner diameter	1.65-1.7mm	2.5%	**- do -**

3.4.e	**Insertion Tube**			
	Length	203-208mm	1%	**- do -**
	Inner diameter	3.6-3.8mm	1%	**- do -**
	Outer diameter	4.3-4.5mm	1%	**- do -**
3.4.f	**Solid Rod**			
	Length of the Stem	188-193mm	1%	**- do -**
	Tip diameter	2.5-2.8mm	1%	**- do -**
	Stem diameter	2.3-2.6mm	1%	**- do -**
3.4.g	**Flange**			
	Hold diameter	Approx. 4.14mm		

3.5 Flange Displacement force

Moulded flanges selected at random after 24 hours of moulding when assembled on insertion tubes selected at random and allowed to age for 24 hours shall show a displacement force between 180-630 gms. This test should not be carried out in the finished product – Sampling Plan General Inspections level II – AQL 2.5%.

3.6 Flexibility

The standard flexibility test measures the deflection in mm when a 20gm weight is applied to the cross arm of the T for 30 seconds at a distance of 12mm from the stem of the T. T units are subjected to the test between 24 and 96 hours after moulding. Before measurements are made the Ts are equilibrated for atleast 6 hours at within $\pm$ 1.5^{0}C of the temperatures they will encounter during measurements. Measurements made at other than 24^{0}C, but within the range 20^{0}C - 29^{0}C, may be corrected by subtracting 0.125 units for each degree above 24^{0}C and adding a similar amount for each degree below. Sample 50 units of moulded Ts from each batch. Not more than 5 of the 50 samples shall show a flexibility of less than 4.8mm or more than 6.5mm. None shall show a flexibility above 7.0mm. A batch shall be defined a units made with a single moulding mixture and in an uninterrupted manner except for momentary turn off.

3.7 Memory

Memory is measured in terms of recovery after acute flexation. The horizontal arms are folded and inserted to a depth of 6.35mm in a hole of 4mm diameter. They are allowed to remain in this position for 5 minutes and then removed and allowed to recover their shape under zero load for 1 Minute. The recovery of the arms must be such that the tips of the arms are not displaced by more than 5mm from the horizontal. Test shall be conducted on 10 pcs. from a batch and if the average recovery is greater than 5.5mm then reject. If between 5 and 5.5mm then sample another 10 units and the average of the 20 tested shall be below 5mm.

4. Standards for the finished product

4.a Amount of Copper wire

The weight of the wire on the T arm shall be between 165-187mg. Sampling plan Single Plan General Inspection level II – AQL 1%.

4.a.1 The ends of the copper wire shall be round and shall not have any sharp point at the edges and the end of the wire shall not protrude out more than 0.25mm from the outer surface of the copper wire winding on T-Sampling Plan: Single Plan General Inspection level II – AQL 0.65%.

4.b Dimension and position of the copper collar

The outer diameter of the copper collar on the finished product shall be smooth and shall be between 2.05-2.11mm and shall be positioned at a distance of 5.4±0.4mm from the ends of the horizontal arm of the T – Sampling Plan: Single Plan General Inspections level II – AQL 1.5%.

4.c Length of the Tie

The length of the Tie attached to the T arm shall be 100mm minimum from the ball end of the T – Sampling Plan: Single Plan General Inspections level II – AQL 2.5%.

4.d Strength of the Tie

Place the IUD in the tensile machine. The upper part of the IUD in the upper clamp and thread at a distance of 5 cm from the attachment of the lower clamp. Apply the force steadily at a separation speed of 3.3. ± 0.3mm/sec (200 ± mm/min.). The thread shall not come out of the T or break a load of less than 9.5N-Sampling Plan: Single Plan General Inspections level II - AQL 0.65%.

4.e Pouch Burst Strength

Select one pouch at random from each 800 units of finished goods or at least a total of 32 units. Apply 60 mm Hg or equivalent air pressure inside the pouch section extending approximately 20cm beyond the added seal. The pouch shall hold the pressure for 30 seconds. No seal may open. If one opens repeat the sampling procedure. Not more than total or one seal may open in the combined sampling.

4.f Copper Collar Pull force

The Copper Collar on the finished product shall withstand a minimum pull force of 5N or 500gm when a force is steadily applied at the rate of 200 ± 20mm/min. Sampling Plan: Single Plan General Inspections level ll – AQL 4%.

4.g Sterility

The device shall meet the requirements of the sterility test as specified in the latest Indian Pharmacopoeia.

5. Batch size of Copper-T 380A shall not exceed 35,000 nos.

The sampling shall be as per IS 2500 (Part 1) and the samples size shall be as per single normal plan general inspection level 1.

Hence when the batch size is between 3201 to 10000, then 120 pcs. shall be sampled and if the batch size is between 10001 to 35000 then 165 pcs. shall be sampled. The above said samples will be tested as follows;

	120 pcs.	**165 pcs.**
Amount of Copper Wire	80	125
Dimensions and position of Copper Collar	80	125
Length of Tie	80	125
Strength of Tie	80	125
Pouch Burst Strength	32	44
Copper Collar Pull Force	80	125
Sterility	20	20

In addition to the tests to be conducted on the finished product as above, the following tests are to be added-

Visual Inspection for (80/125)

(i) Package integrity
(ii) Pouch contents & integrity of components

6. In the case of supply and field samples, the sample packed in each inner carton shall not exceed 50 nos.

Annexure-B

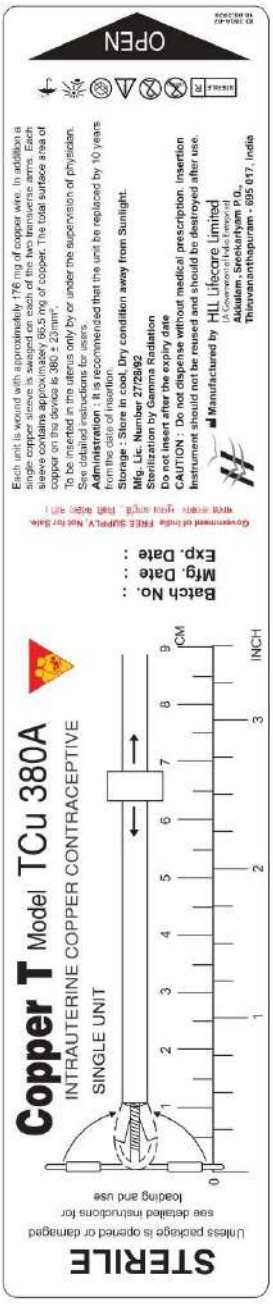
Inspection

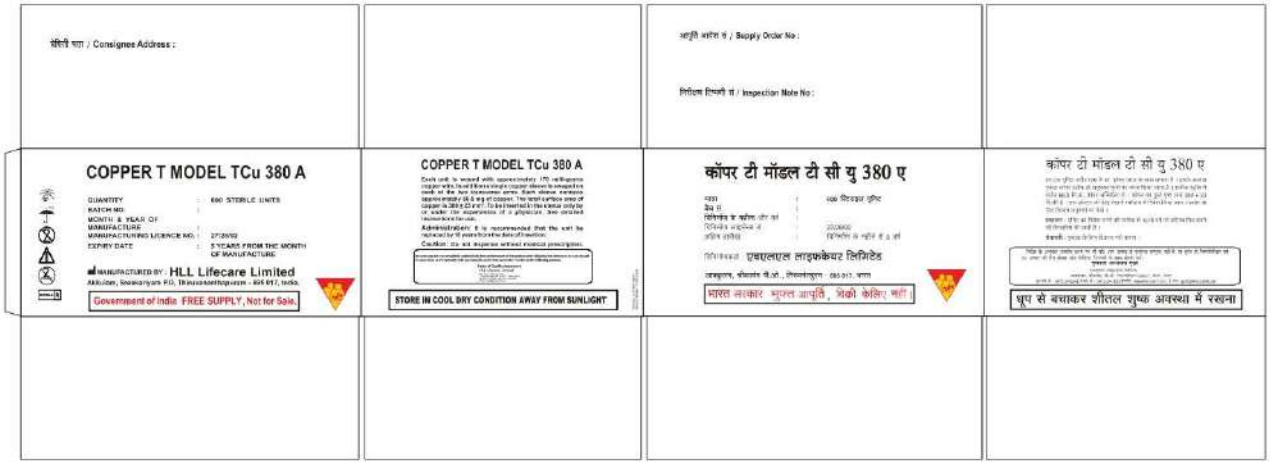
a) The mode of offering supply and procedure adopted for sampling will be governed by specification No. IS: 12418 (Part-4) 2000.

b) A packing slip indicating the quantity of the contents in the box should invariably be kept in each box by the manufacturer/supplier. Quantities withdrawn from the boxes as samples for test should be indicated in the packing slip contained therein.

i) ISI specification is meant to be a reference to the latest issue of the said specification.

ISI specifications are priced publication and can be procure on payments from the Bureau Standards Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi-2 or from any of the regional offices


OPEN
Each unit is wound with approximately 176 mg of copper wire. In addition a single copper sleeve is swaged on each of the two transverse arms. Each sleeve contains approximately 66.5 mg of copper. The total surface area of copper on the device is 380 ± 23mm².
To be inserted in the uterus only by or under the supervision of physician.
See detailed instructions for users.
Administration : It is recommended that the unit be replaced by 10 years from the date of insertion.
Storage : Store in cool, Dry condition away from Sunlight.
Mfg. Lic. Number 27/28/92
Sterilization by Gamma Radiation
Do not insert after the expiry date
CAUTION : Do not dispense without medical prescription. Insertion Instrument should not be reused and should be destroyed after use.
Manufactured by HLL Lifecare Limited
(A Government of India Enterprise)
Akkulam, Seeksariyam P.O.,
Thiruvananthapuram - 695 017, India
Batch No. :
Mfg. Date :
Exp. Date :
Copper T Model TCu 380A
INTRAUTERINE COPPER CONTRACEPTIVE
SINGLE UNIT
CM
INCH
STERILE
Unless package is opened or damaged see detailed instructions for loading and use


संविदी पता / Consignee Address :
आपूर्ति आदेश सं / Supply Order No :
निरीक्षण टिप्पणी सं / Inspection Note No :
COPPER T MODEL TCu 380 A
QUANTITY : 600 STERILE UNITS
BATCH NO. :
MONTH & YEAR OF MANUFACTURE :
MANUFACTURING LICENCE NO. : 27/28/92
EXPIRY DATE : 5 YEARS FROM THE MONTH OF MANUFACTURE
MANUFACTURED BY : HLL Lifecare Limited
Akkulam, Sreekaryam P.O, Thiruvananthapuram - 695 017, India.
Government of India FREE SUPPLY, Not for Sale.
COPPER T MODEL TCu 380 A
STORE IN COOL DRY CONDITION AWAY FROM SUNLIGHT
कॉपर टी मॉडल टी सी यु 380 ए
600 स्टिरइल यूनिट
एचएलएल लाइफकेयर लिमिटेड
भारत सरकार मुफ्त आपूर्ति, बिक्री के लिए नहीं।
कॉपर टी मॉडल टी सी यु 380 ए
धूप से बचाकर शीतल शुष्क अवस्था में रखना

COPPER T MODEL TCu 380 A
कॉपर टी मॉडल टी सी यू 380 ए
INTRAUTERINE COPPER CONTRACEPTIVE.
Manufactured by : H L L Lifecare Limited
STORE IN COOL DRY CONDITION AWAY FROM SUNLIGHT
धूप से बचाकर शीतल शुष्क अवस्था में रखना
Government of India : FREE SUPPLY, Not for Sale.
भारत सरकार : मुफ्त आपूर्ति, बिक्री के लिए नहीं।
USE BEFORE 5 YEARS FROM THE MONTH OF MANUFACTURE.
निर्माण के महीने से 5 वर्ष में उपयोग करें

Schedule-VII

Specifications for

Copper Intra Uterine Contraceptive Device 375

1. Scope

1.1 The standard covers the shape, dimensions and other requirements for Copper intra-uterine contraceptive device, 375 and its components.

2. Normative references

The following Indian and international standards are necessary adjunct to this standard. However subsequent amendments have been made to the contents of the following references as per the requirements of this standard.

- *IS 3395: 1984, Low density polyethylene materials for moulding and extrusion (First revision)*
- *IS 12418 (Part 3):1987, Intra Uterine Contraceptive device: Part 3 Packaging and labeling*
- *The Cu 375 Intra Uterine Contraceptive Device (IUD) WHO/UNFPA Specification, 2011 (UNFPA/CPH/09/31)*
- *ASTM D638: 2010, 10 Standard Test Method for Tensile Properties of Plastics*
- *ASTM D790 - 10 Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials*
- *ISO 10993: Standards for evaluating the biocompatibility of a medical device prior to a clinical study. Special reference to ISO 10993:1; ISO:10993: 5; ISO 10993:18*

Dr. SUSHMA DUREJA
Deputy Commissioner (Family Planning)
Ministry of Health & F.W.
Govt. of India, New Delhi

3. Shapes and Dimensions

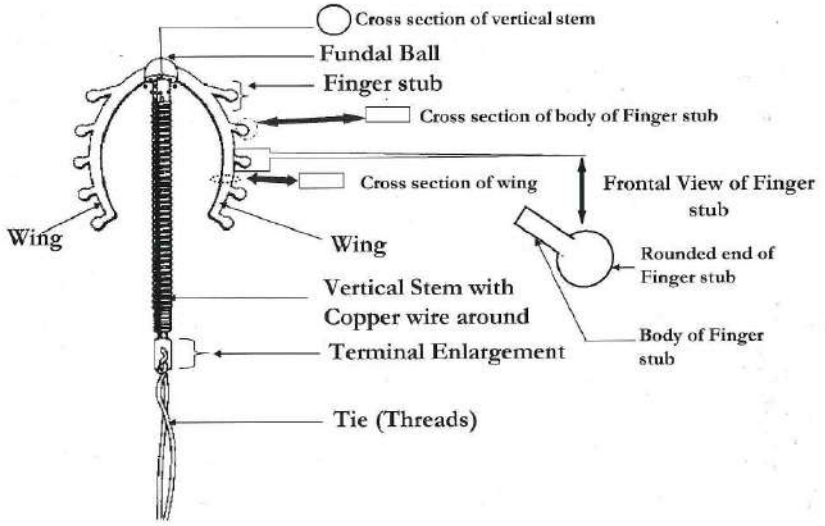
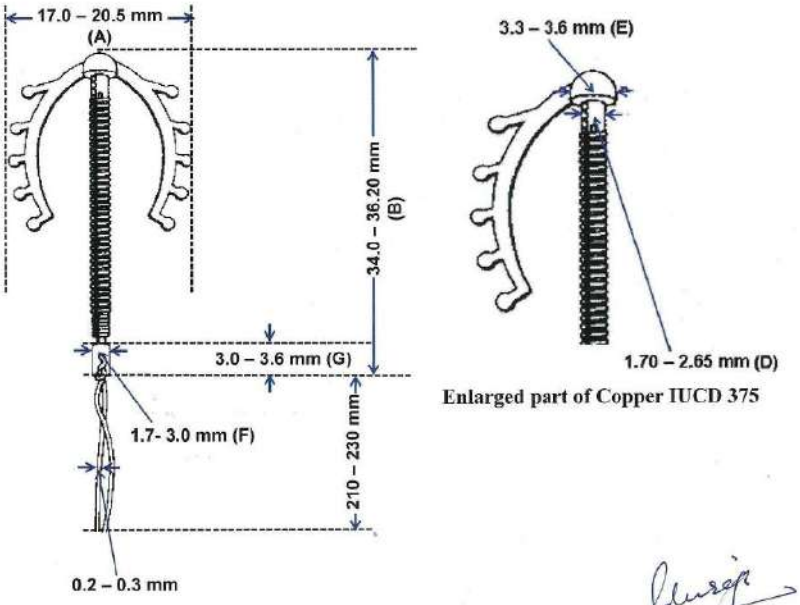


Figure1 Copper IUCD 375 (FRONTAL VIEW)



Enlarged part of Copper IUCD 375

Figure2 Copper IUCD 375 with dimensions

Dr. SUSHMA DUREJA
Deputy Commissioner (Family Planning
Ministry of Health & F.W.
Govt. of India, New Delhi

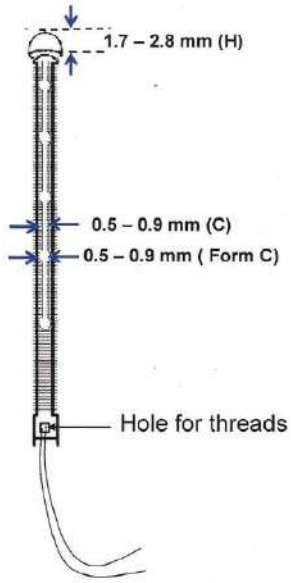
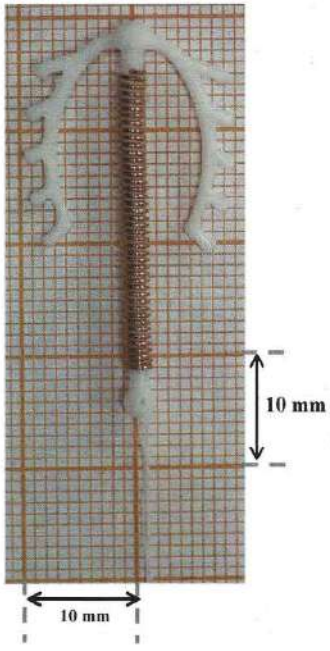


Figure3 Copper IUCD 375 (CORONAL VIEW)



Copper IUCD 375 (FRONTAL VIEW)

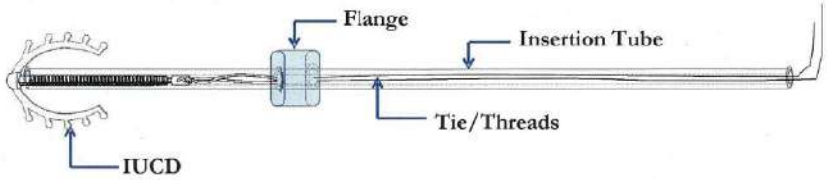


Figure 4 Copper IUCD 375 with Insertion Tube

3.1 General Description

The IUCD as shown in Figure 1 represents the IUCD in the "Frontal plane" and IUCD as shown in Figure 3 is in the "Coronal plane".

The Copper IUCD 375 consists of a ∩ shaped frame comprising of two 'Wings' joined to an enlargement of the Vertical Stem termed the "Fundal Ball". The shape is loosely described as inverted 'U' shape. The shape shall be as shown in Figure 1.
The vertical stem has a terminal enlargement at the bottom to guard against cervical penetration. A small hole is located on the vertical stem to act as an anchor for the

copper wire which is wound over vertical stem. A filament is tied in a knot through a small hole in the terminal enlargement to provide two equal length marker threads (termed as "Tie"), as a means to locate and remove the device. There will be 5 'Finger stubs' on both wings.

The device is supplied with a tubular insertion instrument as shown in Figure 4. A moveable plastic flange is positioned on the insertion tube to assist in positioning the IUCD correctly in relation to the uterine fundus during insertion thus minimizing risk of perforation of the uterus.
The IUCD device with the insertion instrument is pre-positioned ready for insertion as shown in Figure 5 is supplied sterile within a sealed primary pack.

The IUCD and associated components are made up of:

- **Frame -** Low-density polyethylene(LDPE) or High Density Polyethylene (HDPE) + ethylene vinyl acetate copolymer
- **Wire wound around Vertical stem** - Copper
- **Tie** – Nylon
- **Insertion Tube** - HDPE (High Density Polyethylene) or gamma radiation resistant Polypropylene
- **Flange** – Polyvinyl chloride
- **Package** – Polyester and polyethylene

FRAME

Material
The Frame shall be made from Low-Density polyethylene (LDPE) or Gamma Radiation resistant High Density Polyethylene (HDPE) + ethylene vinyl acetate copolymer free of stabilizers having a minimum tensile strength of 15 MPa and a 2% secant flexural modulus in the range 133.5 MPa to 180.6 MPa.
The material shall be blended with 20% to 24% barium sulphate with a particle size of 95% less than 10 micron. The implant material shall pass the cytotoxicity tests, implantation test and extractables test as per the international standards.
The finger stubs shall be moulded together with the wings and have the same material as that of the frame.

Dimensions and Form

- Dimension A: Width of horizontal wings shall lie between 17.00 to 20.5 mm
- Dimension B: Vertical stem length shall lie between 34.00 to 36.20 mm
- Dimension C: Thickness of wings shall lie between 0.5 to 0.9 mm
- Dimension D: Diameter of vertical stem (before winding) shall lie between 1.70 to 2.65 mm, a uniform over the length of the stem between fundal ball and terminal enlargement.
- Dimension E: Fundal ball should be solid hemisphere with diameter 3.3 to 3.6 mm
- The size of the terminal enlargement should be in the range of:
  Dimension F: Lateral – 1.7 to 3.0 mm
  Dimension G: Vertical - 3.0 to 3.6 mm
- Dimension H: Height of the fundal ball shall lie between 1.7 to 2.8 mm
- Form A: Hole for anchoring an end of the copper wire may be provided.
- Form B: Cross section of the wings should be rectangular.

Dr. SUSHMA DUREJA
Deputy Commissioner (Family Planning)
Ministry of Health & F.W.
Govt. of India, New Delhi

- Form C:
  - ✓ There will be 5 finger stubs on the either side.
  - ✓ The stubs will be knob shaped as shown in Figure 1 and the thickness of the stubs will be 0.5 to 0.9 mm as shown in figure 3.
  - ✓ Cross sections of the finger stubs should be rectangular.
  - ✓ Finger Stubs will be sloping downwards in the frontal view.
  - ✓ Slope angle as shown in figure 5 is to be in the range of 40° to 70°

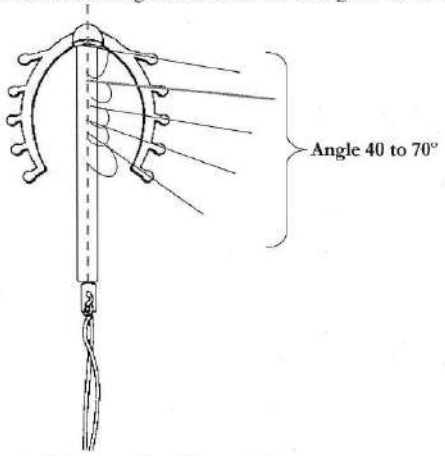


Figure 5 Measurement of slope angle of finger stubs

Requirements and Tests

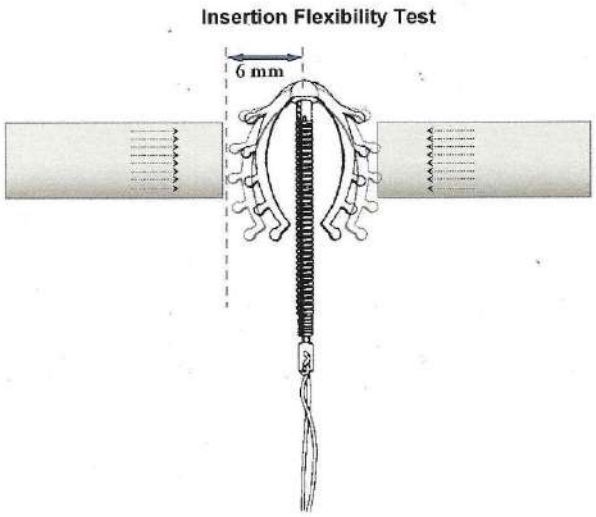
The material of the frame to meet the ISO 10993 standards for chronic biomedical implants Specifically the ISO 10993: 5 Cytotoxicity test, 10993:18 Implantation and extractables test must give comparable biocompatibity as USP grade negative control.

Memory test

Memory is measured in terms of recovery after acute flexion quantified by restoration of width of the horizontal wings (Dimension A). On removal and observation after 1 minute of the frame following an insertion into 6 mm internal diameter tubing for 2 minutes. Dimension A to be no less than 25% less than the original pre stressed width of the wings (Provisional).

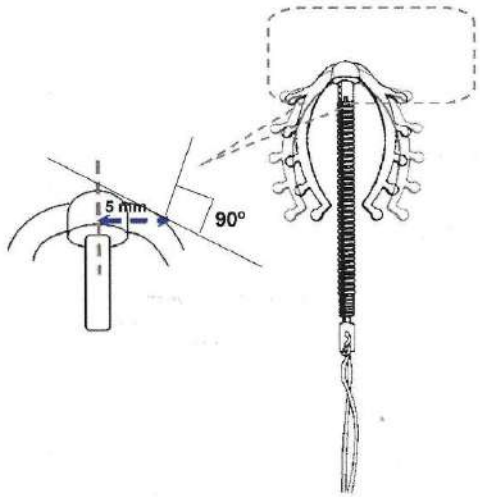
Dr. SUSHMA DUREJA
Deputy Commissioner (Foreign Training)
Ministry of Health & F.W.,
Govt. of India, New Delhi

Insertion Flexibility test



Insertion flexibility relates to the recoiled force exerted by the wings onto the inner wall of the uterine cervix at the time of insertion of IUCD. The force to compress the wings to bring the width of the wings to 6 mm should not exceed 1 N (Provisional)

Implant Flexibility test



Dr. SUSHMA DUREJA
Deputy Commissioner (Family Planning)
Ministry of Health & F.W.
Govt. of India, New Delhi

Implant flexibility relates to the recoiled force when the wings are compressed by uterine contractions under normal placement of the IUCD within the uterus. The force is quantified by the bending of the wings on application of the bilateral force perpendicular to the wings at a point where a horizontal line of length 6 mm is calculated from the base of the first finger stub to the centre of the fundal ball.The force required to displace the point towards the vertical stem by 1.5 mm is to be in the range of 7-12 N (Provisional)

Frame shall be radio-opaque and shall have two ties for easy removal

Ash Content
Ash Content (as barium sulphate) of moulded frame shall be between 20-24 percent when tested in accordance with the method specified in latest Indian Pharmacopoeia.

Sterility Test
When Copper 375 is distributed as sterile, it shall be capable of meeting the requirements of any suitable sterility test specified in latest Indian Pharmacopoeia

WIRE
The copper wire should be wound tightly around the vertical stem with the loops even spaced. "Single" or "Double"wounding format may be used. The two ends of the copper wire are so closely positioned on the vertical stem surface that there are no projections of the wire end.

Material
The wire shall be made from 99.99% pure copper.

Dimensions
Copper wire of should be of 349 - 392 mm^2 surface area and of diameter 0.38 to 0.41mm
The mass of copper wire wound shall be 310 to 360 mg.

TIE (THREADS)
Material
The thread shall be made from Polyamide Nylon 6 or polyamide nylon 66 monofilament thread. The material shall pass ISO 10993 test as applicable for chronic implantation.

Dimension

Thread Length
Thread Length shall be 210 to 230 mm.
Colour of the thread should be medical grade green.

Thread Knot
The knot shall be secure and not promote breakage under normal use.

Thread dimension
The thread shall be made of Nylon of diameter 0.20 to 0.30mm.
Tensile strength of the thread shall be more than 9.5 N for a force applied for 30 S.

Dr. SUSHMA DUREJA
Deputy Commissioner (Family Plan
Ministry of Health & FW
India, New Del

Extractables test
The thread shall pass currently applicable USP extractable test class II and shall be evaluated for biological safety in accordance with ISO 10993-1: 2003 requirements for mucosal membrane contact devices intended for permanent contact.

INSERTION TUBE

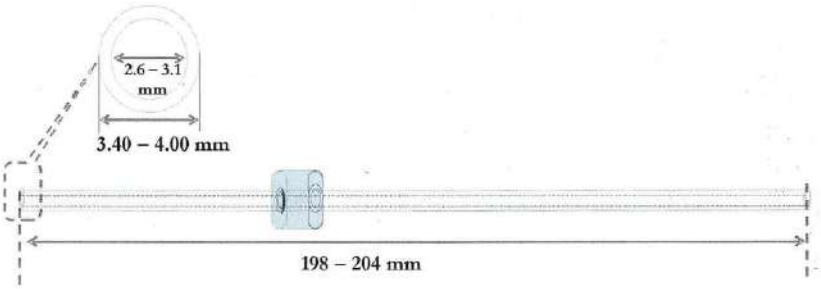


Figure 6 Insertion Tube Dimensions

Material
The insertion tube shall be made of HDPE (High Density Polyethylene) or gamma radiation resistant Polypropylene. The material shall pass the 10993:18 Implantation and extractables test and must give comparable biocompatibity as USP grade negative control

Dimensions
Length must lie between 198 to 204mm.
Internal Diameter must lie within 2.6 to 3.1mm.
Outside Diameter must lie within 3.40 to 4.00 mm (As shown in Figure 6)

Requirement
The insertion tube must slip out of the tie and vertical stem without exerting excessive drag force on the frame when the insertion tube is pulled in a direction axial to the vertical stem and away from the fundal ball.

Test
When gripping the fundal ball, the frame and insertion tube assembly is held in a position with the vertical stem being vertical and the fundal ball being topmost the insertion tube should slip out by virtue of its own weight.

FLANGE

Material
The flange shall be made of polyvinyl chloride containing titanium dioxide.

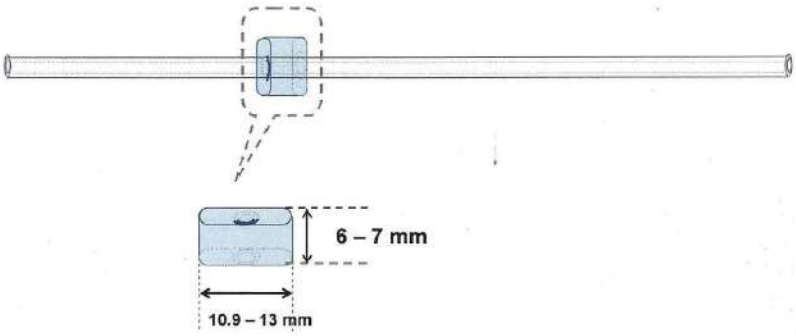


Figure 7 Insertion tube with Flange and Flange Dimensions

Dimension
The lateral length of the flange shall be in the range of 10.9 to 13 mm (as shown in Figure 7).
The vertical length of the flange shall be in the range of 6 to 7 mm.
Diameter of central hole shall be chosen and specified with a tolerance to achieve the flange displacement force. The shape and dimensions of the central hole may be changed to facilitate meeting the specified flange displacement force

Flange Displacement Force
Flange selected at random is placed on the insertion tube selected at random and allowed to age in place for minimum of 24 hours. The resistance to displace the flange by a steadily applied force shall be between 1.8-10 N.

PACKAGING AND LABELING
The packaging shall be done in film film pouch. Double cover packaging preferred for withstanding adverse storage conditions.
Continuous pin hole free Gamma radiation resistant polymer films shall be used. Manufacturers shall select films that reduce the risk of tarnishing the copper & withstand extremes of storage conditions. For optimum protection against tarnishing continuous pin hole free polyester-polyethylene laminate or other material giving equivalent or better protection may be used.

Sealed Pouch
IUCD shall be packed in individual sealed pouches.

Sealed Pouch Integrity

Sealed pouch integrity shall be tested according to ASTM D3078:1994 (Standard test method for determination of leaks in flexible packaging by bubble emission).
The integrity is to be maintained under test exposure to an envoirnment of temperature 60 deg.and80% relative humidity for a period of 12 hrs.

Sealed Pouch Peel Strength

When tested according to ASTM F 88: 2000 (Standard test method for seal strength of flexible barrier materials) the peel force shall be not less than 4 N and not greater than 17 N. when a double cover packaging is used & the pealable inner cover is not the primary barrierthe peeling force of the inner packaging will be in the range of 4N-17 N.The outer cover of a double layer pouch is to be "tear open'.

Labelling and Inserts

Information required in accordance with ISO 7439: 2002 including information intended for the women shall be provided in accordance with the contractual requirements agreed with the purchaser.
The Expiry Date is the date after which the product cannot be inserted.
The Expiry shall be printed on the sealed pouch/ID card and shall be based on the maximum product shelf-life from the date of sterilization.
The sterilization shall be completed within 30 days of sealing the finished device in the pouch.
In addition, the duration of the maximum period the device can remain *in utero* shall be printed on the primary container. This period shall not exceed 5 years from the date of insertion.

Printing

All printing shall be clear and readily legible.

Cleanliness

The device, insertion tube, flange and any insert such as instructions included in the pack shall be free of visible particulate matter and cuttings should be non-adherent.

Pouch Peeling Force

The packing pouch shall peel off when a force of 4 to 17 N is applied on both the edges of the pouch.

Product Shelf Life before Insertion

The maximum permitted shelf life for storage of the device prior to insertion is 4 years.

General Requirements

The materials of which the frame, insertion tube, flange and tie are made shall be sufficiently resistant to the unintended influence by body fluids and tissues, and shall be biologically compatible without causing undue/unacceptable allergic, toxic or inflammatory reaction.

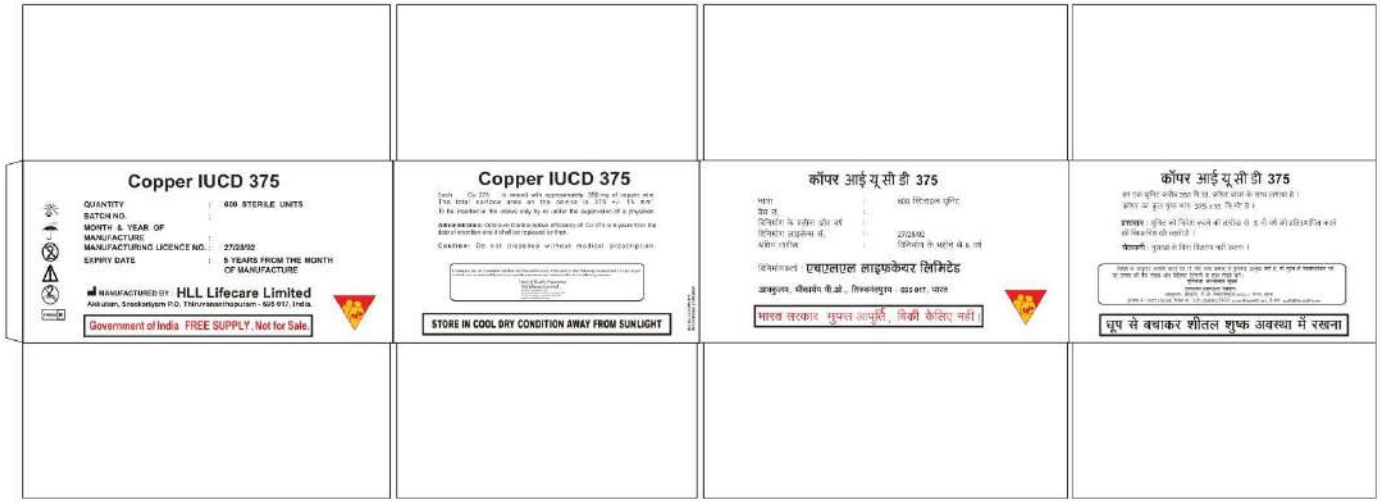
The tie or thread attached to the frame shall be monofilament which is easily feelable after the insertion of the Copper IUCD375.

Copper IUCD 375 shall be free from sharp edges, rough surfaces and shall be finished smooth.

Copper IUCD 375 when inserted shall produce an acceptable level of efficacy and minimal incidence of adverse reactions.

Dr. SUSHMA DUREJA
Deputy Commissioner (Family Planning)
Ministry of Health & F.W.
Govt. of India, New Delhi

OPEN
INTRAUTERINE COPPER CONTRACEPTIVE
HLL Lifecare Limited
(A Government of India Enterprise)
CM
INCH
STERILE
Unless package is opened or damaged
see detailed instructions for use
Copper IUCD 375
Batch No. :
Mfg. Date :
Exp. Date :


Copper IUCD 375
QUANTITY : 400 STERILE UNITS
BATCH NO. :
MONTH & YEAR OF MANUFACTURE :
MANUFACTURING LICENCE NO. : 27/28/02
EXPIRY DATE : 5 YEARS FROM THE MONTH OF MANUFACTURE
MANUFACTURED BY : HLL Lifecare Limited
Akkulam, Sreekariyam P.O, Thiruvananthapuram - 695 017, India.
Government of India FREE SUPPLY. Not for Sale.
Copper IUCD 375
STORE IN COOL DRY CONDITION AWAY FROM SUNLIGHT
कॉपर आई यू सी डी 375
एचएलएल लाइफकेयर लिमिटेड
अक्कुलम, श्रीकरियम पी.ओ., तिरुवनंतपुरम - 695 017, भारत
भारत सरकार मुफ्त आपूर्ति, बिक्री के लिए नहीं।
कॉपर आई यू सी डी 375
धूप से बचाकर शीतल शुष्क अवस्था में रखना

Copper IUCD 375
कॉपर आईयूसीडी 375
INTRAUTERINE COPPER CONTRACEPTIVE
Manufactured by : HLL Lifecare Limited
STORE IN COOL DRY CONDITION AWAY FROM SUNLIGHT
धूप से बचाकर शीतल शुष्क अवस्था में रखना
Government of India: FREE SUPPLY. Not for Sale.
USE BEFORE 5 YEARS FROM
THE MONTH OF MANUFACTURE.

For the user

Batch No.
Doctor's name
Address
Contact No.

Dear customer,

Your doctor has inserted Cu 375 for you. Now you can stay away safely from pregnancy for at least 5 years. Your doctor would have briefed you on all aspects. You have to be aware and vigilant about the following:

1) Some women may have increased menstrual flow and abdominal pain after insertion. However they will return to normalcy in most cases within 3 menstrual cycles. Still, if symptoms are severe, please consult your doctor. In some, periods may appear early in the first 2 cycles after insertion, or experience slight bleeding in between 2 cycles. They will also be normal in 2 or 3 cycles. Other rare symptoms are pain on the back or legs or pain during intercourse or mild itching of the skin. These may be reported to the doctor if severe, also ignored.

2) Pregnancy after inserting Cu 375 : Though chances are extremely rare, you may become pregnant even after inserting Cu 375. You should be very vigilant about this. Pregnancy can develop either

i) Inside the uterus If Cu 375 is either expelled or displaced. Expulsion can happen mostly within the first 3 cycles. Threads are attached to the tip of Cu 375 which can be felt by you outside the cervix through the vagina with your fingers. Check for threads after each period. Before attempting, you should ensure that the fingers are clean. The step will help you to ascertain whether inserted Cu 375 has not passed the uterine wall. Contact your doctor if you cannot feel the IF heads.

If your periods are delayed by 2 weeks or more, you should report to your doctor for necessary action.

ii) Pregnancy outside the uterus (ectopic) is very dangerous. Following are the symptoms:

a) Delay in periods for 2 weeks or more.
b) Severe pain or cramp in the abdomen.
c) Vaginal bleeding.
d) Pain on the shoulder tip.
e) Feeling of unsteadiness or fainting.

Contact your doctor at the earliest if you will experience any of the above symptoms.

3) Infections of the genito-urinary tract after insertion of Cu 375:

If you experience any of the following symptoms, please consult your doctor:

i) High fever.
ii) Persistent lower abdominal pain.
iii) Heavy vaginal bleeding or foul smelling discharge.
iv) Pain on burning sensation while passing urine.

If you have to undergo physiotherapy for any ailment on the lower abdomen or back, please inform the physiotherapist that Cu 375 has been inserted.

Periodical check ups are suggested. The schedule is given below by your doctor.

Activity	Date	Month	Year
Cu 375 insertion			
1st follow up visit			
2nd follow up visit			
3rd follow up visit			
4th follow up visit			
5th follow up visit			

You can conceive if desired once Cu 375 is removed without any waiting if there is no other problem.

Wishing you a contented, harmonious and enjoyable days ahead.

HLL Lifecare Limited,

Pioneers and leaders in contraceptive products and services and committed to women's health.

Effectiveness:

Cu 375 is one of the most effective reversible method of birth control available with 99.2 to 99.4 % effectiveness.

Of special caution: Pregnancies with Cu 375 happen when the device slides out without the women realising it. Immediate removal is mandatory.

Safety during lactation:

Cu 375 is safe for use in lactating mothers.

Monitoring:

After insertion monitoring is very important. A part of this information insert is addressed to the beneficiary who should be properly explained about follow up at her end for trouble-free contraceptive benefit.

Failure:

Pregnancy after inserting Cu 375 has following risks:

- Ectopic pregnancy. Early diagnosis is vital.
- Pelvic infection
- Miscarriage
- Early labour and delivery

Life of Cu 375:

Optimum contraceptive efficacy is for 5 years, after which it may be replaced.

Removal:

Cu 375 may have to be removed due to:

- desire for another pregnancy. Normally fertility returns immediately to and within a few months after removal unless there is some other cause.
- Heavy bleeding or pain
- PID
- Accidental pregnancy-normal or possibly ectopic
- Spontaneous expulsion
- Perforation of uterus or missing threads which will have to be evaluated and investigated with the help of X-rays, ultrasound or hysteroscopy.

Procedure:

Clean the whole area using antiseptic, grasp both threads of Cu 375 with a forceps near to the external os and withdraw the device from the uterus gently without using excessive force and straightening out the uterine axis using a speculum thereby minimising the possibility of side arms breakage.

Return to fertility:

Immediately on removal and within a few cycles, if there is no other underlying aetiology.

Pack:

One device individually packed in a pouch with shelf life upto 5 years from the date of manufacturing.

Storage condition:

Keep in cool & dry place away from sunlight

HLL Lifecare Limited
(A Government of India Enterprise)
AKKULAM FACTORY
Sreekariyam P.O.
Thiruvananthapuram- 695 017,
Kerala, India
Tel: + 91-471-2442641/42/52
Fax: + 91-471-2441383
email:qaaft@lifecarehll.com
www.lifecarehll.com

Copper IUCD 375

Customer Care Address

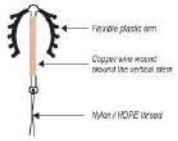
Head of Quality Assurance
HLL Lifecare Limited

Cu 375

Cu 375 with a pearl index of <1 is one of the most effective intra uterine reversible contraceptive device which is more convenient to insert than other IUCDs.

Structure:

Cu 375 made of polyethylene impregnated with barium sulphate for visibility on X-ray consists of a 3.5 cm. long vertical rod wound with copper wire having surface area of 375 sq mm. and holding a pair of flexible side arms covering a width of 1.8 cm. This structure and shape offers more convenience during insertion and helps to keep the device adjacent to the fundus without stretching the uterine cavity. A thin monofilament nylon/HDPE thread is attached to the bottom end of the vertical rod.



Contraceptive action:

Cu 375 induces a spermicidal inflammatory response on the endometrium resulting in release of leucocytes and prostaglandins making it hostile to the sperm and largely prevents fertilisation as also implantation if at all the former occurs. Contraception is immediate if inserted early in the cycle.

Contra-indications:

Absolute, permanent:

- Very distorted uterine cavity, or cavity depth less than 5.5 cm
- Uterine or cervical cancer
- Allergy to known constituent
- Wilson's disease or disorders of copper metabolism
- Previous history of bacterial endocarditis

Absolute, temporary:

Suspected pregnancy

Undiagnosed, irregular vaginal bleeding

Significant pelvic infection

Significant immuno suppression

Relative - usable with caution:

- Nulliparous, young age
- Definite history of pelvic infection
- Known HIV infection or high risk of STD
- Structural heart disease, with risk of endocarditis
- History of ectopic pregnancy or tubal disease, endo-metritis or pelvic peritonitis.
- Thrombo-cytopenia or treatment with anti-coagulants
- Benign trophoblastic disease
- Severe cervical stenosis
- Fibroids or congenital abnormality of uterus, but no marked distortion of the cavity
- Polygamy

For detailed information on Medical Eligibility Criteria for IUC, refer www.who.int/reproductive-health/publication/mec/mec.pdf

Ideal time for insertion:

During menstrual period, the cervix is more open and there is little chance of a current pregnancy which is the most ideal. There is, however, a greater chance of expulsion if Cu 375 is introduced early in the cycle. It would seem that the best time for insertion is just after the period. Cu 375 can also be inserted during termination of pregnancy or carefully just after normal delivery. After caesarean section, insertion may be done after 3 months.

Cu 375 can be employed for emergency contraception if inserted within 120 hours of the coitus.

Directions for insertion:

Cu 375 has been carefully sterilised. Do not use if the pack is not intact. Cu 375 should be inserted by a registered medical practitioner or by a trained person under medical supervision. Cu 375 with flexible side arms for easy insertion is pre-loaded in a tube. Cu 375 should be placed correctly while minimising the woman's discomfort and the risk of complications. Women in whom Cu 375 is contra-indicated should be excluded.

Successful Cu 375 insertion requires :

• explaining the procedure to the woman and responding to her questions and concerns. This helps her relax, making insertion easier and less painful.

• infection-prevention procedures include use of sterile environment, disinfected instruments and cleaning of the cervix and vaginal walls with antiseptic and wiping off secretions if any. No-touch technique has to be followed to ensure sterility.

• speculum examination and bimanual pelvic examination. The speculum exam should come first, to check for signs of genital tract infection. The bimanual exam determines the size, position, consistency, and mobility of the uterus and identifies any tenderness, which might indicate infection. A retroverted uterus requires special care during insertion.

4. The flexibility of Cu375 allows it to go through the cervix easily

• sounding of the uterus slowly and gently determining its depth and direction and reducing the risk of perforating the uterus.

• careful and slow technique during all phases of sounding and insertion will be apt. This reduces discomfort and minimises the chances of uterine perforation, cervical laceration, and other complications. Parenteral local anaesthetic or para cervical block may be employed as per requirement.

5. This picture shows Cu375 when completely inserted into the womb.

• Cu 375 placement high in the uterus at the fundus minimises expulsion, accidental pregnancy, and possible bleeding.

• holding the distal end of the insertion tube, carefully insert Cu 375 into the uterus until it touches the fundus and the cervical stop rests on the external os while maintaining steady downward traction with the tenaculum to straighten the uterine axis without forcing. When Cu 375 touches the fundus it is inserted into the uterine cavity by simply withdrawing the insertion tube ensuring that the device is entirely within the uterine cavity. Trim the thread to 2 to 3 cm. outside so that they reach the vagina enabling the user to check with fingers.

6. After the removal of the insertion tube Cu375 is left high in the womb.

Side effects:

Some women may experience side effects, but most cases will normalise over 3 cycles. Increased menstrual flow, dysmenorrhoea and or low back pain will respond to appropriate NSAIDs. Spotting has also been reported.

Possible complications:

Serious problems with Cu 375 are rare. It is critical to observe any symptoms to avoid further complications.

Perforation: The device, very rarely, may be pushed through the uterine wall during insertion. Generally, this can be discovered and corrected right away. If not, it can move into other parts of the pelvic area and may damage internal organs. Surgery may then be needed to remove the device.

Infection: Although there is some risk of pelvic inflammatory disease associated with Cu 375 use, the risk is small after the first 20 days following insertion. Generally, PID after first 3 weeks of insertion is sexually transmitted. The risk of infection is higher with multiple partners.

Expulsion: Cu 375 can partially or completely slip out of the uterus with the risk of pregnancy. This is more likely to happen in younger women, women who have never had a baby, and during the first few months of use. Cu 375 must be removed if it becomes partially expelled. User must be vigilant about this and should monitor the threads periodically especially during menstrual period.

Tear off

User guide

Copper IUCD 375

Name:

Age:

Address:

No. of children:

Date of insertion:

HLL Lifecare Limited
(A Government of India Enterprise)

Schedule-VIII

Specification for Tubal Rings

(Undertaking should be given by the manufacturers that Implantation Test will be done by the manufacturers**)**

Technical Specifications of Tubal Rings under Family Planning Programme:

Specifications: IS 13009:2021 (relevant IS enclosed).
Units: Pair
Life: 4 Years

Packing and Marking :

The store should be packed as per details given in Specifications IS-13009:2021. The pouch should be made of Tyvek on one side and Transparent Polyester Polyethylene film on other side, as per past practice. Each will have to following printed in indelible ink across each label '**Government of India FREE SUPPLY, Not for Sale'.**

The packing will also be marked as under

i) Nomenclature of the stores.

ii) Manufacturers name, Address and License No.

iii) Date of Manufacture, Expiry and Batch No.

iv) Quantity contained therein.

v) Inspection Note No. and Date.

vi) Any other particulars required under the Drugs and Cosmetics Act of India and the Rules framed there under.

भारतीय मानक
Indian Standard

IS 13009 : 2021
ISO 19351 : 2019

डिम्बवाही रिंग्स — अपेक्षाएँ और परीक्षण पद्धतियां

(दूसरा पुनरीक्षण)

Fallopian Rings — Requirements and Test Methods

(Second Revision)

ICS 11.200

भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS
मानक भवन, 9 बहादुरशाह ज़फर मार्ग, नई दिल्ली – 110002
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI-110002
www.bis.gov.in www.standardsbis.in

September 2021 Price Group 10

NATIONAL FOREWORD

This Indian Standard (Second Revision) which is identical with ISO 19351 : 2019 'Fallopian rings — Requirements and test methods' issued by the International Organization for Standardization is adopted by the Bureau of Indian Standards on recommendation of the Obstetrics and Gynaecological Instruments and Appliances Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

This standard was first published in 1990 as IS 13009 : 1990 'Contraceptive devices — Tubal ring — Specification' at the instance of Ministry of Health and Family Welfare, Government of India. This standard was subsequently revised in 2000 based on the experience gained through its implementation by the Ministry of Health and Family Welfare. The second revision of this standard has been undertaken to align it with the latest version of ISO 19351 : 2019.

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain terminologies and conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker, while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards, which are to be substituted in their respective places, are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 10993-1 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	IS/ISO 10993-1 : 2018 Biological evaluation of medical devices: Part 1 Evaluation and testing within a risk management process	Identical with ISO 10993-1 : 2018
ISO 10993-3 Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	IS/ISO 10993-3 : 2014 Biological evaluation of medical devices: Part 3 Tests for genotoxicity, carcinogenicity and reproductive (*first revision*)	Identical with ISO 10993-3 : 2014
ISO 10993-5 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	IS/ISO 10993-5 : 2009 Biological evaluation of medical devices: Part 5 Tests for in vitro cytotoxicity	Identical with ISO 10993-5 : 2009
ISO 10993-6 Biological evaluation of medical devices — Part 6: Tests for local effects after implantation	IS/ISO 10993-6 : 2016 Biological evaluation of medical devices: Part 6 Tests for local effects after implantation	Identical with ISO 10993-6 : 2016
ISO 10993-10 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	IS/ISO 10993-10 : 2010 Biological evaluation of medical devices: Part 10 Tests for irritation and skin sensitization	Identical with ISO 10993-10 : 2010
ISO 10993-11 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity	IS/ISO 10993-11 : 2017 Biological evaluation of medical devices: Part 11 Tests for systemic toxicity	Identical with ISO 10993-11 : 2017

(*Continued on third cover*)

Introduction

Fallopian rings are devices which provide permanent contraception. These devices are elastic bands made from medical grade silicone. They are implanted bilaterally using a laparoscopic surgical procedure. After the rings are applied to each fallopian tube, they cut off the blood supply and occlude the tubal lumen. This stops the ova from travelling to the uterus, thereby preventing fertilisation. Fallopian rings are provided sterile and packaged as a set of two.

This document has been necessitated as a result of the product marketing experience gained by manufacturers and procurement agencies.

Indian Standard

FALLOPIAN RINGS — REQUIREMENTS AND TEST METHODS

(Second Revision)

1 Scope

This document specifies the minimum requirements and test methods for fallopian rings used for tubal occlusion in women for permanent contraception. This document does not address the applicator or other accessories used to place the fallopian rings.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-3, *Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*

ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

ISO 10993-6, *Biological evaluation of medical devices — Part 6: Tests for local effects after implantation*

ISO 10993-10, *Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization*

ISO 10993-11, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 15223-2, *Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation*

ASTM F640, *Standard test methods for determining radiopacity for medical use*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
fallopian rings
elastic band made of medical grade silicone placed around a loop of fallopian tube bilaterally using a laparoscopic surgical procedure or open surgery, cutting off the blood supply to occlude the tubal lumen and prevent fertilization

3.2
lot
collection of *fallopian rings* (3.1) manufactured at essentially the same time, using raw materials of the same specifications, the same process and common equipment, packed in the same type of individual container

Note 1 to entry: The recommended maximum individual lot size for production is 10 000 pairs, but it is possible for a purchaser to specify the lot size as part of the purchasing contract and quality management system of the manufacturer.

3.3
lot number
number or combination of numerals, symbols or letters used by the manufacturer to identify a *lot* (3.2) or individually packaged product, and from which it is possible to trace that lot through all stages of manufacture up to packaging

3.4
lot test
test to assess the conformity of a *lot* (3.2)

Note 1 to entry: A lot test may be limited to include only those parameters which may change from lot to lot.

3.5
inspection level
relationship between lot size and sample size

Note 1 to entry: Inspection level designates the relative amount of inspection.

3.6
sampling plan
specific plan which indicates the number of units of products from each *lot* (3.2) which are to be inspected (sample size or series of sample sizes) and the associated criteria for determining the acceptability of the lot (acceptance and of manufacture to the use before date)

3.7
shelf life
period of time from the date of manufacture during which the *fallopian rings* (3.1) are required to confirm to the requirements specified in this document

3.8
radio-opacity
quality or state of being radio-opaque

Note 1 to entry: It is the property of the material in obstructing the passage of radiation energy such as X-rays and will produce a white image on the exposed X-ray film, which confirms that the implanted device is in position.

3.9
visible defects
defects which are visible to unaided eye during inspection, such as discolouration, any fibres or protrusions on the fallopian ring

3.10
laparoscope
instrument inserted through an incision in the abdominal wall and used to visualize the surgical field, where it has working channels with the applicator to insert the *fallopian rings* (3.1)

4 Requirements

4.1 Quality verification

Fallopian rings are mass produced articles manufactured in very large quantities. Inevitably, there will be some variation between individual rings, and a small proportion of rings in each production run might not meet the requirements of this document. Further, the majority of the test methods described in this document are destructive. For these reasons, the only practicable method of assessing conformity with this document is by testing a representative sample from a lot or series of lots. Basic sampling plans are given in ISO 2859-1. Reference should be made to ISO/TR 8550 (all parts) for guidance on the use of acceptance sampling system, scheme or plan for the inspection of discrete items in lots. When on-going verification is required of the quality of fallopian rings, it is suggested that, instead of concentrating solely on evaluation of the final product, attention is also directed at the manufacturer's quality system. It should be noted that ISO 13485 covers the provision of an integrated quality system for the manufacture of medical devices. Sampling plans shall be selected to provide an acceptable level of consumer protection. Suitable sampling plans are given in Annexes A and B.

a) Annex A describes sampling plans based on ISO 2859-1 and is most applicable to manufacturers or purchasers assessing the conformity of a continuing series of lots. The full level of consumer protection available depends upon the switch to tightened inspection if deterioration in quality is detected. The switching rules, described in ISO 2859-1:1999, Clause 9, cannot offer their full protection for the first two lots tested but become progressively more effective as the number of lots in a series increases. Use the sampling plans in Annex A when five or more lots are being tested.

b) Annex B describes sampling plans, based on ISO 2859-1, that are recommended for the assessment of isolated lots. The sampling plans in Annex B provide approximately the same level of consumer protection as those given in Annex A when used with the switching rules. It is recommended that these sampling plans are used for the assessment of fewer than five lots, for example in cases of dispute, for referee purposes, for type testing, for qualification purposes or for short runs of continuing lots.

It is necessary to know the lot size in order to derive the number of fallopian rings to be tested from ISO 2859-1. The lot size will vary between manufacturers and is regarded as part of the process and quality controls used by the manufacturer. If the lot size is not known or cannot be confirmed by the manufacturer, then a lot size of 10,000 fallopian rings shall be assumed for determining the sample sizes for testing.

4.2 Physical requirements

4.2.1 Dimensions

Fallopian rings are tested for the inner diameter and outer diameter in accordance with Annex C and shall conform to the requirements given in Figure 1.

Cut rings shall be free from fibrous protrusions at the outer and inner surface. Angle of cut shall be at 90° (≤5° angulations is allowed).

Dimensions in millimetres

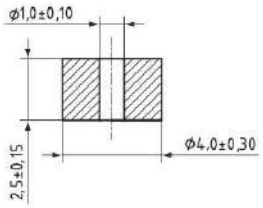


Figure 1 — Fallopian ring

4.2.2 Tensile properties

Fallopian rings tested in accordance with Annex D for the tensile properties shall conform to the requirements stated below.

a) The force at break shall be ≥20,50 N.

b) Elongation at force at break shall be ≥560 %.

4.2.3 Loading force on ring applicator

Fallopian rings tested in accordance with Annex E for the force of loading on ring applicator shall conform to the requirement stated below.

The force required to load fallopian rings on the ring applicator shall be ≤35 N.

4.2.4 Elastic memory

Fallopian rings tested in accordance with Annex F for the elastic memory shall conform to the requirement stated below.

The recovery of the inner diameter shall be such that the increase in the inner diameter ≤25 % of the original diameter.

4.2.5 Repeat loading strength

Fallopian rings tested in accordance with Annex G for the repeat loading strength shall neither break nor develop any cracks when viewed using ×20 magnification.

4.2.6 Visible defects

Fallopian rings tested for the visible defects shall not have defects such as discolouration, any fibres or protrusions on the ring.

4.3 Packaging

4.3.1 Packing mode

One pair of fallopian rings shall be packaged in peel open pouch/blister pack with seal width ≥2 mm.

4.3.2 Primary pouch

Each pouch/blister pack shall ensure:

a) adequate protection of the contents during normal handling, transit and storage for a period of 4 years;

b) maintenance of sterility of the contents under dry, clean and adequately ventilated storage conditions at a temperature(s) ranging from 0 °C to 50 °C; and

c) minimal risk for contamination of the contents during removal from the pouch/blister pack.

4.3.3 Instruction for use

Every dispenser box shall be provided with at least one instruction for use describing the method to be adopted for:

a) loading of rings on the ring applicator; and

b) storage and handling requirements in clean and dry place.

4.3.4 Package seal strength

Fallopian rings packs shall be tested for package seal integrity and seal strength in accordance with Annex J and peel force shall be 4,4 N to 19,0 N.

4.3.5 Package seal integrity

Fallopian rings packs shall be tested for package seal integrity and seal strength in accordance with Annex J and there shall be no evidence of leakage of the package.

4.3.6 Sterility

Fallopian rings supplied as sterile shall meet the requirements of sterility test as specified in the latest version of national/international pharmacopoeia.

The manufacturer shall establish procedures and systems to validate the type of sterilization used for the fallopian rings as sterility testing alone cannot be deemed as the criteria for confirming the sterility of the product. Validation of ethylene oxide sterilization process shall be done according to ISO 11135 and gamma sterilization shall be done according to ISO 11137-1 and ISO 11137-2.

4.4 Biological requirements

The biological safety of fallopian rings shall be evaluated in accordance with the principles given in ISO 10993-1, according to which fallopian rings are classified as a permanent contact implant device, and the following tests shall be complied with:

a) cytotoxicity as per ISO 10993-5;

b) sensitization as per ISO 10993-10;

c) irritation or intracutaneous reactivity as per ISO 10993-10;

d) subchronic (Subacute) toxicity as per ISO 10993-11;

e) genotoxicity as per ISO 10993-3;

f) acute systemic toxicity as per ISO 10993-11;

g) implantation as per ISO 10993-6.

These tests shall be repeated only in the case of a significant change such as change in formulation or grade of silicone tubing material, change in sterilization method, change in manufacturing process, etc.

The results of the test shall be reviewed and interpreted by a qualified toxicologist.

4.5 Radio-opacity

Fallopian rings shall be radiopaque. This test shall be a type test used for the initial evaluation of the silicone elastomeric tubing material. ASTM F640 shall be referred for determining radio-opacity of the elastomeric material.

4.6 Clinical evaluation

4.6.1 General

Fallopian rings made of silicone-based elastomer have been used to effect female sterilization for nearly 50 years. They have been studied extensively, and clinical reports from the published literature[8] show a long history of safety and effectiveness. Rings manufactured in accordance with the requirements of this document are expected to have comparable clinical performance. This means the manufacturers' fallopian rings are similar to the fallopian rings used in the cited published clinical studies and comply with this document with respect to the following characteristics:

— peak load;

— elongation at peak load;

— strain capacity;

— loading force on ring applicator;

— elastic memory;

— repeat loading strength.

To establish conformance with this document for a new design of fallopian rings, the manufacturer shall demonstrate, using a one-sided test, that the upper limit of the 95 % confidence interval for a one-year pregnancy rate is ≤2,0 %. To establish this, the manufacturer shall sponsor a clinical study of its new design and demonstrate clinical safety and effectiveness. Completion of the one-year phase of the study is sufficient to begin marketing. However, the women in the study should be followed for an additional four years to record any additional pregnancies and serious adverse events.

4.6.2 New clinical study of manufacturer's fallopian rings

A manufacturer may make significant changes to the fallopian ring with respect to design, materials or manufacturing procedures. In this case, the manufacturer shall sponsor a clinical study of its fallopian ring and demonstrate clinical safety and effectiveness. To this end, the sponsor shall conduct a single-arm clinical study, enrolling sexually-active women of reproductive age, following these women for a total of five years. Biostatistical analysis of the study shall show, using a one-sided test, that the upper limit on the 95 % confidence interval for the one-year failure rate (pregnancy) is less than 2,0 %. Completion of the one-year phase of the study is sufficient to begin marketing. However, the women in the study should be followed for an additional four years (a total of five years) to record any additional pregnancies and serious adverse events. Any unusual findings shall be included in updated labelling.

5 Storage condition

The fallopian rings shall be stored at a temperature ranging from 0 °C to 50 °C.

6 Labelling

6.1 If symbols are used on packaging information and marketing materials, the symbols shall meet the requirements as given in ISO 15223-1 and ISO 15223-2.

6.2 Printing and illustrations shall be clear, legible and indelible. If labels are used, they shall be free from gross particulate matter and fibres.

6.3 Each individual container shall be marked with the following:

a) full name and address of manufacturer;

b) batch number;

c) method, month and year of sterilization (for year use four digits);

d) storage directives;

e) use/implant before (specify month and year, or year and month as per the national regulation; use four digits for year).

6.4 In addition to those stated in 6.3, each individual package shall carry the following text:

a) warning-sterile unless package is opened or damaged;

b) fallopian rings shall not be kept loaded on the applicator for more than 15 minutes;

c) a reference to this document (i.e. ISO 19351:2019) and reference to the instructions for use;

d) the pouch/blister pack, once opened, shall not be resealed;

e) any other requirement(s) mandated by the regulatory authorities in the country of use.

7 Shelf life

7.1 General

The fallopian rings shall meet performance specification as per the requirements given in Clause 4 for the complete duration of the declared shelf life.

In case of a significant change in formulation, grade or source of the silicone tubing raw material, change in construction of the primary packing material, sterilization method, or manufacturing process, the shelf life of the fallopian rings shall be established by the following processes.

7.2 Procedure for determining shelf life by real-time stability studies

After testing in accordance with Annex H, the fallopian rings shall meet the requirements given in Clause 4. If the real time data indicate a shorter shelf life than that claimed on the basis of accelerated stability studies, the manufacturer shall notify the relevant regulatory authorities and direct purchasers on the shelf life of the product. The manufacturer shall change the shelf life claim for the product based upon the real time study. In no case shall the shelf life exceed 4 years. Real-time stability studies shall be performed for the full period of the shelf-life claim.

7.3 Procedure for determining shelf life by accelerated stability studies

After testing in accordance with Annex I, the fallopian rings shall meet the requirements given in Clause 4.

Annex A
(normative)

Sampling plan and acceptance criteria for a continuing series of lot

A.1 If a party wishes to establish, by inspection and testing of samples of the final product, whether a continuing series of lots are in compliance with the requirements of this document, the sampling plans and acceptance criteria given in Table A.1 shall be applied.

A.2 Manufacturers may use the schemes in Table A.1 or they may devise and implement validated alternative quality control methods that result in at least equivalent consumer protection.

Table A.1 — Sampling plans and acceptance criteria for a continuing series of lots

Attributes	Inspection level	Acceptance criteria
Dimensions	20 pairs from each lot	All samples shall meet the requirements for dimensions
Tensile properties	Level S3 as in ISO 2859-1	AQL 0,65
Loading force on ring applicator	Level S3 as in ISO 2859-1	AQL 0,65
Elastic memory	Level S3 as in ISO 2859-1	AQL 0,65
Repeat loading strength	Level S2 as in ISO 2859-1	AQL 0,65
Visible defects	20 pairs from each Lot	No discoloration, fibres, protrusions
Package seal integrity and seal strength	Level S3 as in ISO 2859-1	AQL 0,65
Packaging and labelling	20 pairs from each Lot	No printing defects
Sterility	As per National/International pharmacopeia	Shall comply

A.3 Applications for these sampling plans include the following:

a) on-going production testing and quality control by a manufacturer;

b) on-going testing by a purchaser for contractual purposes; and

c) on-going inspection by a regulatory or certification authority.

Annex B
(informative)

Sampling plans intended for assessing compliance of isolated lots

B.1 The sampling plans given in Table B.1, normal inspection, when applied to isolated lots, provide approximately the same level of consumer protection as those given in Annex A when used in conjunction with the switching rules. Attention is drawn to the possibility of using double or multiple sampling plans, which may reduce the total number of fallopian rings that need to be tested to demonstrate compliance when quality is significantly better than the AQLs. Sample sizes may be increased independently of the lot size to achieve a more reliable estimate of lot quantity.

Table B.1 — Sampling plans and acceptance criteria for isolated lots

Attributes	Inspection level	Acceptance criteria
Dimensions	20 pairs from each lot	All samples shall meet the required dimensions
Tensile properties	Level S4 to letter code J as in ISO 2859-1	AQL 0,65
Loading force on ring applicator	Level S4 to letter code J as in ISO 2859-1	AQL 0,65
Elastic memory	Level S4 to letter code J as in ISO 2859-1	AQL 0,65
Repeat loading strength	Level S4 to letter code J as in ISO 2859-1	AQL 0,65
Visible defects	20 pairs from each Lot	No discoloration, fibres, protrusions
Package seal integrity and seal strength	Level S4 to letter code J as in ISO 2859-1	AQL 0,65
Packaging and labelling	20 pairs from each Lot	No printing defects
Sterility	As per National/International pharmacopeia	Shall comply

B.2 Applications for these sampling plans include the following:

a) type testing as part of a certification procedure;

b) in case where the total number of lots being assessed are insufficient to allow the switching rules to be effective;

c) in case of dispute involving isolated lots, e.g. for referee testing.

Annex C
(normative)

Determination of dimensions

C.1 General

This test is used to determine the dimensions of the fallopian rings.

C.2 Apparatus

C.2.1 Profile projector (minimum × 20 magnification).

C.2.2 Thickness gauge of least count 0,01 mm.

C.3 Procedure

Open the pouch and remove the rings carefully.

Place the ring on the profile projector, and measure the inner diameter and outer diameter.

Thickness of the ring is measured using no load thickness gauge.

The test sampling plan and acceptance criteria are given in Annex A and Annex B.

Test shall be carried at (25 ± 2) °C.

The test report shall be prepared as given in Annex K.

Annex D
(normative)

Determination of tensile properties

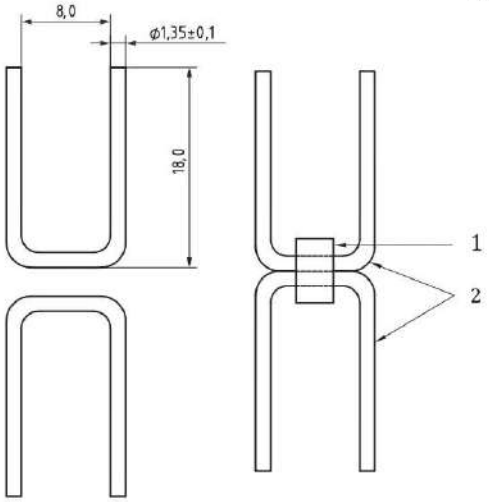
D.1 General

This test is used to determine the force at break (maximum load) and elongation at maximum load.

D.2 Apparatus

D.2.1 U-shaped steel clips.

Dimensions in millimetres



Key
1 fallopian ring
2 U-shaped steel clips

Figure D.1 — Fallopian ring testing using U-shaped steel clips

D.2.2 Universal testing machine (UTM), table top type universal testing machine having the following specification shall be used to perform the tensile test:

— machine type: one–pillar traction;

— drive: motor;

— measuring range: 0 kN to 50 kN;

— test speed: 0 mm/min to 200 mm/min.

D.3 Procedure

D.3.1 The test is performed on a universal testing machine with special adaptors to hold two 'U' shaped steel clips (see Figure D.1). The crosshead separation speed is kept at 100 mm/min.

D.3.2 Place the fallopian rings on two U-shaped steel clips and insert these clips into two adapter tubes, one attached to the fixed crosshead and other to the moving crosshead.

D.3.3 The jaws are separated 100 mm/min and measure the load with the help of a load cell.

Annex E
(normative)

Determination of loading force on ring applicator

E.1 General

This test is used to determine the force required to load the fallopian rings on a ring applicator.

E.2 Apparatus

E.2.1 Example of dilator cone.

Dimensions in millimetres

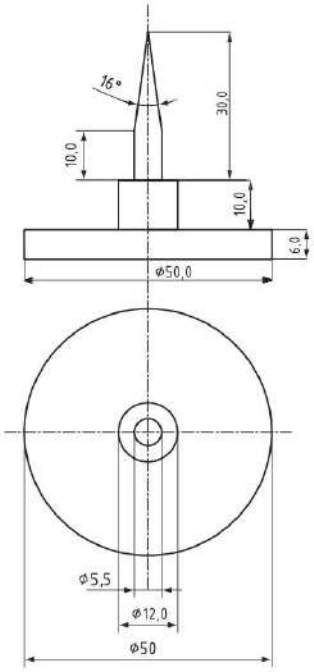


Figure E.1 — Dilator cone

E.2.2 Eye bolt.

Dimensions in millimetres

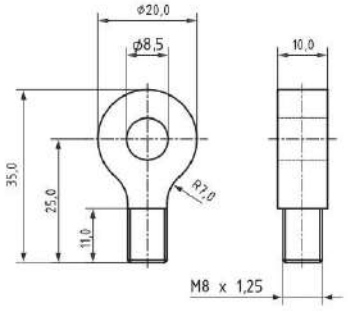


Figure E.2 — Eye bolt (for attaching to UTM)

E.2.3 Adaptor/fallopian rings pusher.

Dimensions in millimetres

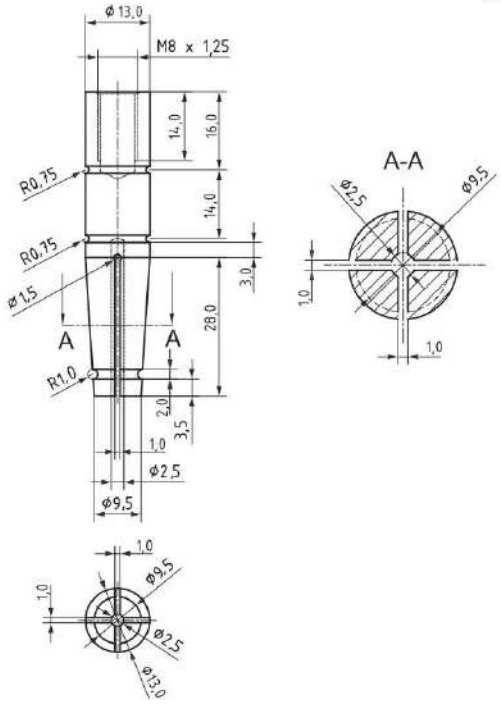


Figure E.3 — Adaptor/fallopian rings pusher

E.2.4 "O" ring.

Dimensions in millimetres

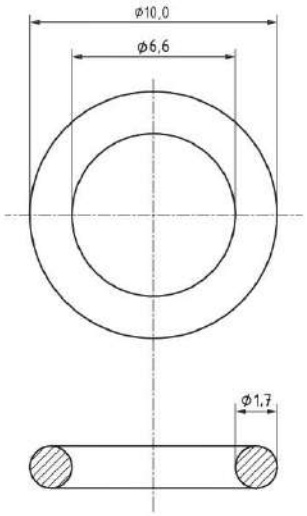


Figure E.4 — "O" ring

H.4 Test method

The relative humidity (RH) for the real time stability study shall be maintained at (65 ± 5) % RH and temperature (30 ± 2) °C.

The sample shall be evaluated for the attributes mentioned in Table H.1 at a frequency not more than 12 months between two consecutive test periods.

H.5 Test report

The test report shall be prepared as given in Annex K.

Annex I
(normative)

Determination of shelf life by accelerated stability study

I.1 General

Accelerated stability study shall be conducted under varied set of storage conditions to determine the minimum shelf life until the real time stability studies are completed.

I.2 Apparatus

Humidity chamber and hot air oven would be used to maintain the storage conditions for the accelerated stability studies.

I.3 Procedure

The study shall be conducted from the representative samples from three consecutive lots manufactured. The fallopian rings shall be stored in its primary package under conditions mentioned in I.4. Sufficient number of samples shall be taken for evaluation of properties mentioned in Table H.1.

I.4 Test method

The test samples will be maintained at three sets of storage conditions and tested at intervals as below:

Set 1	The test samples will be maintained at a relative humidity of 75 % and temperature of 50 °C. The samples will be tested at intervals of 30, 60, 90, 120, 150 and 180 days.
Set 2	The test samples will be maintained at a temperature of 60 °C maintained with dry heat. The samples will be tested at intervals of 7, 14, 30, 60 and 90 days.
Set 3	The test samples will be maintained at a temperature of 70 °C maintained with dry heat. The samples will be tested at intervals of 7, 14, 30, 60 and 90 days.

The critical parameters to measure are as below:

a) tensile properties;

b) elastic memory;

c) package seal integrity and seal strength.

The sampling plan is as per Table H.1.

NOTE Minimum stability requirements are finalized based on the results of the protocol on accelerated stability study. This study is in progress.

Annex J
(normative)

Package seal integrity and seal strength

J.1 General

This test is used to determine the seal strength of the packs and the package seal integrity of the packed fallopian rings. This test is based on ISO 11607-1 and ISO 11607-2.

J.2 Apparatus

J.2.1 Package seal integrity tester, capable of generating an absolute pressure of (20 ± 5) kPa.

J.2.2 Universal testing machine (UTM), table top type universal testing machine having the following specification shall be used to perform the tensile test:

— machine type: two-pillar traction;

— drive: motor;

— measuring range: 0 kN to 50 kN; and

— test speed: 0 mm/min to 200 mm/min.

J.3 Procedure

J.3.1 Package seal strength

The test is performed on a universal testing machine attached with jaws to carry out the peel strength of the sealed layer.

The test method measures the force required to separate the standard seal in 25 mm width specimen from the flexible packaging material.

The test specimen cut down from the pouches are clean and cut perpendicular to the direction of the seal.

The free ends of the specimen are fixed in a suitable grip for holding in a universal testing machine adjusted with a cross head speed of 100 mm/min.

Continuously increasing tensile force is applied with sample supported at an angle of 90° by hand and the maximum force required to separate the seal is recorded.

The test report shall be prepared as given in Annex K.

J.3.2 Package seal integrity

Individual containers are subjected to vacuum at (20 ± 5) kPa absolute pressure.

Hold the vacuum for (60 ± 5) sec.

Any containers not expanding, when subjected on completion of the holding period is deemed to have failed in the package seal integrity test.

The test report shall be prepared as given in Annex K.

Annex K
(normative)

Reporting of test results

K.1 The test report shall contain at least the following information:

a) name and address of the test laboratory;

b) name and address of the client;

c) identification of the test report;

d) identification of the sample (device name, sample size, lot number and lot size);

e) origin of the sample, date of the sample's arrival to the laboratory and identity of the responsible party who has taken the sample;

f) a reference to this document, i.e. ISO 19351:2019, and the relevant annexes;

g) description of all deviations from this document;

h) results according to relevant annexes including mean, standard deviation, maximum value, minimum value, etc.;

i) measurement error, if available; and

j) date of test report and signature and title of the person(s) responsible for the report.

Bibliography

[1] ISO/TR 8550-1:2007, *Guidance on the selection and usage of acceptance sampling systems for inspection of discrete items in lots — Part 1: Acceptance sampling*

[2] ISO/TR 8550-2:2007, *Guidance on the selection and usage of acceptance sampling systems for inspection of discrete items in lots — Part 2: Sampling by attributes*

[3] ISO/TR 8550-3:2007, *Guidance on the selection and usage of acceptance sampling systems for inspection of discrete items in lots — Part 3: Sampling by variables*

[4] ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

[5] ISO 2859-1:1999, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

[6] ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

[7] ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

[8] United States Pharmacopeia, 38 (2015) Sterility tests <71>

[9] *European Pharmacopoeia*, 8, 2014 (Ph. Eur. 2014, para. 2.6.1)

[10] ASTM F88 / *F88M-15, Standard test method for seal strength of flexible barrier materials*

National Annex A

(National Foreword)

A-1 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

(*Continued from second cover*)

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 11135 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	IS/ISO 11135 : 2014 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	Identical with ISO 11135 : 2014
ISO 11137-1 Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	IS/ISO 11137-1 : 2006 Sterilization of health care products — Radiation: Part 1 Requirements for development, validation and routine control of a sterilization process for medical devices	Identical with ISO 11137-1 : 2006
ISO 11137-2 Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose	IS/ISO 11137-2 : 2013 Sterilization of health care products — Radiation: Part 2 Establishing the sterilization dose	Identical with ISO 11137-2 : 2013
ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements	IS/ISO 15223-1 : 2016 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied: Part 1 General requirements (*second revision*)	Identical
ISO 15223-2 Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation	IS/ISO 15223-2 : 2010 Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied: Part 2 Symbol development, selection and validation	Identical with ISO 15223-2 : 2010

The technical committee has reviewed the provisions of the following International Standard referred in this adopted standard and has decided that it is acceptable for use in conjunction with this standard:

Other Publication	*Title*
ASTM F640	Standard test methods for determining radiopacity for medical use

The standard also makes a reference to the BIS Certification Marking of the product. Details of which are given in National Annex A.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be same as that of the specified value in this standard.

Bureau of Indian Standards

BIS is a statutory institution established under the *Bureau of Indian Standards Act*, 2016 to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards: Monthly Additions'.

This Indian Standard has been developed from Doc No.: MHD 03 (16781).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

BUREAU OF INDIAN STANDARDS

Headquarters:

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002
Telephones: 2323 0131, 2323 3375, 2323 9402 *Website*: www.bis.gov.in

Regional Offices: *Telephones*

Central : Manak Bhavan, 9 Bahadur Shah Zafar Marg, NEW DELHI 110002 — 2323 7617, 2323 3841

Eastern : 1/14 C.I.T. Scheme VII M, V.I.P. Road, Kankurgachi, KOLKATA 700054 — 2337 8499, 2337 8561, 2337 8626, 2337 9120

Northern : Plot No. 4-A, Sector 27-B, Madhya Marg, CHANDIGARH 160019 — 265 0206, 265 0290

Southern : C.I.T. Campus, IV Cross Road, CHENNAI 600113 — 2254 1216, 2254 1442, 2254 2519, 2254 2315

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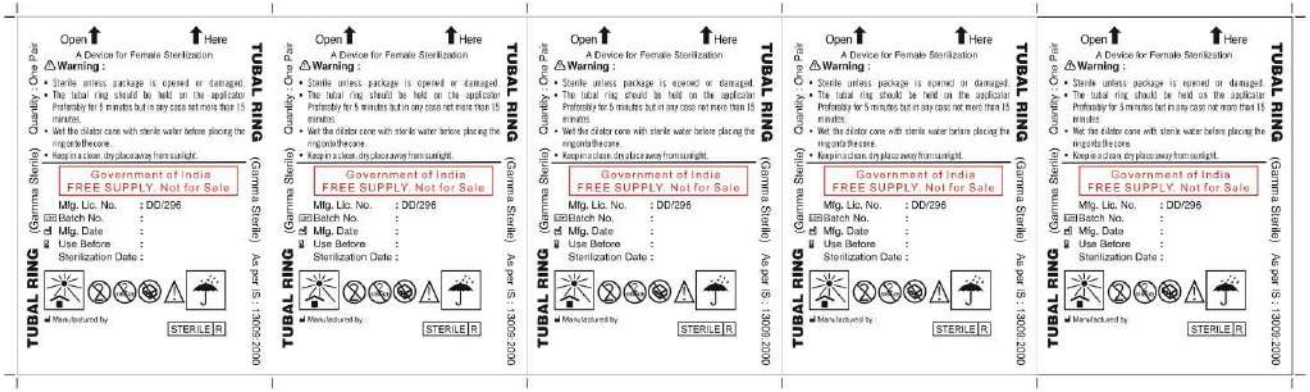
Published by BIS, New Delhi

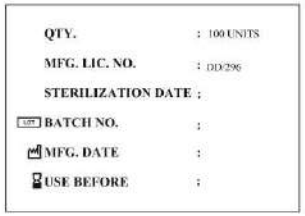
Annexure-12 a

Tubal Ring Artwork for DAMAN: Pouch Size: 250 X 70 mm



Tubal Ring Inner carton without CE mark for MOH INDIA, Front side | SPE/QA/7030/D | Date - 26/12/2016 | Size - 165 x 60 mm.

Tubal Ring Inner carton without CE mark for MOH INDIA, Right Side | SPE/QA/7030/D | Date - 26/12/2016 | Size - 85 x 60 mm.



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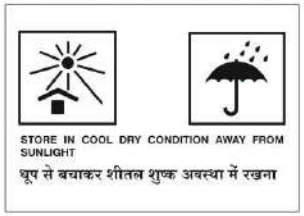


Tubal Ring Outer carton without CE mark for MOH INDIA, Back Side | SPE/QA/7031/D | Date - 18/09/2017 | Size - 470 x 325 mm.

TUBAL RING

(A DEVICE FOR FEMALE STERILIZATION)

STERILE	R

Manufactured by :

Government of India
FREE SUPPLY. Not for Sale.

Tubal Ring Inner carton without CE mark for MOH INDIA, Top side | SPE/QA/7038/D | Date - 26/12/2016 | Size - 165 x 85 mm

TUBAL RING
(A Device for Female Sterilization)

STERILE R

- Wet the dilator cone with sterile water before placing the ring into the cone.
- Ring should preferably be kept on the Laparoscope in stretched state for less than 5 minutes and in no case longer than 15 minutes.

Tubal Ring Outer carton without CE mark for MOH INDIA, Front Side | SPE/QA/7031/D | Date -18/09/2017 | Size - 470 x 325 mm.

TUBAL RING
(A DEVICE FOR FEMALE STERILIZATION)

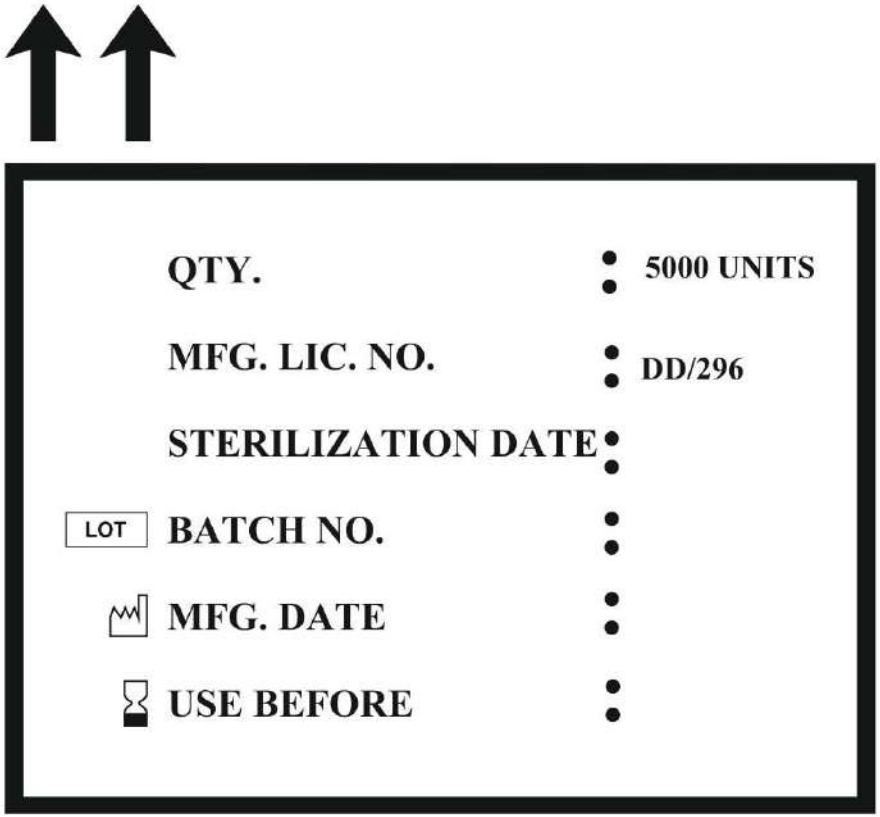
Manufactured by :

PREGNA
INTERNATIONAL LTD.

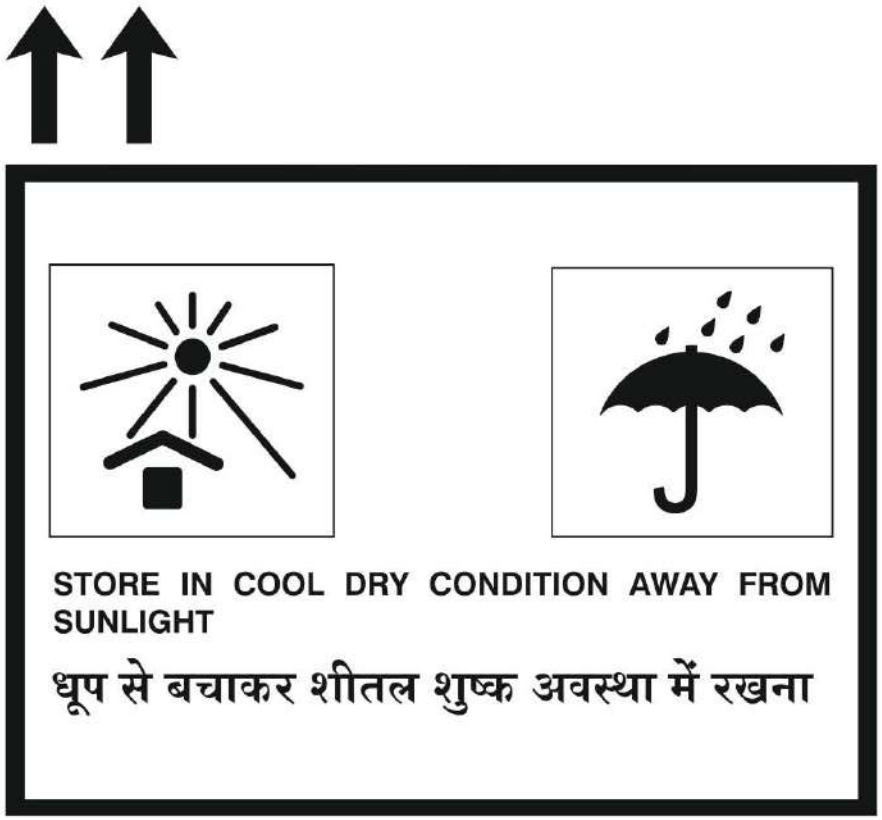
WORKS : Plot No.: 219, Survey No.: 168
Dabhel Industrial Co-Operative Society Ltd.,
Dabhel, Daman (U.T) - 396 210 - India
OFFICE : 13 SURYODAY ESTATE,
136 TARDEO ROAD,
MUMBAI - 400 034, INDIA
Email : sales@pregna.com
Website : www.pregna.com

Government of India FREE SUPPLY.
Not for Sale

Tubal Ring Outer carton without CE mark for MOH INDIA, Right Side | SPE/QA/7031/D | Date - 26/12/2016 | Size - 350 x 325 mm.



Tubal Ring Outer carton without CE mark for MOH INDIA, Left Side | SPE/QA/7031/D | Date - 26/12/2016 | Size - 350 x 325 mm.



SECTION VII: GENERAL CONDITIONS OF CONTRACT (GCC)

1. General	**1.1 Tenets of Interpretation** Unless where the context requires otherwise, throughout the contract: 1) The heading of these conditions shall not affect the interpretation or construction thereof. 2) Writing or written includes matter either whole or in part, in digital communications, manuscript, typewritten, lithographed, cyclostyled, photographed, or printed under or over signature or seal or digitally acceptable authentication, as the case may be. 3) Words in the singular include the plural and vice-versa. 4) Words importing the masculine gender shall be taken to include other genders, and words importing persons shall include any company or association or body of individuals, whether incorporated or not. 5) Terms and expression not herein defined shall have the meanings assigned to them in the contract Act, 1872 (as amended) or the Sale of Goods Act, 1930 (as amended) or the General Clauses Act, 1897 (as amended) or of INCOTERMS, (current edition published by the International Chamber of Commerce, Paris) as the case may be. 6) Any reference to 'Goods' shall be deemed to include the incidental Works/ Services also. 7) Any generic reference to GCC shall also imply a reference to SCC as well. 8) In case of conflict, provisions of SCC shall prevail over those in GCC. 9) Any reference to 'Contract' shall be deemed to include all other documents (inter-alia GCC, SCC) as described in GCC-clause 2.5. 10) Any reference to any legal Act, Government Policies or orders shall be deemed to include all amendments to such instruments, from time to time, till date. 11) Deleted. **1.2 Definitions** In the contract, unless the context otherwise requires:

	1) “Agent” is a person employed to do any act for another or represent another in dealings with a third person. In the context of public procurement, an Agent is a representative participating in the Tender Process or Execution of a Contract for and on behalf of its principals. 2) “Allied Firm” are all business entities that are within the ‘controlling ownership interest’ (ownership of or entitlement to more than twenty-five percent of the company's shares or capital or profits) or ‘control’(including the right to appoint a majority of the directors or to control the management or policy decisions including by virtue of their shareholding or management rights or shareholder agreements or voting agreements) of the principal firm acting alone or together or through one or more juridical persons. All successor firms or assigns of the principal firm shall be considered allied firms. 3) "bid" (including the term ‘tender’, ‘offer’, ‘quotation’ or ‘proposal’ in specific contexts) means an offer to supply goods, services or execution of works made as per the terms and conditions set out in a document inviting such offers. 4) "Bidder" (including the term 'Bidder', 'consultant' or 'service provider' in specific contexts) means any person or firm or company, including any member of a consortium or joint venture (that is an association of several persons, or firms or companies), every artificial juridical person not falling in any of the descriptions of bidders stated hereinbefore, including any agency branch or office controlled by such person, participating in a Tender Process. 5) “Bill of Quantities” (including the term Price Schedule or BOQ) means the priced and completed Bill of Quantities forming part of the bid. 6) "Commercial Bank" means a bank, defined as a scheduled bank under section 2(e) of the Reserve Bank of India Act, 1934. 7) “Consignee” means the person to whom the goods are required to be delivered as stipulated in the contract. A contract may provide the goods to be delivered to an interim consignee for further dispatch to the ultimate consignee. 8) “Contract” (including the terms ‘Purchase Order’ or ‘Supply Order’ or ‘Withdrawal Order’ or ‘Work Order’ or ‘Consultancy Contract’ or ‘Contract for Services’, ‘rate contract’ or ‘framework contract’ or ‘Letter of Award – LoA’ (letter or memorandum communicating to the contractor the acceptance of his bid) or ‘Agreement’ or a ‘repeat order’ accepted/ acted upon by the contractor or a ‘formal agreement’, under specific

	contexts), means a formal legal agreement in writing relating to the subject matter of procurement, entered into between the Procuring Entity and the contractor on mutually acceptable terms and conditions and which are in compliance with all the relevant provisions of the laws of the country; 9) "Contractor" (including the terms 'Supplier' or 'Service Provider' or 'Consultant' or 'Firm' or 'Vendor' or 'Manufacturer' or 'Successful Bidder' under specific contexts) means the person, firm, company, or a Joint Venture with whom the contract is entered into and shall be deemed to include the contractor's successors (approved by the Procuring Entity), agents, subcontractor, representatives, heirs, executors, and administrators as the case may be unless excluded by the terms of the contract.; 10) "Day", "Month", "Year" shall mean calendar day/ month or year (unless reference to financial year is clear from the context). 11) "Drawing" means the drawing or drawings stipulated in or annexed to the Specifications or the Tender Document/ Contract; 12) "General Conditions" means the General Conditions of Contract, also referred to as GCC. 13) "Goods" (including the terms 'Stores', 'Material(s)' in specific contexts) includes all articles, material, commodity, livestock, medicines, furniture, fixtures, raw material, consumables, spare parts, instruments, machinery, equipment, industrial plant, vehicles, aircrafts, ships, railway rolling stock assemblies, sub-assemblies, accessories, a group of machines comprising an integrated production process or such other categories of goods or intangible, products like technology transfer, licenses, patents or other intellectual properties (but excludes books, publications, periodicals, etc., for a library) under specific context), procured or otherwise acquired by a Procuring Entity. Any reference to Goods shall be deemed to include specific small work or some services that are incidental or consequential to the supply of such goods; 14) "Government" means the Central Government or a State Government as the case may be and includes agencies and Public Sector Enterprises under it, in specific contexts; 15) "Inspection" means activities such as measuring, examining, testing, analysing, gauging one or more characteristics of the goods or services or works, and comparing the same with the specified requirement to determine conformity.

	16) "Inspecting Officer" means the person or organisation stipulated in the contract for inspection under the contract and includes his/ their authorised representative; 17) "Intellectual Property Rights" (IPR) means the rights of the intellectual property owner concerning a tangible or intangible possession/ exploitation of such property by others. It includes rights to Patents, Copyrights, Trademarks, Industrial Designs, Geographical indications (GI). 18) **"**Parties": The parties to the contract are the "Contractor" and the Procuring Entity, as defined in this clause; 19) "Performance Security" (includes the terms 'Security Deposit' or 'Performance Bond' or 'Performance Bank Guarantee' or other specified financial instruments in specific contexts) means a monetary guarantee to be furnished by the successful Bidder or Contractor in the form prescribed for the due performance of the contract; 20) "Place of Delivery" the delivery of the Goods shall be deemed to take place on delivery of the Goods, at consignees' premises, unless otherwise stipulated in the contract. 21) "Procurement" or "public procurement" (or 'Purchase', or 'Government Procurement/ Purchase' including an award of Public-Private Partnership projects, in specific contexts) means the acquisition of Goods/ Services/ works by way of purchase, lease, license or otherwise, either using public funds or any other source of funds (e.g. grant, loans, gifts, private investment etc.) of goods, works or services or any combination thereof, by a Procuring Entity, whether directly or through an agency with which a contract for procurement services is entered into, but does not include any acquisition without consideration. The term "procure"/ "procured" or "purchase"/ "purchased" shall be construed accordingly; 22) "The Procuring Entity" means the entity in The Procuring Organization procuring Goods or Works or Services; 23) "Procurement Officer" means the officer signing the Letter of Award (LoA) and/or the contract on behalf of the Procuring Entity; 24) "Service(s)" (including the term 'non-consultancy services' or 'Outsourcing of Services' in specific contexts) are defined by exclusion as services that cannot be classified as Consultancy Services. Services (non-consultancy) involve routine, repetitive physical, procedural, and non-intellectual outcomes for which quantum and performance standards can be tangibly identified and consistently applied and are bid and contracted on such basis

	but does not include the appointment of an individual made under any law, rules, regulations, or order issued in this behalf. Any reference to Services shall be deemed to include the supply of goods or performance of consultancy service or small works, which are incidental or consequential to such services; 25) "Special Conditions" means Special Conditions of Contract, which override the General Conditions, also referred to as SCC. 26) "Specification" or "Technical Specification" means the drawing/ document/ standard or any other details governing the construction, manufacture or supply of goods or performance of services that prescribes the requirement to which goods or services have to conform as per the contract. 27) "Signed" means ink signed or digitally signed with a valid Digital Signature as per IT Act 2000 (as amended from time to time). It also includes stamped, except in the case of Letter of Award or amendment thereof.; 28) "Tender"; "Tender Document"; "Tender Enquiry" or "Tender Process": 'Tender Process' is the whole process from the publishing of the Tender Document till the resultant award of the contract. 'Tender Document' means the document (including all its sections, appendices, forms, formats, etc.) published by the Procuring Entity to invite bids in a Tender Process. The Tender Document and Tender Process may be generically referred to as "Tender" or "Tender Enquiry", which would be clear from context without ambiguity. 29) "Test" means such test as is prescribed by the particulars governing the construction, manufacture or supply of Goods as may be prescribed by the contract or considered necessary by the Inspecting Officer whether performed or made by the Inspecting Officer or any agency acting under the direction of the Inspecting Officer; 30) "Works" refer to any activity involving construction, fabrication, repair, overhaul, renovation, decoration, installation, erection, excavation, dredging, and so on, which make use of a combination of one or more of engineering design, architectural design, material and technology, labour, machinery, and equipment. **1.3 Document Conventions** All words and phrases defined in GCC-clause 1.2 are written as 'Capitalized word' and shall have the defined meaning. The rest of the words shall be as per grammar, inter-alia 'Goods' shall indicate definition as given in the GCC while 'goods' shall have usual

dictionary meaning.

1.4 Abbreviations:

Abbreviation	Definition
BOQ	Bill of Quantities (Excel sheet of Price Schedule)
BSD	Bid Securing Declaration
CGST	Central Goods and Services Tax
CPPP	Central Public Procurement Portal
DoE	Department of Expenditure
DP	Delivery Period
DPIIT	Department for Promotion of Industry and Internal Trade
DSC	Digital Signature Certificate
EFT/ NEFT	(National) Electronic Funds Transfer
GCC	General Conditions of Contract
GeM	Government e-Marketplace
GRIR	Goods Receipt and Inspection Report
GST	Goods and Services Tax
GTE	Global Tender Enquiry (International Competitive Bidding)
HSN	Harmonized System of Nomenclature
IEM	Independent External Monitor
IPR	Intellectual Property Rights
INR	Indian Rupee
ITB	Instructions To Bidders
ITC (HS)	Indian Tariff Classification (Harmonised System)
LoA	Letter of Award (Acceptance)
MII	Make in India
MSE	Micro and Small Enterprises
MSME	Micro, Small and Medium Enterprises

		MSMED	MSME Development (Act)
		NIT	Notice Inviting Tender
		OEM	Original Equipment Manufacturer
		PAN	Permanent Account Number
		PC	(Indian) Penal Code
		PPD	Procurement Policy Division
		PQB	Pre-Qualification Bidding
		RCM	Reverse Charge Mechanism
		SC	Scheduled Caste
		SCC	Special Conditions of Contract
		ST	Scheduled Tribe
		TCS	Tax Collected at Source
		TDS	Tax Deducted at Source
		TIA	Tender Inviting Authority
		TIS	Tender Information Summary

2. The	**2. The Contract** **2.1 Language of Contract** The contract shall be written in the English Language. All correspondence and other contract documents, which the parties exchange, shall also be written accordingly in English language. **2.2 The Entire Agreement** This Contract and its documents (referred to in GCC-clause 2.5 below) constitutes the entire agreement between the Procuring Entity and the contractor and supersedes all other communications, negotiations, and agreements (whether written or oral) of the Parties made before the date of this Contract. No agent or representative of either Party has the authority to make, and the Parties shall not be bound by or be liable for, any statement, representation, promise or agreement not outlined in this Contract. **2.3 Severability** If any provision or condition of this Contract is prohibited or rendered invalid or unenforceable, such prohibition, invalidity or unenforceability shall not affect the validity or enforceability of any other provisions and conditions of this Contract.

2.4 Parties

The parties to the contract are the contractor and the Procuring Entity, as defined in GCC-clause 1.2 above and nominated in the contract.

2.5 Contract Documents and their Precedence

The following conditions and documents in indicated order of precedence (higher to lower) shall be considered an integral part of the contract, irrespective of whether these are not appended/ referred to in it. Any generic reference to 'Contract' shall imply reference to all these documents as well:

1) Valid and authorized Amendments issued to the contract.
2) the Agreement consisting of the initial paragraphs, recitals and other clauses set forth immediately before the GCC and including the formats annexed to it and signatures of Procuring Entity;
3) the Letter of Award (LoA)
4) Final written submissions made by the contractor during negotiations, if any;
5) the SCC
6) the GCC
7) the contractor's bid;
8) any other document listed in the SCC as forming part of this Contract.
9) Integrity Pact, if any

2.6 Modifications/ Amendments, Waivers and Forbearances

2.6.1 Modifications/ Amendments of Contract

1) If any of the contract provisions must be modified after the contract documents have been signed, the modifications shall be made in writing and signed by the Procuring Entity, and no modified provisions shall be applicable unless such modifications have been done. No variation in or modification of the contract terms shall be made except by a written amendment signed by the Procuring Entity. Requests for changes and modifications may be submitted in writing by the contractor to the Procuring Entity. At any time during the currency of the contract, the Procuring Entity may suo-moto or, on request from the contractor, by written order, amend the contract by making alterations and modifications within the general scope of the Contract.

	2) If the contractor does not agree to the suo-moto modifications/ amendments made by the Procuring Entity, he shall convey his views within 03 working days from the date of amendment/ modification. Otherwise, it shall be assumed that the contractor has consented to the amendment. 3) Any verbal or written arrangement abandoning, modifying, extending, reducing, or supplementing the contract or any of the terms thereof shall be deemed conditional and shall not be binding on the Procuring Entity unless and until the same is incorporated in a formal instrument and signed by the Procuring Entity, and till then the Procuring Entity shall have the right to repudiate such arrangements. **2.6.2 Waivers and Forbearances** The following shall apply concerning any waivers, forbearance, or similar action taken under this Contract: 1) Any waiver of a Procuring Entity's rights, powers, or remedies under this Contract must be in writing, dated, and signed by an authorized representative of the Procuring Entity granting such waiver and must specify the terms under which the waiver is being granted. 2) No relaxation, forbearance, delay, or indulgence by Procuring Entity in enforcing any of the terms and conditions of this Contract or granting of an extension of time by Procuring Entity to the contractor shall, in any way whatsoever, prejudice, affect, or restrict the rights of Procuring Entity under this Contract, neither shall any waiver by Procuring Entity of any breach of Contract operate as a waiver of any subsequent or continuing breach of Contract.
3. Governing Laws and Jurisdiction	**3.1 Governing Laws and Jurisdiction** 1) This Contract, its meaning and interpretation, and the relation between the Parties shall be governed by the Laws of India for the time being in force. 2) Irrespective of the place of delivery, or the place of performance or the place of payments under the contract, the contract shall be deemed to have been made at the place from which the Letter of Award (LoA or the contract Agreement, in the absence of LoA) has been issued. The courts of such a place shall alone have jurisdiction to decide any dispute arising out or in respect of the contract.

	3.2 Changes in Laws and Regulations Unless otherwise stipulated in the contract, if after the last deadline for the bid submission (Techno-commercial), any law, regulation, ordinance, order or bye-law having the force of law is enacted, promulgated, abrogated, or changed in India (which shall be deemed to include any change in interpretation or application by the competent authorities) that subsequently affects the Delivery Date and/ or the contract Price, then such Delivery Date and/ or Contract Price shall be correspondingly increased or decreased, to the extent that the contractor has thereby been affected in the performance of any of its obligations under the contract. Notwithstanding the foregoing, such additional or reduced cost shall not be separately paid or credited if the same has already been accounted for in the price adjustment provisions where applicable.
4. Communications	**4.1 Communications** 1) All communications under the contract shall be served by the parties on each other in writing, in the contract's language, and served in a manner customary and acceptable in business and commercial transactions. 2) The effective date of such communications shall be either the date when delivered to the recipient or the effective date mentioned explicitly in the communication, whichever is later. 3) No communication shall amount to an amendment of the terms and conditions of the contract, except a formal letter of amendment of the contract, so designated. 4) Such communications would be an instruction or a notification or an acceptance or a certificate from the Procuring Entity, or it would be a submission or a notification from the contractor. A notification or certificate which the contract requires must be communicated separately from other communications. **4.2 The person signing the Communications** For all purposes of the contract, including arbitration, thereunder all communications to the other party shall be signed by: 1) The person who has signed the contract on behalf of the contractor shall sign all correspondences. A person signing communication in respect of the contract or purported to be on behalf of the contractor, without disclosing his authority to do so, shall be deemed to warrant that he has authority to bind the contractor. If it is discovered at any time that the person, so signing has no authority to do so, the Procuring Entity reserves its

	right to, without prejudice to any other right or remedy, to terminate the contract for default in terms of the contract and avail any or all the remedies thereunder and hold such person personally and/ or the contractor liable to the Procuring Entity for all costs and damages arising from such remedies. 2) Unless otherwise stipulated in the contract, the Procurement Officer signing the contract shall administer the contract and sign communications on behalf of the Procuring Entity. Interim or ultimate consignees; Inspecting Agency/ officers and the paying authorities mentioned in the contract shall also administer respective functions during Contract Execution. **4.3 Address of the parties for sending communications by the other party.** 1) For all purposes of the contract, including arbitration, thereunder the address of parties to which the other party shall address all communications and notices shall be: a) The address of the contractor as mentioned in the contract unless the contractor has notified the change of address by a separate communication containing no other topic to the Procuring Entity. The Contractor shall be solely responsible for the consequence of an omission to notify a change of address in the manner aforesaid, and b) The address of the Procuring Entity shall be the address mentioned in the contract. The contractor shall also send additional copies to officers of the Procuring Entity presently dealing with the contract. c) In case of the communications from the contractor, copies of communications shall be marked to the Procurement Officer signing the contract, and as relevant also to Inspecting Agency/ Officer; interim/ ultimate consignee and paying authorities mentioned in the contract. Unless already stipulated in the contract before the contract's start, the Procuring Entity and the contractor shall notify each other if additional copies of communications are to be addressed to additional addresses.
5. Contractor's Obligations and restrictions on its Rights	**5.1 Changes in Constitution/ financial stakes/ responsibilities of a Contract's Business** The Contractor must proactively keep the Procuring Entity informed of any changes in its constitution/ financial stakes/ responsibilities during the execution of the contract. Where the contractor is a partnership firm, the following restrictions shall apply to changes in the constitution during the execution of the contract:

1) A new partner shall not be introduced in the firm except with the previous consent in writing of the Procuring Entity, which shall be granted only upon execution of a written undertaking by the new partner to perform the contract and accept all liabilities incurred by the firm under the contract before the date of such undertaking.

2) On the death or retirement of any partner of the contractor firm before the complete performance of the contract, the Procuring Entity may, at his option, terminate the contract for default as per the Contract and avail any or all remedies thereunder.

3) If the contract is not terminated as provided in Sub-clause (2) above notwithstanding the retirement of a partner from the firm, that partner shall continue to be liable under the contract for acts of the firm until a copy of the public notice given by him under Section 32 of the Partnership Act, has been sent by him to the Procuring Entity in writing or electronically.

5.2 Obligation to Maintain Eligibility and Qualifications

1) The contract has been awarded to the contractor based on specific eligibility and qualification criteria. The Contractor is contractually bound to maintain such eligibility and qualifications during the execution of the contract. Any change which would vitiate the basis on which the contract was awarded to the contractor should be pro-actively brought to the notice of the Procuring Entity within 7 days of it coming to the Contractor's knowledge. These changes include but are not restricted to:

   a) Change regarding declarations made by it in its bid in Form 1.2: Eligibility Declaration
   b) Change in its qualification criteria submitted in its bid in Form 4: Qualification Criteria - Compliance and its sub-form(s).

5.3 Restriction on Potential Conflict of Interests

Neither the contractor nor its Subcontractors nor the Personnel shall engage, either directly or indirectly, in any of the following activities:

1) during the term of this Contract, any business or professional activities in India that would conflict with the activities assigned to them under this Contract.

2) after the termination of this Contract, such other activities as may be stipulated in the contract.

5.4 Consequences of a breach of Obligations

Should the contractor or any of its partners or its Subcontractors or the

	Personnel commit a default or breach of GCC-clause 5.1 to 5.7, the Contractor shall remedy such breaches within 21 days, keeping the Procuring Entity informed. However, at its discretion, the Procuring Entity shall be entitled, and it shall be lawful on his part, to treat it as a breach of contract and avail any or all remedies thereunder. The decision of the Procuring Entity as to any matter or thing concerning or arising out of GCC-clause 5.1 to 5.7 or on any question whether the contractor or any partner of the contractor firm has committed a default or breach of any of the conditions shall be final and binding on the contractor. **5.5 Assignment and Sub-contracting** 1) the contractor shall not, save with the previous consent in writing of the Procuring Entity, sublet, transfer, or assign the contract or any part thereof or interest therein or benefit or advantage thereof in any manner whatsoever. 2) the contractor shall notify the Procuring Entity in writing all subcontracts awarded under the contract if not already stipulated in the contract. In its original bid or later, such notification shall not relieve the contractor from any of its liability or obligation under the terms and conditions of the contract. Subcontract shall be only for bought out items and incidental Works/ Services. Subcontracts must comply with and should not circumvent Contractor's compliance with its obligations under GCC-clause 5.1 to 5.7, based on which the contract was awarded to him. 3) If the Contractor sublets or assigns this contract or any part thereof without such permission, the Procuring Entity shall be entitled, and it shall be lawful on his part, to treat it as a breach of contract and avail any or all remedies thereunder. **5.6 Indemnities for breach of IPR Rights** 1) the contractor shall indemnify and hold harmless, free of costs, the Procuring Entity and its employees and officers from and against all suits, actions or administrative proceedings, claims, demands, losses, damages, costs, and expenses of any nature, including attorney's fees and expenses, which may arise in respect of the Goods provided by the contractor under this Contract, as a result of any infringement or alleged infringement of any patent, utility model, registered design, copyright, or other Intellectual Proprietary Rights (IPR) or trademarks, registered or otherwise existing on the date of the contract arising out of or in connection with:

a) any design, data, drawing, specification, or other documents or Goods provided or designed by the contractor for or on behalf of the Procuring Entity, and
b) The installation of the Goods by the contractor or the use of the Goods at the Procuring Entity's Site

2) Such indemnity shall not cover any use of the Goods or any part thereof or any products produced thereby:

a) other than for the purpose indicated by or to be reasonably inferred from the contract
b) in association or combination with any other equipment, plant, or materials not supplied by the contractor.

3) If any proceedings are brought, or any claim is made against the Procuring Entity arising out of the matters referred above, the Procuring Entity shall promptly give the contractor a notice thereof. At its own expense and in the Procuring Entity's name, the contractor may conduct such proceedings and negotiations to settle any such proceedings or claim, keeping the Procuring Entity informed.

4) If the contractor fails to notify the Procuring Entity within twenty-eight (28) days after receiving such notice that it intends to conduct any such proceedings or claim, then the Procuring Entity shall be free to conduct the same on its behalf at the risk and cost to the contractor.

5) At the contractor's request, the Procuring Entity shall afford all available assistance to the contractor in conducting such proceedings or claim and shall be reimbursed by the contractor for all reasonable expenses incurred in so doing.

5.7 Confidentiality, Secrecy and IPR Rights

5.7.1 IPR Rights

All deliverables, outputs, plans, drawings, specifications, designs, reports, and other documents and software submitted by the contractor under this Contract shall become and remain the property of the Procuring Entity and subject to laws of copyright and must not be shared with third parties or reproduced, whether in whole or part, without the Procuring Entity's prior written consent. The contractor shall, not later than upon termination or expiration of this Contract, deliver all such documents and software to the Procuring Entity, together with a detailed inventory thereof. The contractor may retain a copy of such documents and software but shall not use it for any commercial purpose**.**

	5.7.2 Confidentiality All documents, drawings, samples, data, associated correspondence or other information furnished by or on behalf of the Procuring Entity to the contractor, in connection with the contract, whether such information has been furnished before, during or following completion or termination of the contract, are confidential and shall remain the property of the Procuring Entity and shall not, without the prior written consent of Procuring Entity neither be divulged by the contractor to any third party, nor be used by him for any purpose other than the design, procurement, or other services and work required for the performance of this Contract. If advised by the Procuring Entity, all copies of all such information in original shall be returned on completion of the contractor's performance and obligations under this contract. **5.7.3 Secrecy** If the Contract declares the subject matter of this Contract as coming under the Official Secrets Act, 1923 or if the contract is marked as "Secret", the contractor shall take all reasonable steps necessary to ensure that all persons employed in any connection with the contract, have acknowledged their responsibilities and penalties for violations under the Official Secrets Act and any regulations framed thereunder. **5.7.4 Obligations of the contractor** 1) Without the Procuring Entity's prior written consent, the contractor shall not use the information mentioned above except for the sole purpose of performing this contract. 2) The contractor shall treat and mark all information as confidential (or secret – as the case may) and shall not, without the written consent of the Procuring Entity, divulge to any person other than the person(s) employed by the contractor in the performance of the contract. Further, any such disclosure to any such employed person shall be made in confidence and only so far as necessary for such performance for this contract. 3) Notwithstanding the above, the contractor may furnish to its holding company or its Subcontractor(s) such documents, data, and other information it receives from the Procuring Entity to the extent required for performing the contract. In this event, the contractor shall obtain from such holding company/ Subcontractor(s) an undertaking of confidentiality (or secrecy – as the case may be) similar to that imposed on the contractor under the above clauses.

4) The obligation of the contractor under sub-clauses above, however, shall not apply to information that:

   a) the contractor needs to share with the institution(s) participating in the financing of the contract;
   b) now or hereafter is or enters the public domain through no fault of Contractor;
   c) can be proven to have been possessed by the contractor at the time of disclosure and which was not previously obtained, directly or indirectly, from the Procuring Entity; or
   d) Otherwise lawfully becomes available to the contractor from a third party that has no obligation of confidentiality.

5) The above provisions shall not in any way modify any undertaking of confidentiality (or Secrecy – as the case may be) given by the contractor before the date of the contract in respect of the contract/ the Tender Document or any part thereof.

6) The provisions of this clause shall survive completion or termination for whatever reason of the contract.

5.8 Performance Security

1) Unless stipulated otherwise in SCC, within fourteen days after the issue of Letter of Award (LoA or the contract, if LoA is skipped) by the Procuring Entity, the contractor shall furnish to the Procuring Entity, performance security, as per details given in SCC.

2) The Performance security shall be denominated in Indian Rupees or the currency of the contract and shall be in one of the following forms:

   a) Unless otherwise stipulated in Tender Document or Contract, Account Payee Demand Draft or Fixed Deposit Receipt or Banker's Cheque drawn on any commercial bank in India, favoring Central Medical Services Society payable at New Delhi.
   b) Bank Guarantee issued by a commercial bank in India, in the prescribed form provided in Format 1.1.

3) If the contractor, having been called upon by the Procuring Entity to furnish Performance Security, fails to do so within the specified period, it shall be lawful for the Procuring Entity at its discretion to annul the award and forfeit the EMD/ enforce Bid Securing Declaration, as the case may be.

	4) If the contractor during the currency of the Contract fails to maintain the requisite Performance Security, it shall be lawful for the Procuring Entity at its discretion a) to terminate the Contract for Default besides availing any or all contractual remedies provided for breaches/ default, or b) without terminating the Contract: 1. Recover from the contractor the amount of such security deposit by deducting the amount from the pending bills of the contractor under the contract or any other contract with the Procuring Entity or 2. Treat it as a breach of contract and avail any or all contractual remedies provided for breaches/ default. 5) In the event of any amendment issued to the contract, the contractor shall furnish suitably amended value and validity of the Performance Security in terms of the amended contract within fourteen days of issue of the amendment. 6) The Procuring Entity shall be entitled, and it shall be lawful on his part, a) to deduct from the performance securities or to forfeit the said security in whole or in part in the event of: i. any default, or failure or neglect on the part of the contractor in the fulfilment or performance in all respect of the contract under reference or any other contract with the Procuring Organisation or any part thereof ii. for any loss or damage recoverable from the contractor which the Procuring Entity may suffer or be put to for reasons of or due to above defaults/ failures/ neglect b) and in either of the events aforesaid to call upon the contractor to maintain the said performance security at its original limit by making further deposits, provided further that the Procuring Entity shall be entitled, and it shall be lawful on his part, to recover any such claim from any sum then due or which at any time after that may become due to the contractor for similar reasons. 7) Subject to the sub-clause above, the Procuring Entity shall release the performance security without any interest to the contractor on completing all contractual obligations, including the warranty obligations, if any.

8) No claim shall lie against the Procuring Entity regarding interest on cash deposits or Government Securities or depreciation thereof.

5.9 Permits, Approvals and Licenses

Whenever the supply of Goods and incidental Works/ Services requires that the contractor obtain permits, approvals, and licenses from local public authorities, it shall be the contractor's sole responsibility to obtain these and keep these current and valid. Such requirements may include but not be restricted to export licence or environmental clearance if required. If requested by the contractor, the Procuring Entity shall make its best effort to assist the contractor in complying with such requirements in a timely and expeditious manner, without any dilution of the Contractor's responsibility in this regard.

5.10 Book Examination Clause

The Procuring Entity reserves the right for 'Book Examination' as follows:

1) the contractor shall, whenever called upon and required to produce or cause to be produced, for examination by any Government Officer duly authorised in that behalf, any cost or other book of account, voucher, receipt, letter, memorandum, paper or writing or any copy of or extract from any such document. The Contractor shall also furnish information relating to the execution of this contract or relevant for verifying or ascertaining the cost of executing this contract to such Government Officer in such manner as may be required. The decision of such Government Officer on the question of relevancy of any document, information of return being final and binding on the parties. The obligation imposed by this clause is without prejudice to the contractor's obligations under any other statute, rules or orders which shall be concurrently binding on the contractor.

2) the contractor shall, if the authorised Government Officer so requires (whether before or after the prices have been finally fixed), afford facilities to the Government Officer concerned to visit the contractor's premises to examine the processes of production and estimate or ascertaining the cost of performance of Contract. The authorised Government Officer shall have power, mutadis mutandis, to examine all the relevant books of Contractor's subcontractor, or any subsidiary or allied firm or

	company, If any portion of the contract is entrusted or carried out by such entities. 3) If on such examination, it is established that the contracted price is more than the actual cost-plus reasonable margin of profit, the Procuring Entity shall have the right to reduce the price and determine the amount to a reasonable level. 4) The Contractor or its agency is bound to allow examination of its books within 60 days from the date the notice is received by the contractor or its agencies calling for the production of documents under sub-clause (1) above. In the event of the contractor's or his agency's failure to do so, the contract price would be reduced and determined according to the best judgment of the Procuring Entity, which would be final and binding on the contractor and his agencies. **5.11– Deleted.** **5.12– Deleted**
6. Scope of Supply and Technical Specifications	**6.1 The Scope of Supply** 1) The contract is for supply of goods as stipulated in "Schedule of Requirement" conforming to specification as indicated in the "Technical Specification and Quality Assurance" and as per terms and conditions as indicated in GCC (General Condition of contract) read with SCC (Special Condition of Contract). 2) Incidental Works/ Services: If so stipulated, the contractor shall be required to perform specified incidental Works/ Services as an integral part of the Goods in the contract. **6.2 Technical Specifications and Standards** The Goods & incidental Works/ Services to be provided by the contractor under this contract shall conform to the technical specifications and quality control parameters mentioned in 'Technical Specification and Quality Assurance' under Section VI of the Tender Document and as stipulated in the contract. Wherever references are made in the Contract to codes and standards by which it shall be executed, the edition or the revised version of such codes and standards shall be those specified in the Contract. During Contract execution, any changes in any such codes and standards shall be applied only after approval by the Purchaser. For standards and requirements where no applicable specifications/ Quality Assurance are mentioned, appropriate latest authoritative standards and quality assurance issued by the concerned institution shall be applicable. The

	Goods supplied shall be. 1) Entirely brand new, unused, and incorporate all recent improvements in design and materials unless prescribed otherwise by the Procuring Entity in the contract. 2) conform to materials, manufacture and workmanship as stipulated in the contract, free of all defects and faults using specified/ appropriate materials, manufacture, and workmanship throughout and consistent with the established and generally accepted standards for Goods of the type ordered and in full conformity with the contract specification, drawing or sample, if any. 3) No modification can be made in artwork of product unless prior approved from programme division **6.3 Quantity Tolerance** Purchaser reserves the right to treat the supply obligations of contractor complete if goods have been supplied to the extent of 98% of the contracted quantity. Only the supplied quantity shall be paid for as per the terms of the contract. **6.4 Eligible Goods - Country of Origin and Minimum Local Content** The country of origin of 'Goods' and 'incidental Works/ Service' to be supplied under the contract shall have their origin in India and must conform to the declaration made by the contractor in its bid regarding but not limited to i) restrictions on certain countries with land-borders with India; ii) minimum local content and location of value addition (Make in India Policy); iii) Contractor's status as MSE or Start-up. The term "origin" used in this clause means where the goods (including subcontracted components) are mined, grown, produced, or manufactured or from where the incidental Works/ Services are arranged and supplied. For purposes of this Clause, the term 'Goods' shall have the meaning as defined in GCC-clause 1.2. **6.5- Option Quantity Clause** In exceptional situation where the requirement is of an emergent nature and/ or it is necessary to ensure continued supplies from the existing vendors, the purchaser reserves the right to place repeat order up to 50% of the quantity of the goods and/or services contained in the contract till the last scheduled date of supplies OR up to a period of twelve months from the date of Long Term agreement (LTA), whichever is later, at the same rate or a rate negotiated (downwardly) with the existing vendors considering the reasonability of rates based on prevailing market conditions and the impact of reduction in duties

	and taxes etc. The delivery period for the aforesaid ordered quantity shall be scheduled after the completion of the delivery of the original tendered quantity or on mutual consent between the supplier and CMSS. **6.6 - Deleted.** **6.7 Warranty/ Guarantee** The following warranty/ Guarantee clause shall apply: 1) the contractor hereby covenants that it is a condition of the contract that all Goods supplied to the Procuring Entity under this contract shall comply to technical specification, free of all defects and faults arising from design, materials or workmanship or from any act or omission of the contractor, that may develop under the conditions prevailing in India. 2) the contractor also guarantees that the said Goods would continue to conform to the description and quality as aforesaid, throughout the specified shelf life as stipulated in the contract. 3) Obligations of the contractor under the warranty clause shall survive even though: a) The Goods may have been inspected, accepted, and paid for by the Procuring Entity. b) The contract is terminated for any reason whatsoever. 4) The Procuring Entity shall promptly notify in writing to the contractor, if during the period above, the said goods/ stores/ articles are discovered not to conform to the description and quality or have deteriorated. The decision of the Procuring Entity in that behalf being final and conclusive. If the said goods/ stores/ articles are declared not to conform to the description and quality or have deteriorated during its shelf life in any particular batch/different batches at any of the consignee location, such cases shall be treated as localised failure of the goods supplied and the entire quantity of the batch (Consumed as well as not consumed) supplied to that particular location shall stand rejected. However, if the aforesaid deterioration in quality is observed in same/ different batches at more than one locations, such cases shall be treated as widespread failure of the goods supplied and the entire quantity of the batch (Consumed as well as not consumed) supplied under the contract at all the locations shall stand rejected.

	If any sample is declared as not to conform to the description or "Not of Standard Quality such batch/ batches will be deemed to be rejected goods and notice through Return Orders shall be issued to Contractor. 5) Upon receipt of such notice, the contractor shall, within 03 working days acknowledge the receipt of such notices and its commitment to expeditiously, but not later within 60 days from the date of receipt of such notice, replace the defective Goods free of cost, at the Consignee destination. The Contractor shall take over the replaced parts/ Goods after providing their replacements, and no claim shall lie on the Procuring Entity for such replaced parts/ Goods after that. 6) If the contractor, having been notified, fails to replace the defect(s) within the aforesaid period of 60 days it shall amount to breach of Contract for default under GCC-clause 12.1, and the Procuring Entity shall avail any or all remedial action(s) thereunder. 7) The warranty shall apply to replacement batches also. **6.8 – Deleted**
7. Inspection and Quality Assurance	**7.1 QUALITY CONTROL** 1) Quality Control is an essential part of the current procurement and it is the responsibility of the supplier to ensure the products conform to the standards as specified in 'Technical Specification and Quality Assurance' under Section VI of the Tender Document during its entire shelf life. 2) The bidder/ supplier understand that the tendered item/items is/are critical health goods and the quality parameters of supplied goods are to be ensured during complete specified shelf life as indicated in technical specification/bid document/ official compendium. Bidder/Supplier also appreciate that failure in quality checks is serious default as it may derail entire programme and can also risk the life of users of supplied health goods. 3) Purchaser will embark on stringent quality checks to ensure that tendered goods meet required standards throughout specified shelf life. For this purpose, Purchaser reserves the right to carry necessary inspections/tests at any of, or any combination of or/ all of following stages: a) Pre-dispatch inspection

	b) Delivery Stage Inspection c) Post-Delivery Surveillance 4) The goods supplied under the contract shall be subjected to PDI/ Delivery Stage Inspection/ "Accepted without PDI and Delivery Stage Inspection", as indicated in SCC. This is however without prejudice to the Purchaser's right to alter Inspection at any stage for whole/ part of the supplies. The purchaser's decision in this regard shall be final. **Pre-dispatch inspection** 5) Pre-dispatch inspection (PDI) for passing the quality of the goods, would be done before direct shipment to the consignees from supplier manufacturing premises. If the contract stipulates pre-dispatch inspection, the supplier after completion of manufacturing process, should offer goods for PDI inspection in writing to Quality Assurance Department of the Purchaser at least 10 days before proposed inspection date, which in turn shall inform the contractor in writing of its programme for such inspection and the officials' identity to be deputed for this purpose. The samples of each batch 3 sets (Testing, Control and Reserve) will be collected and Testing sample shall be sent to designated laboratories (Government/ Private Drugs Testing Laboratories) for testing as decided by the Purchaser. Sample quantities will be borne by the supplier. However, handling and testing charges will be borne by the Purchaser. After satisfactory quality report of testing lab, dispatch clearance shall be given to supplier by Quality Assurance Department of Purchaser. Only after getting dispatch clearance, supplier will deliver the items to the consignees as per the schedule mentioned in the Purchase Order. If the supplier delivers/dispatches goods without complying with aforesaid Quality Assurance and dispatch clearance process, The Purchaser shall not accept such supplies and will not process the bills for payments of such goods. The supplier will be solemnly responsible for any of its actions. 6) In the event of the samples of Drugs/goods supplied fails in quality tests/ found "Not of Standard Quality" (NSQ), and the supplier disputes the rejection of goods, the control samples collected during PDI shall be sent to designated laboratories (Government/ Private Drugs Testing Laboratories) for testing as decided by the Purchaser. If, the control samples also fail in quality tests/ found "Not of Standard Quality", purchaser shall take actions against the supplier as per provisions of the contract

	including cancellation of contract, forfeiture of PBG and blacklisting/debarment of the supplier for the quoted product for a specific period. 7) In the event of the samples of Drugs/goods supplied fails in quality tests/ found "Not of Standard Quality" (NSQ), and the supplier does not dispute rejection of samples as detailed in sub para above, the purchaser at its discretion may give one more opportunity to the supplier to offer a fresh batch for pre-dispatch inspection. If, the batch so offered also fails in quality tests/ found "Not of Standard Quality", the purchaser shall take actions against the supplier as per provisions of the contract including cancellation of contract, forfeiture of PBG and blacklisting/debarment of the supplier of the supplier for the quoted product for a specific period. **Delivery Stage Inspection** 8) Delivery stage inspection is done after the goods reach at consignee location. If the contract stipulates inspection at delivery stage, the supplier will deliver/dispatch the manufactured items (as per the technical specifications) to consignee's location. The samples will be collected from the consignee's location and sent to designate Quality Control Labs, as decided by Purchaser. Sample quantities will be borne by Purchaser. Also, handling and testing charges will be borne by Purchaser. The supplies will be deemed to be completed only upon receipt of the quality certificates from the laboratories. "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be deemed to be rejected goods. 9) If the said goods/ stores/ articles are declared not to conform to the description or Not of Standard quality after analysis at CMSS empaneled Lab and the entire quantity of the batch supplied shall stand rejected. Upon receipt of such rejection notice, the contractor shall, within 03 working days acknowledge it and confirm its commitment to expeditiously, but not later within 60 days from the date of receipt of such notice, to replace the defective Goods free of cost, at the ultimate destination, failing which supplier will be liable for punitive actions as per tender terms and conditions. Notwithstanding above, the LD will be applicable as per original scheduled delivery.

10) In case, a batch is declared 'of standard Quality' from one location and from other location it is declared as 'not of standard quality', then complete batch shall be declared as NSQ for all locations.

Post-Delivery Surveillance

11) Notwithstanding pre-dispatch/ delivery stage inspection, purchaser shall also carry out Post Delivery Surveillance/ Quality Monitoring Activities to ensure that the supplied Drugs/goods have the active ingredients and all other parameters at the prescribed level as indicated in official compendiums or technical specifications throughout the shelf-life period of the drugs/ goods. Samples, which do not meet quality requirement/specifications, shall render the relevant batches liable to be rejected and procedure of handling post surveillance complaint is as per Warranty clause defined above at GCC 6.7.

Consequence of Rejection

12) In the event of the samples of Drugs/goods supplied fails in quality tests or found to be not as per specifications at any of stage mentioned above, depending upon the type, nature and seriousness of failure, consequences resulting from such default, availability of alternate sources, the Purchaser is at liberty to either:

a) Short Close the Purchase Order for entire quantity of batch (localized/ widespread, as the case may be), which failed in quality test and recover the cost of entire batch paid for (whether consumed fully/ partially).
   or
b) Ask the supplier to replace the entire quantity of relevant batches (localized/ widespread, as the case may be), under its warranty obligation.
   or
c) To make alternative purchase of the items of Drugs from other approved suppliers or in the open market or from any other Tenderer who might have quoted higher rates, at the risk and the cost of the supplier.
d) In addition to above, action to debar/blacklist the supplier for suitable period, as decided by Purchaser may also be

	initiated. In addition to forfeiture of Performance Security Deposit. e) In addition, the FDA/ Drugs Control Authority of concerned State will be informed for initiating necessary action on the Tenderer in their state. f) The decision of the Purchaser or any officer authorized by Purchaser, as to the quality of the supplied drugs, medicines, vaccines etc., shall be final and binding. 13) In case, supplier is asked to make replacement of rejected batches and if replaced batch is also found "NOT OF STANDARD QUALITY", the supplier shall be blacklisted for the product and no further supplies shall be accepted for the particular product category. In addition, the licensing authority will be informed for initiating necessary action on the supplier in their state. The performance security will also be forfeited. The decision of Purchaser, as to the quality of the supplied goods shall be final and binding. 14) If the product is non-Pharmacopeial then the supplier must provide the in-house test method along with the required reference standards if asked for. The Master Formula (BMR) of the products shall be provided whenever asked for. 15) The Purchaser may engage the services of a Quality Control Agent & Quality Control Testing Laboratories for the purpose of Inspection & Quality Control. In case of failure of batches during or at any stage, the testing charges of all samples (testing/control/reserve/field samples) would be claimed from the defaulting vendor. 16) Upon the Goods being rejected by the Testing lab and Inspecting Officer or Interim Consignee or Consignee at a place other than the premises of the contractor, the Procuring Entity shall be at liberty to: a) Demand that such stores shall be removed by the contractor at his cost subject as hereinafter stipulated, within 60 days of the date of intimation of such rejection. Provided that the Inspecting Officer may call upon the contractor to remove dangerous, infected, or perishable stores within 48 hours of the receipt of such communication and the decision of the Inspecting Officer in this regard shall be final in all respects. Provided further that where the price or part thereof has been paid, the consignee is entitled without prejudice to his other rights to retain the rejected stores till the price paid for such

	stores is refunded by the contractor or dispose off such rejected Goods as per clause below save that such retention shall not in any circumstances be deemed to be acceptance of the stores or waiver of rejection thereon. The Contractor shall bear all cost of such replacement, including testing, taxes and freight, if any, on replacing and replacing Goods without being entitled to any extra payment on that or any other account. b) All rejected Goods shall, in any event, and circumstances remain and always be at the contractor's risk immediately on such rejection. If the contractor does not remove such Goods within the periods aforementioned, the Procuring entity /inspecting officer, as the case may be as per the place of rejection, may remove the rejected Goods. The Procuring Entity or Inspecting Officer may either return the same to the contractor at his risk and cost by such mode of transport as it may decide or dispose off such Goods at the contractor's risk and on his account and retain such portion of the proceeds from such disposal, as may be necessary to recover any expense incurred in connection with such disposals (or any price refundable as a consequence of such rejection). The Procuring Entity shall, in addition, be entitled to recover from the contractor ground rent/ demurrage charges on the rejected Goods after the expiry of the time-limit mentioned above. c) Disposal of rejected goods in an aforesaid manner shall not exonerate contractor but still hold him liable to pay to the procuring entity, the dues as may arise as per the terms of contract besides the cost of goods if already paid to the contractor and any inspection charges. The Purchaser can take action as per contract terms if the contractor fails to pay the amount due to him. d) Deleted. **7.2 Inspections at the last moment** 1) If the contract stipulates pre-dispatch inspection of the ordered Goods at Contractors premises, he shall put up the Goods for inspection well ahead of the delivery period to complete the inspection within that period. After completion of manufacturing process, the supplier should offer goods for PDI inspection in writing to Quality Assurance department of CMSS at least 10 days before proposed inspection date. 2) In cases where only a portion of the Goods ordered is tendered for inspection at the last moments of the delivery period and also

	in cases where inspection is not completed in respect of the portion of the Goods tendered for inspection during the delivery period, the inspector shall carry out the inspection and complete the formality beyond the contractual delivery period at the specific written request by and at the risk and expense of the contractor. The fact that the Goods have been inspected after the contractual delivery period shall not amount to keeping the contract alive, and this shall be without any prejudice to the legal rights and remedies available to the Procuring Entity under the terms & conditions of the contract. 3) If the Goods tendered for inspection during or at the last moments of the delivery period are not found acceptable after carrying out the inspection, the Procuring Entity is entitled to cancel the contract in respect of the same at the risk and expense of the contractor. If the Goods tendered for inspection are found acceptable, the Procuring Entity may grant an extension of the delivery period subject to conditions mentioned in GCC-clause 9.11 below. **7.3 Consignee's right of Rejection of Inspected Goods** 1) Goods accepted by the Procuring Entity and/ or its inspector at the initial inspection and final inspection in terms of the contract shall in no way dilute the Procuring Entity's right to reject the same later if found deficient concerning 'Technical Specifications and Quality Assurance'. 2) Deleted. **7.4 Handling of quality complaints** **1)** In case of quality complaints at any stage during its shelf life, purchaser shall investigate the nature of complaint by collecting field samples and its discretion test the samples so collected at any Govt. Lab/ purchasers approved lab, if considered necessary. On evaluation, if it is established that the samples are not of standard quality, the same may be rejected and supplier shall be asked to give replacement supplies as prescribed in the preceding paragraphs. **2)** In case manufacturer raises objection/disputes purchaser's decision, the control samples collected during PDI/ delivery stage inspection shall be tested at any Govt. Lab/ purchasers approved lab. The findings of the control sample shall be binding on both the parties. **3)** Purchaser at its discretion may also test control sample at any stage of investigation of complaint/ as part of post-delivery surveillance.

	4) In case replacement supplies are not completed within the stipulated period, liquidated damages as per GCC-9.12 shall be levied for delayed supplies beyond the stipulated period.
8. Packing, Transportation, Insurance and Receipt	**8.1 Packing Specifications and Quality** 1) The marking of the Goods must comply with the Goods of the laws relating to merchandise marks for the time being in force in India. 2) The packing for the Goods to be provided by the contractor should be strong and durable enough to withstand, without limitation, the entire journey during transit, including transshipment (if any), rough handling, open storage etc., without any damage, deterioration etc. If necessary, the size, weights, and volumes of the packing cases, the remoteness of the goods' final destination, and availability or otherwise of transport and handling facilities at all points during transit up to the final destination shall also be considered. 3) The packaging unit should be strong, able to be stacked to a height of 4 pallets as static storage and 2 pallets during transport, and resistant to puncturing. Special attention of suppliers is invited to ensure the material is of good quality and is free from development of fungus/termites. In case fungus/termites develops within 15 days of delivery at specified locations, suppliers at their own cost would lift the entire batch from various locations and supply fresh replaced batches. For LD purposes the date of receipt of replaced batches would count. In addition, the expenses on pest control to be undertaken by CMSS would be borne by the tenderer. 4) The quality of packing, the manner of marking within & outside the packages, and accompanying documentation shall strictly comply with the `Technical Specification and Quality Assurance' and in the contract. If the packing requirements are amended due to any amendment to the contract, the contractor shall comply accordingly. 5) Unless otherwise provided in the contract, all containers (including packing cases, boxes, tins, drums, and wrappings) in which the contractor supplies the Goods shall be considered non-returnable and their cost included in the contract price. **8.2 Packing instructions** The suppliers are required to supply the product(s) with printed text "GOVERNMENT OF INDIA SUPPLIES – NOT FOR SALE" (Unless otherwise indicated differently in SCC) in red-colour on the

strips, blisters, vials, ampoules & bottles and also on the external packings. The type/thickness of packing materials used in Blister packs may also be specified. Goods received without this print will not be accepted by Consignee. Affixing of rubber stamp shall not be accepted. However, the approved art work will prevail.

Unless otherwise mentioned in the `Technical Specification and Quality Assurance' under Sections VI and SCC under Section VII, the contractor shall make separate packages for each consignee (in case there is more than one consignee mentioned in the contract) and mark each package on three sides with the following with indelible paint of proper quality:

1) An iconic graphical mark to visually identify a particular consignment.
2) Name of the Procuring Entity; contract number and date
3) brief description of Goods including quantity.
4) the gross weight of the package
5) Serial number of this package and the total number of packages in the consignment
6) packing list reference number
7) country of origin of goods
8) consignee's name and full address and
9) Contractor's name and address

8.3 Transfer of Title of Goods

1) Unless otherwise stated in the contract, notwithstanding any inspection and approval by the Inspecting Officer on the contractor's premises, or any payments made to the contractor, property in the Goods (and resultant rights and liabilities) shall not pass on to the Procuring Entity until the Goods have been received, inspected, and accepted by the consignee. The Goods and every constituent part thereof, whether in the possession or control of the contractor, his agents or servants or a carrier, or the joint possession of the contractor, his agents or servants and the Procuring Entity, his agents, or servants, shall remain in every respect at the risk of the contractor, until their actual delivery to a person stipulated in the contract as the interim consignee for dispatch to the consignee. The Contractor shall be responsible for all loss, destruction, damage, or deterioration of or to the Goods from any cause whatsoever while the Goods after approval by the Inspecting Officer are awaiting dispatch or delivery or are in the

course of transit from the contractor to the consignee. The Contractor shall alone be entitled and responsible for making claims against any carrier in respect of non-delivery, short delivery, mis-delivery, loss, destruction, damage, or deterioration of the Goods entrusted to such carrier by the contractor for transmission to the consignee or the interim consignee as the case may be.

2) Provided that where, under the terms of the contract, the Goods are required to be delivered to an interim consignee for dispatch to the consignee, the Goods shall be at the Procuring Entity's risk after their delivery to the interim consignee.

8.4 Transportation

The contractor shall be responsible for free delivery of consignment at consignees place. Accordingly, the contractor shall arrange transportation, insurance etc. of the ordered Goods as per its procedure.

8.4.1 Distribution of Dispatch Documents for Clearance/ Receipt of Goods

1) Supplier will integrate with e- aushadhi system of CMSS and Supplier Interface Module in which supplier shall be required to enter/upload batch no, qty, mfg & expiry date, tranche no, invoice/challan copy etc. against PO no. Suppliers are requested to submit their Original Invoice along with copies of Lorry Receipt/ Deliver challans and original Consignee Receipt Certificate (CRC) duly signed & stamped with other necessary documents for smooth processing of payment.

2) The contractor shall notify the Procuring Entity, consignee, and others concerned, if mentioned in the contract, the complete details of dispatch and also supply the following documents (as relevant) to them by registered post/ speed post/ courier besides advance intimation by digital means (or as instructed in the contract or SCC):

Required Documents from Supplier for Material Acceptance at Consignee		
S. No.	**Description**	**Remark**
1	LR Copy (Lorry receipt copy)	Transporter's copy (Builty) of delivery of consignment

	2	Invoice copy of material	To be provided by the supplier having the following details: 1. Invoice Number 2. Invoice Date 3. Item Name 4. PO. No. and Date 5. Tranche No. 6. Quantity 7. Batch Number 8. Date of Manufacturing 9. Date of Expiry
	3	Packing list of inward material	To be provided by the supplier having the following details: 1. Total Number of Intact Boxes/ Cartons 2. Quantity per Box 3. No. of Loose Box (if any) 4. Quantity in Loose Box
	4	Certificate of Analysis (COA in case of Drugs)	To be provided by the supplier with the details of Inhouse Quality Test Report with date of Test. The COA contains the following: a) Manufacturer's Name b) Manufacturing Site Address c) Generic name of the product d) Date of Analysis e) Batch No. f) Pharmacopeial Reference and/ or In-house method g) Date of manufacture h) Expiry date i) All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharmacopoeia and/or In-house method. Both the actual results

			and the limits for the individual tests should be given j) Conclusion k) Authorized signatures
	5.	Performance Evaluation Report (In case of Devices)	To be provided by the supplier with the details of Inhouse Quality Test Report with date of Test. The Performance Evaluation Report shall include: a) Manufacturer's Name b) Manufacturing Site Address c) Product name d) Date of Analysis e) Lot/Batch Number f) Date of manufacture g) Date of Expiry h) Testing principle i) Information about reference used j) Testing Procedure-Sensitivity, Specificity etc k) Results l) report number m)Date of Analysis n) Designation and signature of analyst o) Authorized signatory of lab
	5.	E way Bill	To be provided by the supplier, the copy of the E way Bill
	6.	Any other document(s), as and if mentioned explicitly in the contract.	

3) The contractor shall send all the relevant dispatch documents well in time to the Procuring Entity to enable it to clear or receive (as the case may be) the Goods in terms of the contract. 8.5 – Deleted.

8.6 – Deleted.

8.7 Receipt of Consignment

	8.7.1 Preliminary Acknowledgement At the time of the delivery at the destination, the consignee shall receive the Goods on a "subject to inspection and acceptance in terms of contract" basis and shall issue the preliminary receipt to acknowledge having received the claimed quantity (not the quality) of consignment. **8.7.2 Goods Receipt Note (GRN)/Consignee Receipt Certificate (CRC)** If the received consignment successfully passes the quantity and quality checks, procuring Entity shall issue a Goods Receipt Note/Consignee Receipt Certificate (GRN/CRC, or a similar voucher by any other name). The contractor may claim payment based on this document inter-alia other specified documents. **8.7.3 Rejection of Consignment by the Consignee** If the received consignment or part thereof fails to pass quantity and quality checks, the Procuring Entity shall issue a GRN/CRC only for the accepted quantity. **8.7.4 Short Receipt Certificate** If the quantity received is less than claimed/ invoiced, GRN/Rejection Note shall be issued only for the received quantity. **8.7.5 Perishable Goods** For Goods with a limited shelf life, the contractor shall ensure that at least $5/6^{th}$ (or any other period/criteria stipulated in the SCC) of shelf-life remains balance on delivery date. The Procuring Entity reserves rights to reject expired or products with less than such specified shelf life.
9. Terms of Delivery and delays	**9.1 Effective Date of Contract** The effective date of the contract shall be the date on which letter of award (LOA) has been issued by the Procuring Entity. The dates of deliveries shall be counted from such date. No notice to commence the contract shall be issued separately. **9.2 Time is the essence of the contract** The time for and the date for delivering the Goods stipulated in the contract or as extended shall be deemed to be of the essence of the contract. Delivery must be completed not later than the date(s) so specified or extended. **9.3 Destination Places** The destination(s) where the Goods are to be delivered shall be as

	stipulated in the contract or Section V – Schedule of Requirements. **9.4 Terms of Delivery** 1) Terms of delivery is DDP Consignee site unless otherwise stipulated differently in Section V – Schedule of Requirements. Accordingly, the contractor shall arrange transportation, insurance etc. of the ordered Goods as per its own procedure. 2) The delivery shall not be complete unless the Goods are inspected and accepted by the Consignee as provided in the contract. No Goods shall be deliverable to the consignee on Sundays and public holidays or outside designated working hours without the written permission of the consignee. 3) the contractor shall not deliver the Goods after the expiry of the delivery period. The Contractor must apply to the Procuring Entity to extend the delivery period and obtain the same before dispatch. If the contractor dispatches the Goods without obtaining an extension, it would be doing so at its own risk, and no claim for payment for such supply and/ or any other expense related to such supply shall lie against the Procuring Entity. **9.5 – Deleted.** **9.6 Progressing of Deliveries** The Contractor shall allow reasonable facilities and free access to his Works/ records to the Inspecting Officer or such other Officer as may be nominated by the Procuring Entity to ascertain the progress of the deliveries under the contract. The Contractor shall, from time-to-time, render such reports concerning the progress of the contract and/ or supply of the Goods in such form as may be required by the Procuring Entity. The submission, receipt and acceptance of such reports shall not prejudice the rights of the Procuring Entity under the contract, nor shall operate as an estoppel against the Procuring Entity merely because he has not taken notice of/ or subjected to test any information contained in such report. **9.7 Notification of Delivery.** Notification of delivery or dispatch regarding every installment shall be made to the consignee and to the Procuring Entity immediately on dispatch or delivery. The Contractor shall further supply to the consignee, packing list of the consignment and the contract references. All packages, containers, bundles, and loose materials part of every installment shall be fully described in the packing list, and complete details of the contents of the packages and quantity of materials shall be given to enable the consignee to check the Goods on arrival at

	destination. **9.8 Dispatches at the last moment or after the expiry of the delivery** 1) If the contractor supplies a consignment after the expiry of the contracted delivery date, the Consignee may either refuse to receive it or receive it without prejudice to the rights of the Procuring Entity under the terms and conditions of the contract. Such consignments shall lie at the risk and responsibility of the contractor. Such a receipt by the consignee shall not acquiesce or condone the late delivery and shall not intend or amount to an extension of the delivery period or keeping the contract alive. The Contractor must obtain an extension of the delivery date/period from the Procuring Entity. 2) Deleted. 3) Deleted. **9.9 Delay in the contractor's performance** If the contractor fails to deliver the Goods or any instalment thereof or delays incidental Work/ Services within the period fixed for such delivery in the contract or as extended or at any time repudiates the contract before the expiry of such period, the Procuring Entity may without prejudice to his other rights: 1) recover from the contractor liquidated damages as per clause 9.12 below, or 2) treat the delay as a breach of contract as per clause 12.1 below and avail all the remedies therein. **9.10– Deleted.** **9.11 Extension of Delivery Period:** 1) If at any time during the currency of the contract, the contractor encounters conditions hindering timely delivery of the Goods and performance of incidental Works/ Services, he shall promptly inform the Procuring Entity in writing about the same and its likely duration. He must make a request to the Procuring Entity for an extension of the delivery schedule. On receiving the contractor's communication, the Procuring Entity shall examine the situation and, at its discretion, may agree to extend the delivery schedule, with or without liquidated damages and with and without denial clause by issuing an amendment to the contract. 2) **Conditions for Extension of Delivery Period:** When the period of delivery is extended due to unexcused delay by the contractor,

	the amendment extending the delivery period shall, inter alia, be subject to the following conditions: **a) Liquidated Damages:** The Procuring Entity shall recover from the contractor, under the provisions of this clause, liquidated damages on the Goods and incidental Works/ Services, which the contractor has failed to deliver within the delivery period stipulated in the contract. **b) Denial Clause:** i. No increases in price on account of any statutory increase in or fresh Imposition of GST, customs duty or on account of any other taxes/ duty/ cess/ levy), leviable in respect of the Goods and incidental Works/ Services stipulated in the said contract which takes place after the original delivery date, shall be admissible on such of the said Goods, as are delivered after the said date; and ii. Notwithstanding any stipulation in the contract for an increase in price on any other ground, including price variation clause or foreign exchange rate variation, or any other variation clause, no such increase after the original delivery date shall be admissible on such goods delivered after the said date. iii. Nevertheless, the Procuring Entity shall be entitled to the benefit of any decrease in price on account of reduction in or remission of GST, customs duty or on account of any other Tax or duty or any other ground as stipulated in the price variation clause or foreign exchange rate variation or any other variation clause which takes place after the expiry of the original delivery date. **9.12Liquidated damages** 1) Subject to GCC clause 9.11, if the contractor fails to deliver any or all of the Goods or fails to perform the incidental Works/ Services within the time frame(s) incorporated in the contract, the Procuring Entity shall, without prejudice to other rights and remedies available to the Procuring Entity under the contract, deduct from the contract price, as agreed liquidated damages, but not as a penalty, a sum equivalent to the ½ % (half percent) of the delivered price (including elements of GST & freight) of the delayed Goods and/ or incidental Works/ Services for each week of delay to be applied proportionately on per day basis for first four weeks of delay. For subsequent delays, a sum equivalent to 2.5% (two and half percent), instead of 0.5%, for each week of delay to be applied proportionately on per day basis of delivered price shall be deducted as liquidated damages. The maximum deduction on account of LD shall not exceed 10% of the delayed goods or incidental works/service

	contract price(s). Besides liquidated damages during such a delay, the denial clause as per GCC-clause 9.11-2(b) shall also apply. 2) Deleted. **9.13 Force Majeure** 1) On the occurrence of any unforeseen event, beyond the control of either Party, directly interfering with the delivery of Services arising during the currency of the contract, such as war, hostilities, acts of the public enemy, civil commotion, sabotage, fires, floods, explosions, epidemics, quarantine restrictions, strikes, lockouts, or acts of God, the affected Party shall, within a week from the commencement thereof, notify the same in writing to the other Party with reasonable evidence thereof. Unless otherwise directed by the Procuring Entity in writing, the contractor shall continue to perform its obligations under the contract as far as reasonably practicable and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event. If the force majeure condition(s) mentioned above be in force for 90 days or more at any time, either party shall have the option to terminate the contract on expiry of 90 days of commencement of such force majeure by giving 14 days' notice to the other party in writing. In case of such termination, no damages shall be claimed by either party against the other, save and except those which had occurred under any other clause of this contract before such termination. 2) Notwithstanding the remedial provisions contained in GCC-clause 9.12 or 12.1, none of the Party shall seek any such remedies or damages for the delay and/ or failure of the other Party in fulfilling its obligations under the contract if it is the result of an event of Force Majeure.
10 Prices and Payments	**10.1 Prices** **10.1.1Charged Prices** Prices to be charged by the contractor for the supply of Goods and provision of incidental Works/ Services in terms of the contract shall not vary from the corresponding prices quoted by the contractor in its bid or during negotiations, if any, and incorporated in the contract except for any price adjustment authorized in the contract. **10.1.2 Controlled Prices** 1) The price charged by the contractor shall not be higher than the controlled price fixed by law for the Goods, or where there is no controlled price, it shall not exceed the minimum of Maximum

	Retail Price (MRP) at which the same or similar Goods are available in the market in the relevant region, or contravene the norms for fixation of prices laid down by Government, or where the Government has not fixed such prices or norms, it shall not exceed the price appearing in any agreement relating to price regulation by any industry in consultation with the Government. 2) **Penalties for overcharging:** If the sub-clause above is violated, unless the contractor had explicitly mentioned this fact in his bid giving reasons for quoting a higher price (s), or makes any mis-statement, it shall be lawful for the Procuring Entity to: a) annul the award and treat it as a misdemeanour as per the contract and take any or all punitive remedies available thereunder, or b) without annulling the award, take action as per GCC-clause 10.4 to recover the overcharged amount, or c) treat it as a breach of contract as per GCC-Clause 12.1 and avail any or all remedies thereunder. **10.1.3– Deleted.** **10.1.4 Firm Prices** Prices stipulated in the contract shall be fixed and firm. **10.1.5– Deleted.** **10.1.6 Fall Clause** 1) The price charged for the Goods supplied under the contract by the contractor shall in no event exceed the lowest price at which the contractor sells the Goods or offers to sell Goods of identical description, to any persons/ organizations including the Procuring Entity or any Department or Undertaking of the Central Government, as the case may be during the currency of the contract. Contractor shall forthwith notify such reduction or sale or offer of sale to the Procuring Entity and the price payable under the contract for the Goods supplied after the date of coming into force or such reduction or sale or offer of sale shall stand correspondingly reduced. 2) The above stipulation shall, however, not apply to: a) Exports by the contractor b) Sale of Goods as original equipment at prices lower than the prices charged for normal replacement c) Sale of perishable Goods having a limited shelf life, such as drugs that have expiry dates

3) the contractor shall furnish the following certificate to the concerned Accounts Officer with each bill for payment of supplies made against the contract.

"We certify that there has been no reduction in the sale price of the Goods of description identical to the Goods supplied to the Procuring Entity under the contract herein, and such Goods have not been offered/ sold by me/ us to any person/ organisation including any Ministry/ Department/ Attached and Subordinate Office/ Public Sector Undertaking of Central or State Government(s) as the case may be upto the date of bill/ the date of completion of Contract at a price lower than the price charged under this contract except for the quantity of Goods categories under (a), (b) and (c) of sub-clause (2) above, details of which are as follows:-"

10.1.7 Compliance with PPP-MI Order

In accordance with provision of Para 9 (c) of PPPMII order dated 19.07.2024, for all contracts above INR 10 Crores, the contractor shall provide local contract certificate from practicing Chartered / Cost Accountant with last bill of each tranche. In case the contractor/ supplier does not meet the stipulated local content requirement and the category of the supplier changes from Class-I to Class-II / Non local or from Class-II to Non-local, a penalty up to 10% of the contract value shall be imposed. However, contract once awarded shall not be terminated on this account.

10.2 Taxes and Duties

1) the contractor shall be entirely responsible for all taxes, duties, fees, levies etc., incurred until delivery of the Goods to the Procuring Entity.
2) If applicable under relevant tax laws and rules, the Procuring Entity shall deduct from all payments and deposit required taxes to respective authorities on account of GST Reverse Charge Mechanism; Tax Deducted at Source (TDS), and Tax Collected at Source (TCS) relating to Income Tax, labour cess, royalty etc.
3) **Payment of GST Tax under the contract:**
    a) The payment of GST and GST Cess to the contractor shall be made only on the latter submitting a GST compliant Bill/ invoice indicating the appropriate HSN code and applicable GST rate thereon duly supported with

	documentary evidence as per the provision of relevant GST Act and the Rules made there under. The delivery shall be shown being made in the name, location/ state, and GSTIN of the consignee only; the location of the procurement office of the procuring entity has no bearing on the invoicing. b) The supply of Goods or services or both, if imported into India, shall be considered as supply under inter-state commerce/ trade and shall attract integrated tax (IGST). The IGST rate and GST cess shall be applicable on the 'Custom Assessable Value' plus the 'Basic Customs duty applicable thereon'. c) While claiming reimbursement of duties, taxes etc. (like GST) from the Procuring Entity, as and if permitted under the contract, the contractor shall also certify that in case it gets any refund out of such taxes and duties from the concerned authorities at a later date, it (the contractor) shall refund to the Procuring Entity, the Procuring Entity's share out of such refund received by the contractor. The Contractor shall also refund the appropriate amount to the Procuring Entity immediately on receiving the same from the concerned authorities. d) All necessary adjustment vouchers such as Credit Notes/ Debit Notes for any short/ excess supplies or revision in prices or any other reason under the contract shall be submitted to the Procuring Entity in compliance with GST provisions. e) In case of Price Variation or Exchange Rate variation, or any other variation is applicable, GST shall be applicable on the net invoice value after the variation is taken into account. f) GST shall be paid as per the rate at which it is liable to be assessed or has been assessed provided the transaction of the sale is legally liable to such taxes and is payable as per the terms of the contract subject to the following conditions: i. The Procuring Entity shall not pay a higher GST rate if leviable due to any misclassification of HSN number or incorrect GST rate incorporated in the contract due to contractor's fault. Wherever the contractor invoices the Goods at GST rate or HSN number, which is different from that incorporated in the contract, payment shall be made as per GST rate,

	which is lower of the GST rates incorporated in the contract or billed. ii. However, the Procuring Entity shall not be responsible for the contractor's tax payment or duty under a misapprehension of the law. iii. Bidder is informed that he shall be required to adjust his basic price to the extent required by a higher tax rate billed as per invoice to match the all-inclusive price mentioned in the contract. iv. In case of profiteering by the contractor relating to GST tax, the Procuring Entity shall treat it as a violation of the Code of Integrity in the contract and avail any or all punitive actions thereunder, in addition to recovery and action by the GST authorities under the Act. v. The contractor should issue Receipt vouchers immediately on receipt of all types of payments along with tax invoices after adjusting advance payments, if any, as per Contractual terms and GST Provisions. 4) **Statutory Variation Clause:** Unless otherwise stated in the contract, statutory increase in applicable GST rate only during the original delivery period shall be to Procuring Entity's account. Any increase in the rates of GST beyond the original completion date during the extended delivery period shall be borne by the contractor. The benefit of any reduction in GST rate must be passed on to the Procuring Entity during the original and extended delivery period. However, GST rate amendments shall be considered for quoted HSN code only, against documentary evidence, provided such an increase of GST rates after the last date of bid submission. **5) Duties/ Taxes on Raw Materials** The Procuring Entity is not liable for any claim from the contractor on account of fresh imposition and/ or increase (including statutory increase) of GST, customs duty, or other duties on raw materials and/ or components used directly in the manufacture of the contracted Goods taking place during the pendency of the contract unless such liability is expressly agreed to in terms of the contract. 6) Deleted. **10.3 Terms and Mode of Payment** **10.3.1** 1) The payments shall only be made in Indian Rupees.

	2) The contractor shall send its claim for payment in writing as per GST compliant Invoice and documents, when contractually due, along with relevant documents etc., as stipulated in Contract and a manner as also specified therein. 3) While claiming payment, the contractor is also to certify in the bill that the payment being claimed is strictly in terms of the contract and all the obligations on the part of the contractor for claiming that payment has been fulfilled as required under the contract. 4) The usual payment term is 100% on receipt of goods and its acceptance by the consignee as per provisions of the contract on submission of the following documents: a) Copy of e-invoice generated from GST Portal. b) Packing list (with Goods Description) of supplied items. c) Copy of certificate of Analysis (COA)/Performance Evaluation Report (PER) as applicable for each batch supplied. d) Proof of delivery i) Lorry receipt duly signed, stamped and dated in case of CMSS Warehouse. ii) Lorry receipt duly signed, stamped and dated along with Original Consignee Receipt Certificate (CRC) in case of Goods Delivered at Consignee's Location other than CMSS Warehouses. e) Copy of e-Way Bill. f) Warranty Certificate g) Undertaking that the payment being claimed is strictly in terms of the contract and all the obligations on the part of the contractor for claiming that payment has been fulfilled as required under the contract. h) Undertaking for Fall Clause as per GCC 10.1.6 i) Local Content Certificate as per GCC 10.1.7 j) Such other documents as indicated in SCC 5) All bills/ Invoices should be raised in duplicate and the bills should be drawn in the name of Central Medical Services Society, 2nd Floor, Vishwa Yuvak Kendra, Pandit Uma Shankar Dikshit Road, Chanakyapuri, New Delhi-110021or in the name of any

	other authority as may be designated. Supplier has to mention e-aushadhi PO No. and tranche/ lot on the invoice. 6) The CMSS shall endeavour to make payment within 75 days in respect of items requiring sterility tests and within 60 days in respect of items requiring non- sterility test from the date of submission of invoice or from the date of receipt of material, whichever is later along with all the relevant documents of tender. 7) Lot/Tranche/PO vise Part payments for supply will be considered only after completion of supply of at least 50% quantity ordered in the individual Purchase Order/Lot/Tranche PROVIDED original consignee receipts are produced and the quality pass reports of Standard Quality on samples testing are received from approved laboratories of CMSS. 8) The payment will be made either by means of Cheque or through RTGS (Real Time Gross Settlement System)/ Core Banking/ NEFT. The Contractor shall give his consent in a mandate form for receipt of payment through NEFT. In case of non-payment through EFT, or where the EFT facility is not available, payment may be released through cheque. 9) The Tenderer shall furnish the relevant details in original in Bid Forms to make the payment through RTGS/Core Banking/ NEFT. The payment will be in INR only. 10) Supplier will integrate with e- aushadhi system of CMSS and Supplier Interface Module in which selected bidders shall be required to enter/upload batch no, qty, mfg. & expiry date, tranche no, invoice/challan copy etc. against PO no. 11) No advance payments towards costs of items will be made to the Tenderer. **10.3.2 – Deleted.** **10.3.3 - Deleted** **10.3.4 – Deleted.** **10.4 Withholding and lien in respect of sums claimed:** 1) Whenever any claim or claims for payment of a sum of money arises against the contractor, out of or under the contract, the Procuring Entity shall be entitled, and it shall be lawful on his part, to withhold and also have a lien to retain such sum or sums, in whole or in part pending finalization or adjudication of any such claim from-

	a) any security or retention money, if any, deposited by the contractor. b) any sum(s) payable till now or hereafter to the contractor under the same Contract or any other contract with the Procuring Entity if the security is insufficient or if no security has been taken from the contractor. 2) Where the contractor is a partnership firm or a limited company, the Procuring Entity shall be entitled, and it shall be lawful on his part, to withhold and also have a lien to retain towards such claimed amount or amounts in whole or in part from any sum found payable to any partner/ limited company, as the case may be, whether in his capacity or otherwise. 3) It is an agreed term of the contract that the sum(s) of money so withheld or retained under the lien referred above shall be kept withheld or retained till the claim arising out of or under the contract is determined under clause GCC 11 and/ or 12. The contractor shall have no claim for interest or damages whatsoever on any account in respect of such withholding or retention under the lien referred to supra and duly notified as such to the contractor. 4) **Lien in respect of Claims in other Contracts:** Any sum of money due and payable to the contractor (including the security deposit returnable to him) under the contract may be withheld or retained by way of lien by the Procuring Entity or Government against any claim of the Procuring Entity or Government in respect of payment of a sum of money arising out of or under any other contract made by the contractor with the Procuring Entity or Government. **10.5 Payment against Time-Barred Claims** All claims against the Procuring Entity shall be legally time-barred after three years calculated from the date when the payment falls due unless the payment claim has been under correspondence. The Procuring Entity is entitled to, and it shall be lawful for it to reject such claims. **10.6 – Deleted.**
11 Resolution of disputes	**Resolution of disputes** **11.1 Disputes and Excepted Matters** All disputes and differences between the parties hereto, as to the construction or operation of this contract, or the respective rights and liabilities of the parties on any matter in question; or any other account whatsoever, but excluding the Excepted Matters (detailed below);

	arising out of or in connection with the contract, within thirty (30) days from aggrieved Party notifying the other Party of such matters; whether before or after the completion/ termination of the contract, that cannot be resolved amicably between the Procurement Officer and the contractor within thirty (30) days from aggrieved Party notifying the other Party of such matters, shall be hereinafter called the "Dispute". The aggrieved party shall give a 'Notice of Dispute' indicating the Dispute and claims citing relevant Contractual clause to the designated authority and requesting for invoking the following dispute resolution mechanisms. The Dispute shall be resolved without recourse to courts through dispute resolution mechanisms detailed subsequently, in the sequence as mentioned below, and the next mechanism shall not be invoked unless the earlier mechanism has been invoked or has failed to resolve it within the deadline mentioned therein. 1) Adjudication 2) Conciliation 3) Arbitration **11.2 Excepted Matters** Matters for which provision has been made in any Clause of the contract shall be deemed as 'excepted matters' (matters not disputable/ arbitrable), and decisions of the Procuring Entity, thereon shall be final and binding on the contractor. The 'excepted matters' shall stand expressly excluded from the purview of the sub-clauses below, including Arbitration. However, where the Procuring Entity has raised the dispute, this sub-clause shall not apply. Unless otherwise stipulated in the contract, excepted matters shall include but not limited to: 1) any controversies or claims brought by a third party for bodily injury, death, property damage or any indirect or consequential loss arising out of or in any way related to the performance of this Contract ("Third Party Claim"), including, but not limited to, a Party's right to seek contribution or indemnity from the other Party in respect of a Third-Party Claim. 2) Issues related to the pre-award tender process or conditions 3) Issues related to ambiguity in contract terms shall not be taken up after a contract has been signed. All such issues should be highlighted before the signing of the contract by the contractor. 4) Provisions incorporated in the contract, which are beyond the purview of The Procurement Entity or are in pursuance of policies of Government, including but not limited to

a) Provisions of restrictions regarding local content and Purchase Preference to Local suppliers in terms of Make in India policy of the Government
b) Provisions regarding restrictions on Entities from Countries having land-borders with India in terms of the Government's policies in this regard
c) Purchase preference policies regarding MSEs and Start-ups

11.3 Adjudication

After exhausting efforts to resolve the Dispute with the Purchasing Officer executing the contract on behalf of the Procuring Entity, the contractor shall give a 'Notice of Adjudication' specifying the matters which are in question, or subject of the dispute or difference indicating the relevant contractual clause, as also the amount of claim item-wise to Head of Procurement or any other authority mentioned in the contract (hereinafter called the "Adjudicator") for invoking resolution of the dispute through Adjudication. During his adjudication, the Adjudicator shall give adequate opportunity to the contractor to present his case. Within 60 days after receiving the representation, the Adjudicator shall make and notify decisions in writing on all matters referred to him. The parties shall not initiate, during the adjudication proceedings, any conciliation or arbitral or judicial proceedings in respect of a dispute that is the subject matter of the adjudication proceedings. If not satisfied by the decision in adjudication, or if the adjudicator fails to notify his decision within the abovementioned time-frame, the contractor may proceed to invoke the process of Conciliation as follows.

11.4 Conciliation of disputes

1) Any party may invoke Conciliation by submitting "Notice of Conciliation" to the Head of the Procuring Organization. Since conciliation is a voluntary process, within 30 days of receipt of "Notice of Conciliation", the Head of the Procuring Organization shall notify a sole Conciliator if the other party is agreeable to enter Conciliation. If the other party is not agreeable to Conciliation, the aggrieved party may invoke Arbitration.
2) The Conciliator shall proactively assist the parties to reach an amicable settlement independently and impartially within the terms of the contract, within 60 days from the date of appointment of the Conciliator.
3) If the parties reach an agreement on a dispute settlement, they shall draw up a written settlement agreement duly signed by the parties and conciliator. When the parties sign the settlement

agreement, it shall be final and binding on the parties. The dispute shall be treated as resolved on the date of such agreement.

4) The parties shall not initiate, during the conciliation proceedings, any arbitral or judicial proceedings in respect of a dispute that is the subject matter of the conciliation proceedings.

5) Termination of Conciliation: Disputes shall remain alive if the conciliation is terminated as follows:

   a) By written declaration of the conciliator, after consultation with the parties, to the effect that further efforts at conciliation are no longer justified, on the date of such declaration; or
   b) By a written declaration of any party to the conciliator to the effect that the conciliation proceedings are terminated, on the date of such declaration; or
   c) If the parties fail to reach an agreement on a settlement of the dispute, within 60 days of the appointment of Conciliator

6) On termination of Conciliation, if the dispute is still alive, the aggrieved party shall be free to invoke Arbitration.

11.5 Arbitration Agreement

11.5.1 This Agreement

1) This Arbitration Agreement (hereinafter referred to as this "Agreement") relating to this Contract (hereinafter called the "Main Agreement" for this agreement) is made under the provisions of The Arbitration and Conciliation Act, 1996 as amended from time to time and the rules thereunder (hereinafter called The Arbitration Act). This Agreement shall continue to survive termination, completion, or closure of the Main Agreement for 120 days after that.

2) Subject to aforesaid provisions, relevant clauses of the contract shall apply to the appointment of arbitrators and arbitration proceedings under this Agreement.

3) The Micro, Small and Medium Enterprises Development (MSMED) Act, 2006 provides parties to a dispute (where one of the parties is a Micro or Small Enterprise) to be referred to Micro and Small Enterprises Facilitation Council if the dispute is regarding any amount due under Section 17 of the MSMED Act, 2006. If a Micro or Small Enterprise, being a party to dispute,

refers to the provisions in MSMED Act 2006, these provisions shall prevail over this Agreement.

11.5.2 Notice for Arbitration

1) **Authority to Appoint Arbitrator(s)**: For this Arbitration Agreement 'The Appointing Authority', to appoint the arbitrator shall be Head of the Procuring Organization named in the contract and includes if there be no such authority, the officer who is for the time being discharging the functions of that authority, whether in addition to other functions or otherwise.

2) In the event of any dispute as per GCC-clause 11.1 above, if the Adjudicator fails to decide within 60 days (as referred in 11.3 above), or the Conciliation is terminated (as referred in sub-clause 11.4 above) then, parties to the contract, after 60 days but within 120 days of 'Notice of Dispute" (clause 11.1 above) shall request the Appointing Authority through a "Notice for Arbitration" in writing requesting that the dispute or difference be referred to arbitration.

3) The "Notice for arbitration" shall specify the matters in question or subject of the dispute or difference indicating the relevant contractual clause, as well as the amount of claim item-wise.

11.5.3 Reference to Arbitration

After appointing Arbitrator(s), the Appointing Authority shall refer the Dispute to them. Only such dispute or difference shall be referred to arbitration regarding which the demand has been made, together with counter-claims or set off. Other matters shall be beyond the jurisdiction of Arbitrator(s)

11.5.4 Appointment of Arbitrator

1) Qualification of Arbitrators:

a) In the case of retired officers of The Procuring organisation, he shall have retired in the rank of senior administrative grade (or equivalent) and shall have retired at least 1 year prior and must not be over 70 years of age on the date of Notice for arbitration.

b) He/ they shall not have had an opportunity to deal with the matters to which the contract relates or who, in the course of his/ their duties as officers of the Procuring Organisation, expressed views on any or all of the matters under dispute or differences. A certification to this effect (as per Format 1.4) shall be taken from Arbitrators. The proceedings of the Arbitral tribunal or the award made by

such Tribunal shall, however, not be invalid merely for the reason that one or more arbitrators had in the course of his service, an opportunity to deal with the matters to which the contract relates or who in the course of his/ their duties expressed views on all or any of the matters under dispute.

c) An Arbitrator may be appointed notwithstanding the total no. of arbitration cases in which he has been appointed in the past.

d) Not be other than the person appointed by The Appointing Authority and that if for any reason that is not possible, the matter shall not be referred to arbitration at all.

2) Replacement of Arbitrators

If one or more of the arbitrators appointed as above refuses to act as arbitrator, withdraws from his office as arbitrator, or in the event of the arbitrator dying, neglecting/ unable or unwilling or refusing to act for any reason, or his award being set aside by the court for any reason, or in the opinion of The Appointing Authority fails to act without undue delay, the Appointing Authority shall appoint new arbitrator/ arbitrators to act in his/ their place in the same manner in which the earlier arbitrator/ arbitrators had been appointed. Such a re-constituted Tribunal may, at its discretion, proceed with the reference from the stage at which it was left by the previous arbitrator (s).

3) Appointment of Arbitrator:

a) In cases where the total value of all claims in question added together does not exceed Rs 50,00,000/ - (Rupees Fifty Lakh only), the Arbitral Tribunal shall consist of sole Arbitrator. For this purpose, The Appointing Authority shall send to the contractor, within 60 days from the day of receipt of a written and valid notice for arbitration, a panel of at least four (4) names of retired officers, duly indicating their retirement dates.

b) The contractor shall be asked to nominate at least two names out of the panel for appointment as his nominee within 30 days from the dispatch date of the request by The Appointing Authority. The Appointing Authority shall appoint at least one out of them as the sole arbitrator within 30 days from the receipt of the names of the contractor's nominees.

c) In cases where the total value of all claims in question added together exceeds Rs 50,00,000/ - (Rupees Fifty Lakh only), the Arbitral Tribunal shall consist of three (3) retired Officers of the Procuring Organisation. For this purpose, The Appointing Authority shall send a panel of at least four (4) names of such

Officer(s) empaneled 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 defense 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 defense 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 defense 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 nine 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.

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 willful misconduct, the aggregate liability of the contractor to the Procuring Entity, whether under the contract, in tort or otherwise, shall not exceed the total Contract Price, provided that this limitation shall not apply to the cost of repairing or replacing defective equipment, or to any obligation of the contractor to indemnify the Procuring Entity concerning IPR infringement.

12.2 Termination for Default/ Convenience of Procuring Entity and Frustration

12.2.1 Notice for Determination of Contract

1) The Procuring Entity reserves the right to terminate the contract, in whole or in part for its (the Procuring Entity's) convenience or frustration of contract as per sub-clause below, by serving written 'Notice for Determination of Contract' on the contractor at any time during the currency of the contract. The notice shall specify that the termination is for the convenience of the Procuring Entity or the frustration of the contract. The notice shall also indicate inter-alia, the extent to which the contractor's performance under the contract is terminated, and the date with effect from which such termination shall become effective.
2) Such termination shall not prejudice or affect the rights and remedies accrued and/ or shall accrue after that to the Parties.
3) Unless otherwise instructed by the Procuring Entity, the contractor shall continue to perform the contract to the extent not terminated.
4) All warranty obligations, if any, shall continue to survive despite the termination.
5) The Goods and incidental Works/ Services that are complete and ready in terms of the contract for delivery and performance within thirty days after the contractor's receipt of the notice of termination shall be accepted by the Procuring Entity as per the contract terms. For the remaining Goods and incidental Works/ Services, the Procuring Entity may decide:
    a) To get any portion of the balance completed and delivered at the contract terms, conditions, and prices; and/ or

b) To cancel the remaining portion of the Goods and incidental Works/ Services and compensate the contractor by paying an agreed amount for the cost incurred by the contractor, if any, towards the remaining portion of the Goods and incidental Works/ Services.

12.2.2 Frustration of Contract

1) **Notice of Frustration Event:** Upon a supervening cause occurring after the effective date of the contract, including a change in law, beyond the control of either party whether as a result of the Force Majeure clause or within the scope of section 56 of the Indian Contract Act, 1872, that makes it impossible to perform the contract within a reasonable timeframe, the affected party shall give a 'Notice of Frustration Event' to the other party giving justification. The parties shall use reasonable efforts to agree to amend the contract, as may be necessary to complete its performance. However, if the parties cannot reach a mutual agreement within 60 days of the initial notice, the Procuring Entity shall issue a 'Notice for Determining the contract' and terminate the contract due to its frustration as in the sub-clause above.

2) However, the following shall not be considered as such a supervening cause.

a) Lack of commercial feasibility or viability or profitability or availability of funds

b) if caused by either party's breach of its obligations under this Contract or failure to act in good faith or use commercially reasonable due diligence to prevent such an event.

12.3 Closure of Contract

12.3.1 No Claim Certificate and Release of Contract Securities

After mutual reconciliations of outstanding payments and assets on either side, the contractor shall submit a 'No-claim certificate' to the Procuring Entity requesting the release of its contractual securities, if any. The Procuring Entity shall release the contractual securities without any interest if no outstanding obligation, asset, or payments are due from the contractor. The contractor shall not be entitled to make any claim whatsoever against the Procuring Entity under or arising out of this Contract, nor shall the Procuring Entity entertain or consider any such claim, if made by the contractor, after he shall have signed a "No Claim" Certificate in favour of the Procuring Entity. The Contractor shall be debarred from disputing the correctness of the items covered by the "No Claim" Certificate or demanding a clearance

	to arbitration in respect thereof. **12.3.2 Closure of Contract** The contract shall stand closed upon 1) successful performance of all obligations by both parties, including completion of warrantee obligations and final payment. 2) termination and settlements after that, if any, as per GCC-clause 12.1 or 12.2 above.
13 Code of Integrity in Public Procurement; Misdemeanors and Penalties	**13.1 Code of Integrity** Procuring authorities as well as bidders, suppliers, contractors, and consultants - should observe the highest standard of ethics and should not indulge in following prohibited practices, either directly or indirectly, at any stage during the Tender Process or during the execution of resultant contracts: 1) **"Corrupt practice"** - making offer, solicitation or acceptance of a bribe, reward or gift or any material benefit, in exchange for an unfair advantage in the Tender Process or to otherwise influence the Tender Process; 2) **"Fraudulent practice"** - any omission or misrepresentation that may mislead or attempt to mislead so that financial or other benefits may be obtained or an obligation avoided. Such practices include a false declaration or false information for participation in a tender process or to secure a contract or in the execution of the contract; 3) **"Anti-competitive practice"** - any collusion, bid-rigging or anti-competitive arrangement, or any other practice coming under the purview of the Competition Act, 2002, between two or more bidders, with or without the knowledge of the Procuring Entity, that may impair the transparency, fairness, and the progress of the Tender Process or to establish bid prices at artificial, non-competitive levels; 4) **"Coercive practice"** - harming or threatening to harm persons or their property to influence their participation in the Tender Process or affect the execution of a contract; 5) **"Conflict of interest"** –participation by a bidding firm or any of its affiliates who are either involved in the Consultancy Contract to which this procurement is linked; or if they are part of more than one bid in the procurement; or if their personnel have a relationship or financial or business transactions with any official of procuring entity who are directly or indirectly related to tender

	or execution process of contract; or improper use of information obtained by the (prospective) bidder from the Procuring Entity with an intent to gain unfair advantage in the Tender Process or for personal gain; 6) **"Obstructive practice"** - materially impede procuring entity's investigation into allegations of one or more of the above mentioned prohibited practices either by deliberately destroying, falsifying, altering; or by concealing of evidence material to the investigation; or by making false statements to investigators and/ or by coercive practices mentioned above, to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or by impeding the Procuring Entity's rights of audit or access to information; **13.2 Obligations for Proactive Disclosures:** 1) Procuring authorities, bidders, suppliers, contractors, and consultants are obliged under this Code of Integrity to suo-moto proactively declare any conflict of interest (coming under the definition mentioned above - pre-existing or as and as soon as these arise at any stage) in any Tender Process or execution of the contract. Failure to do so shall amount to a violation of this code of integrity. 2) Any bidder must declare, whether asked or not in a bid-document, any previous transgressions of such code of integrity during the last three years or of being under any category of debarment by the Central Government or by the Ministry/ Department of the Procuring Organization from participation in Tender Processes. Failure to do so shall amount to a violation of this code of integrity. **13.3 Misdemeanors and Penalties** The following shall be considered misdemeanors - if a bidder/ contractor either directly or indirectly, at any stage during the Tender Process or during the execution of resultant contracts: 1) commits any of the following misdemeanors: a) violates the code of Integrity mentioned in GCC-clause 13.1 or GCC-Clause 10.1.6 (Fall clause) or the Integrity Pact if included in the Tender/ Contract; b) any other misdemeanor, e.g., supply of sub-standard quality of material/ services/ work or non-performance or abandonment of contract or failure to abide by 'Bid Securing Declaration'.

2) commits any of the following misdemeanors:

a) has been convicted of an offence:

i. under the Prevention of Corruption Act, 1988; or

ii. the Indian Penal Code or any other law for the time being in force for causing any loss of life or property or causing a threat to public health as part of the execution of a public procurement contract.

b) is determined by the Government of India to have doubtful loyalty to the country or national security consideration.

c) Employs a government servant, who has been dismissed or removed on account of corruption or employs a non-official convicted for an offence involving corruption or abetment of such an offence, in a position where he could corrupt government servants or employs a government officer within one year of his retirement, who has had business dealings with him in an official capacity before retirement.

13.4 Penalties for Misdemeanors

Without prejudice to and in addition to the rights of the Procuring Entity to other remedies as per the Tender-documents or the contract, If the Procuring Entity concludes that a (prospective) bidder/ contractor directly or through an agent has committed a misdemeanor in competing for the tender or in executing a contract, the Procuring Entity shall be entitled, and it shall be lawful on his part to take appropriate measures, including the following:

13.4.1 If his bids are under consideration in any procurement

1) Enforcement of Bid Securing Declaration in lieu of forfeiture or encashment of Bid Security.

2) calling off of any pre-contract negotiations, and;

3) rejection and exclusion of Bidder from the Tender Process

13.4.2 If a contract has already been awarded

1) Termination of Contract for Default and availing all remedies prescribed thereunder;

2) Encashment and/ or Forfeiture of any contractual security or bond relating to the procurement;

3) Recovery of payments including advance payments, if any, made by the Procuring Entity along with interest thereon at the prevailing rate (MIBID - Mumbai Interbank Bid Rate);

13.4.3 Remedies in addition to the above:

	In addition to the above penalties, the Procuring Entity shall be entitled, and it shall be lawful on his part to: File information against Bidder or any of its successors, with the Competition Commission of India for further processing, in case of anti-competitive practices; Initiate proceedings in a court of law against Bidder or any of its successors, under the Prevention of Corruption Act, 1988 or the Indian Penal Code or any other law for transgression not addressable by other remedies listed in this sub-clause. Remove Bidder or any of its successors from the list of registered suppliers for a period not exceeding two years. Suppliers removed from the list of registered vendors or their related entities may be allowed to apply afresh for registration after the expiry of the period of removal. Initiation of suitable disciplinary or criminal proceedings against any individual or staff found responsible. Debar a bidder / contractor from participation in future procurements without prejudice to Procuring Entity's legal rights and remedies. Debarment shall automatically extend to all the allied firms of the debarred firm. In the case of Joint Venture/ consortium, all its members shall also stand similarly debarred: a) A Ministry/ Department (or any of its CPSUs, attached offices, autonomous bodies) may debar a bidder or any of its successors from participating in any Tender Process undertaken by all its procuring entities for a period not exceeding two years commencing from the date of debarment for misdemeanors listed in sub-clause GCC 13.3 -1) above. The Ministry/Department shall maintain such a list which shall also be displayed on their website. b) Central Government (Department of Expenditure (DoE), Ministry of Finance) may debar a bidder or any of its successors from participating in any Tender Process undertaken by all its procuring entities for a period not exceeding three years commencing from the date of debarment for misdemeanors listed in sub-clause GCC 13.3 - 2) above. DoE shall maintain such a list which shall be displayed on Central Public Procurement Portal (CPPP).

SECTION VIII: SPECIAL CONDITIONS OF CONTRACT

Reference GCC Section	Description
GCC 2.4	The details of Procuring Entity and Contractor are as under: Procuring Entity - The Central Medical Services Society, an autonomous body under Ministry of Health and Family welfare, Government of India Contractor -
GCC 5.8	Within fourteen days after the issue of Letter of Award (LoA or the contract, if LoA is skipped) by the Procuring Entity, the contractor shall furnish to the Procuring Entity performance security for an amount equivalent to 3% of the contract value valid till expiry of shelf life of the last consignment supplied under the contract. Accordingly, PBG validity will be as under: Last date of delivery 270 days Shelf life 730 days B.G. Extension -60 days Total Performance security validity 1060 days **If the shelf life of the quoted item will be more than 2 years or last date of delivery exceed from 270 days, the validity of the performance security should be increased accordingly.**
GCC 7.1.7	**<u>For Sch I only:</u>** For all tranches, the goods supplied under the contract shall be subjected to Pre-Delivery Inspection at manufacturer's manufacturing premises before dispatch. **<u>For Sch II, III, IV, V, VI, VII & VIII only:</u>** For all tranches, the goods supplied under the contract shall be subjected to Inspection at Delivery Stages.
GCC 8.2	The suppliers are required to supply the product(s) with printed text "GOVERNMENT OF INDIA SUPPLIES – NOT FOR SALE"
GCC 8.7.5	The contractor shall ensure that at least 5/6th of shelf-life remains balance on delivery date.

SECTION IX- BIDDING FORMS

Form 1: Bid Form (Covering Letter)
(Ref ITB-clause 9.2)
(To be submitted as part of technical bid, along with supporting documents, if any)
(On Bidder's Letter-head)
(Strike out alternative phrases not relevant to you)
Bidder's Name_____
[Address and Contact Details]
Bidder's Reference No._____ Date…….
To
DG & CEO, Central Medical Services Society, Ministry of Health and Family welfare, Government of India, New Delhi
Address: 2nd floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Road, Opposite Police Station Chanakaya Puri,
New Delhi-110021
Telephones: 011-21410905, 21410906
Ref: Your Tender Document No. Tender No./ xxxx; Tender Title: GOODS

Sir/ Madam
Having examined the above-mentioned Tender Document, we, the undersigned, hereby submit/ upload our Techno-commercial and financial bid (Price Schedule) for the supply of Goods and incidental Works/ Services in conformity with the said Tender Documents.

1) Our Credentials:

a) We are submitting this bid: -

☐ on our behalf, and there are no agents/ dealers involved in this tender, and hence no agency agreement or payments/ commissions/ gratuity is involved. Our company law and taxation regulatory requirements and authorization for signatories and related documents are submitted in Form 1.1 (Bidder Information).

b) We…….. hereby certify that ☐ We are proven, established, and reputed manufacturers with factories at …… which are fitted with modern equipment and where the production methods, quality control, and testing of all materials and parts manufactured or used by us shall be open to inspection by the representative of the Procuring Entity.

2) Our Eligibility and Qualifications to participate

We comply with all the eligibility criteria stipulated in this Tender Document, and the relevant declarations are made along with documents in Form 1.2 of this bid-form. We fully meet the qualification criteria stipulated in this Tender Document, and the relevant details are submitted along with documents in Form 4: 'Qualification Criteria - Compliance.

3) Our Bid to supply Goods:

We offer to supply the subject Goods of requisite quality and within Delivery Schedules in conformity with the Tender Document. The relevant details are submitted in Form 2: 'Schedule of Requirements - Compliance and Form3: 'Technical Specifications and Quality Assurance - Compliance.' The details of schedule wise quantity offered against this tender are given below in tabular form:

Schedule No.	Item Name	UOM	Tendered Quantity	Quoted Quantity
I				

4) Prices:

We hereby offer to perform the Services at our lowest prices and rates mentioned in the separately uploaded Price-Schedule. It is hereby confirmed that the prices quoted therein by us are:

a) based on terms of delivery and delivery schedule confirmed by us; and
b) Cost break-up of the quoted cost, showing inter-alia costs (including taxes and duties thereon) of all the included incidental Goods/ Works considered necessary to make the proposal self-contained and complete, has been indicated therein, and
c) based on the terms and mode of payment as stipulated in the Tender Document. We have understood that if we quote any deviation to terms and mode of payment, our bid is liable to be rejected as nonresponsive, and
d) have been arrived at independently, without restricting competition, any consultation, communication, or agreement with any other bidder or competitor relating to:

   i) those prices; or
   ii) the intention to submit an offer; or
   iii) the methods or factors used to calculate the prices offered.

e) have neither been nor shall be knowingly disclosed by us, directly or indirectly, to any other bidder or competitor before bid opening or contract award unless otherwise required by law.

5) Affirmation to terms and conditions of the Tender Document:

We have understood the complete terms and conditions of the Tender Document. We accept and comply with these terms and conditions without reservations, although we are not signing and submitting some of the sections of the Tender Document. Deviations, if any, are submitted by us in Form 5: 'Terms and Conditions - Compliance'. We also explicitly confirm acceptance of the Arbitration Agreement as given in the Tender Document.

6) Bid Security/Bid Securing Declaration

We have submitted the Bid Security (applicable for all bidders except MSEs and Startups) in stipulated format vide Form 7A / Bid Securing Declaration (applicable for MSEs and Startups) in lieu of Bid Security in stipulated format vide Form 7: 'Documents Relating to bid security.'

7) Abiding by the Bid Validity

We agree to keep our bid valid for acceptance for a period up to 150 days, as required in the Tender Document or for a subsequently extended period, if any, agreed to by us and are aware of penalties in this regard stipulated in the Tender Document in case we fail to do so.

8) Non-tempering of Downloaded Tender Document and Uploaded Scanned Copies

We confirm that we have not changed/ edited the contents of the downloaded Tender Document. We realise that any such change noticed at any stage, including after the contract award, shall be liable to punitive action in this regard stipulated in the Tender Document. We also confirm that scanned copies of documents/ affidavits/ undertakings uploaded along with our Technical bid are valid, true, and correct to the best of our knowledge and belief. If any dispute arises related to the validity and truthfulness of such documents/ affidavits/ undertakings, we shall be responsible for the same. We undertake to submit for scrutiny, on-demand by the Procuring Entity, originals, and self-certified copies of all such certificates, documents, affidavits/ undertakings.

9) A Binding Contract:

We further confirm that, if our bid is accepted, all such terms and conditions shall continue to be acceptable and applicable to the resultant contract, even though some of these documents may not be included in the contract Documents submitted by us. We do hereby undertake that this bid together with your written acceptance of the same shall constitute a binding contract between us.

10) Performance Guarantee and Signing the contract

We further confirm that, if our bid is accepted, we shall provide you with performance security of the required amount stipulated in the Tender Document for the due performance of the contract. We are fully aware that in the event of our failure to deposit the required security amount and/ or failure to execute the agreement, the Procuring Entity has the right to avail any or all punitive actions laid down in this regard, stipulated in the Tender Document.

11) Signatories:

We confirm that we are duly authorized to submit this bid and make commitments on behalf of the Bidder. Supporting documents are submitted in Form 1.1 annexed herewith. We acknowledge that our digital/digitized signature is valid and legally binding.

12) Rights of the Procuring Entity to Reject bid(s):

We further understand that you are not bound to accept the lowest or any bid you may receive against your above-referred Tender Document.

……..
(Signature with date)
……..
(Name and designation)
Duly authorized to sign bid for and on behalf of
[name & address of Bidder and seal of company]

Form 1.1: Bidder Information
(Ref 8.2 of ITB)
(To be submitted as part of technical bid)
(On Company Letter-head)
(Along with supporting documents, if any)
Bidder's Name_____
[Address and Contact Details]
Bidder's Reference No._____ Date…….
Ref: Your Tender Document No. Tender No./ xxxx; Tender Title: GOODS

Note: Bidder shall fill in this Form following the instructions indicated below. No alterations to its format shall be permitted, and no substitutions shall be accepted. Bidder shall enclose certified copies of the documentary proof/ evidence to substantiate the corresponding statement wherever necessary and applicable. Bidder's wrong or misleading information shall be treated as a violation of the Code of Integrity. Such Bids shall be liable to be rejected as nonresponsive, in addition to other punitive actions provided for such misdemeanours in the Tender Document.

(Please tick appropriate boxes or strike out sentences/ phrases not applicable to you)

1) Bidder/ Contractor particulars:

a) Name of the Company:…….
b) Corporate Identity No. (CIN): ……..
c) Registration, if any, with The Procuring Entity: ……..
d) GeM Supplier ID (if registered with GeM, it is mandatory at the time of placement of Contract)
e) Place of Registration/ Principal place of business/ manufacture …….
f) Complete Postal Address: ……..
g) Pin code/ ZIP code: …….
h) Telephone nos. (with country/ area codes): ……
i) Mobile Nos.: (with country/ area codes): ……..
j) Contact persons/ Designation: …….
k) Email IDs: …….

Submit documents to demonstrate eligibility viz. In case of a partnership firm – Deed of Partnership; in case of Company – Notarized and certified copy of its registration certificate; and in case of Society – its Byelaws and registration certificate of the firm.

2) Taxation Registrations:

a) PAN number: …….
b) Type of GST Registration as per the Act (Normal Taxpayer, Composition, Casual Taxable Person, SEZ, etc.): …….
c) GSTIN number: ……. in Consignor and Consignee States
d) Registered/ Certified Works/ Factory where the Goods would be mainly manufactured and Place of Consignor for GST Purpose: …….
e) Contact Names, Nos. & email IDs for GST matters (Please mention primary and secondary contacts): ……

☐ We solemnly declare that our GST rating on the GST portal/ Govt. official

website is not negative/ blacklisted.

Documents to be submitted: Self-attested Copies of PAN card and GSTIN Registration.

3) Authorization of Person(s) signing the bid on behalf of the Bidder

a) Full Name: _____
b) Designation: _____
c) Signing as:

☐ A sole proprietorship firm. The person signing the bid is the sole proprietor/ constituted attorney of the sole proprietor,

☐ A partnership firm. The person signing the bid is duly authorised being a partner to do so, under the partnership agreement or the general power of attorney,

☐ A company. The person signing the bid is the constituted attorney by a resolution passed by the Board of Directors or in pursuance of the Authority conferred by Memorandum of Association.

Documents to be submitted: Partnership Agreement/ Power of Attorney/ Registration Certificate/ Memorandum of Association/ Board Resolution

4) Bidder's Authorized Representative Information

a) Name:
b) Address:
c) Telephone/ Mobile numbers:
d) Email Address:

5) Bidder's Account Details

a) Bank Name:
b) IFSC Code:
c) Account No. :
d) Branch Address:
e) Email Address/ Contact No.:

With a copy of cancelled cheque

(Signature with date)
……..
(Name and designation)
Duly authorized to sign bid for and on behalf of
[name & address of Bidder and seal of company], DA: As above

Form 1.2: Eligibility Declarations
(Ref ITB-clause 9.2)
(To be submitted as part of Technical bid)
(On Company Letter-head)
(Along with supporting documents, if any)
Ref: Your Tender Document No. Tender No./ xxxx; Tender Title: GOODS
Bidder's Name_____
[Address and Contact Details]
Bidder's Reference No._____ Date…….
Note: The list below is indicative only. You may attach more documents as required to confirm your eligibility criteria.

Eligibility Declarations

(Please tick appropriate boxes or cross out any declaration not applicable to the Bidder)
We hereby confirm that we are comply with all the stipulation of bid document and declare as under and shall provide evidence of our continued eligibility to the Procuring Entity as may be requested:

1) Legal Entity of Bidder: _____

2) We solemnly declare that we (including our affiliates or subsidiaries or constituents):

a) are not insolvent, in receivership, bankrupt or being wound up, not have our affairs administered by a court or a judicial officer, not have our business activities suspended and are not the subject of legal proceedings for any of these reasons;
b) (including our Contractors/ subcontractors for any part of the contract):

i. Do not stand declared ineligible/ blacklisted/ banned/ debarred by the Central Medical Services Society or Ministry of Health and Family Welfare, Government of India from participation in its Tender Processes as a whole or for the product offered; and/ or
ii. Are not convicted or stand declared ineligible/ suspended/ blacklisted/ banned/ debarred by appropriate agencies of Government of India from participation in Tender Processes of all of its entities, for offences mentioned in Tender Document in this regard. We have neither changed our name nor created a new "Allied Firm", consequent to the above disqualifications.

c) Do not have any association (as bidder/ partner/ Director/ employee in any capacity) with such retired public official or near relations of such officials of Procuring Entity, as counter-indicated, in the Tender Document.
d) We certify that we fulfil any other additional eligibility condition if prescribed in Tender Document.
e) We have no conflict of interest, which substantially affects fair competition. The prices quoted are competitive and without adopting any unfair/ unethical/ anti-competitive means. No attempt has been made or shall be made by us to induce any other bidder to submit or not to submit an offer to restrict competition.

3) Restrictions on procurement from bidders from a country or countries, or a class of countries under Rule 144 (xi) of the General Financial Rules 2017: We certify as under:

"We have read the clause regarding restrictions on procurement from entities having beneficial ownership of a country which shares a land border with India and on sub-contracting to contractors from such countries, as stipulated vide Department of Expenditure Order No F.7/10/2021-PPD (1), dated 23.02.2023 as amended till date of bid submission, and solemnly certify that we fulfil all requirements in this regard and are eligible to be considered. We certify that:

a) we are not from such a country or, if from such a country, we are registered with the Competent Authority (copy enclosed). and;
b) we shall not subcontract any work to a contractor from such countries unless such contractor is registered with the Competent Authority.

4) MSME Status:

Having read and understood the Public Procurement Policy for Micro and Small Enterprises (MSEs) Order, 2012 (as amended and revised till date), and solemnly declare the following:

a) We are - Micro/ Small/ Medium Enterprise/ SSI/ Govt. Deptt. / PSU/ Others:……
b) We attach herewith, Udhyam Registration Certificate with the Udhyam Registration Number as proof of our being MSE registered on the Udhyam Registration Portal. The certificate is the latest up to the deadline for submission of the bid.
c) Whether Proprietor/ Partner belongs to SC/ ST or Women category. (Please specify names and percentage of shares held by SC/ ST Partners):…….

5) Start-up Status

we confirm that we ☐ are/ ☐ are not a Start-up entity as per the definition of the Department of Promotion of Industrial and Internal Trade – DPIIT.

6) Make in India Status:

Having read and understood the Public Procurement (Preference to Make in India PPP - MII) Order, 2017 (as amended and revised till date) and related notifications from the relevant Nodal Ministry/ Department, and solemnly declare the following:

(a) Self-Certification for the category of suppliers:

(Provide a certificate from the statutory auditor or cost auditor of the company (in the case of companies) OR from a practicing cost accountant or practicing chartered accountant (in respect of suppliers other than companies) in case of Tenders above Rs. 10 Crore for Class-I or Class-II Local Suppliers). Details of local content and location(s) at which value addition is made are as follows:

Sr. No.	Name of Item	Percentage Local Content	Location of value addition

Therefore, we certify that we qualify for the following category of the supplier (tick the appropriate category):

□ Class-I Local Supplier/

□ Class-II Local Supplier/

□ Non-Local Supplier.

I confirm that local content has been calculated in accordance with provisions of PPP-MII Order dated 19.07.2024 read with Department of Pharmaceutical Notification No. **31026/65/2020-MD dated 30.12.2020** / F.No.31026/36/2016-MD dated 16.02.2021. I undertake to produce relevant records before the procuring entity or any authority so nominated by the Department of Pharmaceuticals, Government of India for the purpose of assessing the local content.

7) Integrity Pact

Having read and understood the provisions of Integrity Pact, as detailed in ITB 16, we confirm that we accept the same. Integrity Pact, in prescribed proforma, duly signed is enclosed, with the bid.

8) Penalties for false or misleading declarations:

We hereby confirm that the particulars given above are factually correct and nothing is concealed and undertake to advise any future changes to the above details. We understand that any wrong or misleading self-declaration would violate the Code of Integrity and attract penalties as mentioned in this Tender Document.

……..
(Signature with date)
……..
(Name and designation)
Duly authorized to sign bid for and on behalf of
…….
…….
[name & address of Bidder and seal of company]
DA: As in Sr 9 to 14 above, as applicable

Form 1.3: Local Content Declaration- Compliance
(Certificate to be given by statutory auditor or cost auditor of the company (in the case of companies) OR from a practicing cost accountant or practicing chartered accountant (in respect of suppliers other than companies) for purchases above INR 10 Crores)

Tender Reference No: Date:

Based upon the documents placed before us, we certify that M/s…….. (name of the bidder) having manufacturing premises at ……. (manufacturing place of the bidder) have the following local contents in the goods quoted by them against subject tender enquiry:

Sr. No.	Name of Item	Percentage Local Content	Location of value addition

We confirm that local content has been calculated in accordance with provisions of PPP-MII Order dated 19.07.2024 read with Department of Pharmaceutical Notification No. **31026/65/2020-MD dated 30.12.2020** / F.No.31026/36/2016-MD dated 16.02.2021. We undertake to produce relevant records before the procuring entity or any authority so nominated by the Department of Pharmaceuticals, Government of India for the purpose of assessing the local content.

Statutory Auditor or Cost Auditor for Companies/ Cost or Chartered Accountant for others (with Seal/Stamp)
UDIN ……

Form 1.4 **Integrity Pact Format**

INTEGRITY PACT

Between

[the Procuring Organisation] hereinafter referred to as **"The Principal,"** and _____ hereinafter referred to as **"The Bidder/ Contractor."**

Preamble

The Principal intends to award contract/s for_____, under laid down organizational procedures, The Principal values full compliance with all relevant laws of the land, rules, regulations, economical use of resources, and fairness / transparency in its relations with its Bidder(s) and / or Contractor(s).

To achieve these goals, the Principal shall appoint Independent External Monitors (IEMs) who shall monitor the tender process and the execution of the contract for compliance with the abovementioned principles.

Section 1 – Commitments of the Principal

1) The Principal commits itself to take all measures necessary to prevent corruption and to observe the following principles: -
   a. No employee of the Principal, personally or through family members, shall in connection with the tender for, or the execution of a contract, demand, take a promise for or accept, for self or third person, any material or immaterial benefit which the person is not legally entitled to.
   b. The Principal shall treat all Bidder(s) with equity and reason during the tender process. The Principal shall, in particular, before and during the tender process, provide to all Bidder(s) the same information and shall not provide to any Bidder(s) confidential / additional information through which the Bidder(s) could obtain an advantage in the tender process or the contract execution.
   c. The Principal shall exclude from the process all known persons having conflict of interest.

2) If the Principal obtains information on the conduct of any of its employees which is a criminal offence under the IPC/PC Act, or if there be a substantive suspicion in this regard, the Principal shall inform the Chief Vigilance Officer and in addition shall initiate disciplinary proceedings.

Section 2 – Commitments of the Bidder(s)/ Contractor(s)

1) The Bidder(s)/ Contractor(s) commits themselves to take all measures necessary to prevent corruption. The Bidder(s)/ Contractor(s) commits themselves to observe the following principles during participation in the tender process and the contract execution.

   a. The Bidder(s)/ Contractor(s) shall not, directly or through any other person or firm, offer, promise, or give to any of the Principal's employees involved in the tender process or the execution of the contract or to any third person any material or other benefit which they are not legally entitled to, in order to obtain in exchange any advantage of any kind whatsoever during the tender process or the execution of the contract.

   b. The Bidder(s)/ Contractor(s) shall not enter with other Bidders into any undisclosed agreement or understanding, whether formal or informal, in violation of the Competition Act, 2002 (as amended from time to time). This applies in particular to prices, specifications, certifications, subsidiary contracts, submission or non-submission of bids or any other actions to restrict competitiveness or to introduce cartelisation in the tender process.

c. The Bidder(s)/ Contractor(s) shall not commit any offence under the relevant IPC/PC Act; further, the Bidder(s)/ Contractor(s) shall not use improperly, for purposes of competition or personal gain, or pass on to others, any information or document provided by the Principal as part of the business relationship, regarding plans, technical proposals, and business details, including information contained or transmitted electronically.

d. The Bidder(s)/Contractors(s) of foreign origin shall disclose the name and address of the Agents/representatives in India, if any. Similarly, the Bidder(s)/Contractors(s) of Indian Nationality shall furnish the name and address of the foreign principals, if any. Further details, as mentioned in the "Guidelines on Indian Agents of Foreign Suppliers," shall be disclosed by the Bidder(s)/Contractor(s). Further, as mentioned in the Guidelines, all the payments made to the Indian agent/representative must be in Indian Rupees only. Copy of the "Guidelines on Indian Agents of Foreign Suppliers" is placed on Annex hereto.

e. The Bidder(s)/ Contractor(s) shall, when presenting their bid, disclose any and all payments made, is committed to, or intends to make to agents, brokers, or any other intermediaries in connection with the award of the contract.

f. Bidder(s) /Contractor(s) who have signed the Integrity Pact shall not approach the Courts while representing the matter to IEMs and shall wait for their decision.

2) The Bidder(s)/ Contractor(s) shall not instigate third persons to commit offences outlined above or be an accessory to such offences.

Section 3 - Disqualification from the tender process and exclusion from future contracts

If the Bidder(s)/Contractor(s), before award or during execution, has committed a transgression through a violation of Section 2, above or in any other form such as to put their reliability or credibility in question, the Principal is entitled to disqualify the Bidder(s)/Contractor(s) from the tender process or take action as per laid down procedure to debar the Bidder(s)/Contractor(s) from participating in the future procurement processes of the Government of India.

Section 4 – Compensation for Damages

1) If the Principal has disqualified the Bidder(s) from the tender process before the award according to Section 3, the Principal is entitled to demand and recover the damages equivalent to Earnest Money Deposit/ Bid Security.

2) If the Principal has terminated the contract according to Section 3, or if the Principal is entitled to terminate the contract according to Section 3, the Principal shall be entitled to demand and recover from the Contractor liquidated damages of the Contract value or the amount equivalent to Performance Bank Guarantee.

Section 5 – Previous transgression

1) The Bidder declares that no previous transgressions occurred in the last three years with any other Company in any country conforming to the anti-corruption approach or with any Public Sector Enterprise in India that could justify his exclusion from the tender process.

2) If the Bidder makes an incorrect statement on this subject, the Principal shall act like para 2) of Section 4 above.

Section 6 – Equal treatment of all Bidders / Contractors / Subcontractors

In the case of Sub-contracting, the Principal Contractor shall take responsibility for adopting the Integrity Pact by the Sub-contractor.

a. The Principal shall enter into agreements with identical conditions as this one with all Bidders and Contractors.

b. The Principal shall disqualify from the tender process all bidders who do not sign this Pact or violate its provisions.

Section 7 – Criminal charges against violating Bidder(s) / Contractor(s) / Subcontractor(s)

If the Principal obtains knowledge of the conduct of a Bidder, Contractor, or Subcontractor, or of an employee or a representative or an allied firm of a Bidder, Contractor or Subcontractor which constitutes corruption, or if the Principal has substantive suspicion in this regard, the Principal shall inform the same to the Chief Vigilance Officer.

Section 8 – Independent External Monitor

1) The Principal shall appoint competent and credible Independent External Monitor(s) for this Pact after approval by the Central Vigilance Commission. The task of the Monitor is to review, independently and objectively, whether and to what extent the parties comply with the obligations under this agreement.

2) The Monitor is not subject to instructions by the parties' representatives and performs their functions neutrally and independently. The Monitor would have access to all Contract documents whenever required. It shall be obligatory for them to treat the information and documents of the Bidders/Contractors as confidential. They report to the Management of the Principal.

3) The Bidder(s)/Contractor(s) accepts that the Monitor has the right to access without restriction, all Project documentation of the Principal, including that provided by the Contractor. Upon their request and demonstration of a valid interest, the Contractor shall also grant the Monitor unrestricted and unconditional access to their project documentation. The same applies to Subcontractors.

4) The Monitor is under contractual obligation to treat the information and documents of the Bidder(s)/ Contractor(s)/ Sub-contractor(s) with confidentiality. The Monitor has also signed declarations on 'Non-Disclosure of Confidential Information' and 'Absence of Conflict of Interest.' In case of any conflict of interest arising later, the IEM shall inform the Management of the Principal and recuse themselves from that case.

5) The Principal shall provide the Monitor with sufficient information about all meetings among the parties related to the Project, provided such meetings could impact the contractual relations between the Principal and the Contractor. The parties offer the Monitor the option to participate in such meetings.

6) As soon as the Monitor notices, or believes to notice, a violation of this agreement, they shall inform the Management of the Principal and request the Management to discontinue or take corrective action or other relevant action. The Monitor can, in this regard, submit non-binding recommendations. Beyond this, the Monitor has no right to demand from the parties that they act in a specific manner, refrain from action, or tolerate action.

7) The Monitor shall submit a written report to the Management of the Principal, within 8 to 10 weeks from the date of reference or intimation to him by the Principal and, should the occasion arise, submit proposals for correcting problematic situations.

8) If the Monitor has reported to the Management of the Principal a substantiated suspicion of an offence under the relevant IPC/ PC Act, and the Management of the Principal has not, within the reasonable time, taken visible action to proceed against such offence or reported it to the Chief Vigilance Officer, the Monitor may also transmit this information directly to the Central Vigilance Commissioner.

9) The word **'Monitor'** would include both singular and plural.

Section 9 – Pact Duration

This Pact begins when both parties have legally signed it. It expires for the Contractor 12 months after the last payment under the contract, and for all other Bidders, 6 months after the contract has been awarded. Any violation of the same would entail disqualifying the bidders and exclusion from future business dealings.

If any claim is made / lodged during this time, the same shall be binding and continue to be valid despite the lapse of this Pact as specified above, unless it is discharged / determined by the Management of the Principal.

Section 10 – Other provisions

1) This agreement is subject to Indian Law. The place of performance and jurisdiction is the place from where the Tender/ Contract is issued.
2) Changes, supplements, and termination notices must be submitted in writing. Side agreements have not been made.
3) If the Contractor is a partnership or a consortium, this agreement must be signed by all partners or consortium members.
4) Should one or several provisions of this agreement turn out to be invalid, the remainder of this agreement remains valid. In this case, the parties shall strive to come to an agreement according to their original intentions.
5) Issues like Warranty / Guarantee, etc., shall be outside the purview of IEMs.
6) In the event of any contradiction between the Integrity Pact and its Annex, the Clause in the Integrity Pact shall prevail.

_____	_____
(For & On behalf of the Principal)	(For and on behalf of Bidder/ Contractor)
(Office Seal)	(Office Seal)
Place ---------- Date ----------	
Witness 1: _____	Witness 1: _____
(Name & Address)	(Name & Address)

Form 2: Schedule of Requirements – Compliance & Deviation
Schedule of Requirements
(Ref ITB-clause 9.2, Schedule V: Schedule of Requirements)
(To be submitted as part of Technical bid)
(on Company Letter-head)
Ref: Your Tender Document No. Tender No./ xxxx; Tender Title: GOODS
Bidder's Name_____
[Address and Contact Details]
Bidder's Reference No._____ Date…….
Note to Bidders: Fill up this Form regarding Section V: Schedule of Requirements maintaining the same numbering and structure. Add additional details not covered elsewhere in your bid in this regard.

Tender Title				
Tender Reference No		Tend No./ xxxx		
Schedule	**Description of Goods**	**Local Content (%)**	**HSN Code**	**Bidder's GSTIN**
1	2	3	4	5
I				
II				
III				

We shall comply with, abide by, and accept without variation, deviation, or reservation all requirements detailed in Section V: Schedule of Requirements in the Tender Document, including delivery schedule & terms of delivery except those mentioned below.

a) ……
b) ……..

We understand that if contrary terms and conditions are mentioned elsewhere in our bid, same shall not be recognized and shall be null and void.
(Signature with date)
……..
(Name and designation)
Duly authorized to sign bid for and on behalf of
…….
[name & address of Bidder and seal of company]

Form 3: Technical Specifications and Quality Assurance – Compliance & Deviation
(Ref ITB-clause 9.2, Schedule VI: Technical Specifications and Quality Assurance)
(To be submitted as part of Technical bid)
(on Company Letter-head)
Ref: Your Tender Document No. Tender No./ xxxx; Tender Title: GOODS
Bidder's Name_____
[Address and Contact Details]
Bidder's Reference No._____ Date…….
Note to Bidders: Highlight in this form deviations, if any, from Section VI: Technical Specifications and Quality Assurance, maintaining the same numbering and structure. Add additional details not covered elsewhere in your bid in this regard.

Sl. No.	**Technical specification as per tender**	**Comply (Yes/No)**

Note: - Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life and Certificate of Analysis of one batch of the quoted product should be submitted.
We shall comply with, abide by, and accept without variation, deviation, or reservation all Technical Specifications including artworks, Quality Assurance and Warranty requirements in the Tender Document, except those mentioned below.

a) ……..
b) ……..

We understand that if contrary terms and conditions are mentioned elsewhere in our bid, same shall not be recognized and shall be null and void.

……..
(Signature with date)
……..
(Name and designation)
Duly authorized to sign bid for and on behalf of
…….
[name & address of Bidder and seal of company]
DA: Relevant documents like technical data, literature, drawings, and other documents

Form 4: Qualification Criteria – Compliance & Deviation
(Ref ITB-clause 9.2, Schedule IV Qualification Criteria)
(To be submitted as part of Technical bid)
(on Company Letter-head)
Ref: Your Tender Document No. Tender No./ xxxx; Tender Title: GOODS
Bidder's Name_____
[Address and Contact Details]
Bidder's Reference No._____ Date…….
Note to Bidders: Furnish statements and documents to confirm conformity to Qualification Criteria may be mentioned/ attached here. The list below is indicative only. You may attach more documents as required for qualification criteria. Add additional details not covered elsewhere in your bid in this regard. Non-submission or incomplete submission of documents may lead to rejection of the bid as nonresponsive. Also highlight in this form deviations, if any, from Section IV: Qualification Criteria.
1.

Ref of Qualification Criteria Clause	**Confirmation Yes/No**
Clause (a)	
Clause (b)	
Clause (c)	
Clause (d)	
……	

2. We explicitly confirm that we have not been convicted by the Licensing Authority in past three years prior to the date of bid submission. We undertake that in case we are convicted by the Licensing Authority in the due course i.e. after submission of bid but before the date of award of contract, we shall promptly intimate the same to the Tender Inviting Authority.

   We undertake that any false information in this regard is liable for punitive actions including blacklisting/ debarring and forfeiture of EMD/PBG, as the case maybe.

3. Documents Attached supporting the compliance to qualification criteria:

Sr	**Document Attached, duly filled, signed, and copies self-attested**
1	
2	
3	

We shall comply with, abide by, and accept without variation, deviation, or reservation all the Qualification Criteria mentioned in the Tender Document, except those mentioned below.

a) ……
b) ……..

We understand that if contrary terms and conditions are mentioned elsewhere in our bid, same

shall not be recognised and shall be null and void.

……..
(Signature with date)
……..
(Name and designation)
Duly authorized to sign bid for and on behalf of
…….
[name & address of Bidder and seal of company]
DA: As above, if any

Form 4.1: PROFORMA FOR PERFORMANCE STATEMENT

(FOR A PERIOD OF LAST 2 YEARS)

Name of Bidder with Address_____
Manufacturer with Address_____
Tender No. & Date_____
Sr. No. of the Quoted Product _____
Name of the Quoted Product _____

Financial Year 2023-24								
Domestic Purchase Orders								
GST Invoice No. and Date	E-Way Bill No. and Date	Purchase Order No and Date	Description of Goods	Unit	Qty.	Unit Price All Incl.	Total Value	Name of Purchaser with Contact Details
Export Purchase Orders								
Bill of lading/ Airway Bill No. and Date	Any other document issued by Custom Authority	Purchase Order No and Date	Description of Goods	Unit	Qty.	Unit Price All Incl.	Total Value	Name of Purchaser with Contact Details
Financial Year 2024-25								
Domestic Purchase Orders								
GST Invoice No. and Date	E-Way Bill No. and Date	Purchase Order No and Date	Description of Goods	Unit	Qty.	Unit Price All Incl.	Total Value	Name of Purchaser with Contact Details
Export Purchase Orders								
Bill of lading/ Airway Bill No. and Date	Any other document issued by Custom Authority	Purchase Order No and Date	Description of Goods	Unit	Qty.	Unit Price All Incl.	Total Value	Name of Purchaser with Contact Details

Note:

1. The copies of GST invoice and E-way bill against the proof of execution of order for every submitted Purchase Order must be submitted. If GST invoice is not applicable for any Purchase Order, the affidavit to that effect on stamp paper of Rs. 100/- should be submitted.
2. For the supply of export, bidder should submit the copy of invoice, bill of lading/airway bill/any other document issued by custom authority against the proof of execution of order for every submitted Purchase Order.

Signature of Tenderer	Signature of Practicing Chartered Accountant
Name in Capitals	Name in Capitals
Date:	Date
Seal:	Seal
	UDIN-

Form 4.2: ANNUAL TURN OVER STATEMENT

The Annual Turnover (Sales) of M/s._____ for the past three years are given below and certified that the statement is true and correct.

Sl. No.	Financial Year	Turnover in Lakhs (Rs)
1.	2021-2022 / 2022-23	-
2.	2022-2023/ 2023-24	-
3.	2023-2024 /2024-25	-

Total - Rs. _____ Lakhs.

Average Turnover Per Annum in the last three years mentioned above - Rs._____ Lakh

Date:
Seal: Signature of Auditor/Chartered Accountant
(Name in Capital)
UDIN-

Form 5: Terms and Conditions - Compliance
(Ref ITB-clause 9.2)
(To be submitted as part of Technical bid)
(on Company Letter-head)
Bidder's Name_____
[Address and Contact Details]
Bidder's Reference No._____ Date…….
Ref: Your Tender Document No. Tender No./ xxxx; Tender Title: GOODS
Note to Bidders: Fill up this Form regarding Terms and Conditions in the Tender Document, maintaining the same numbering and structure. Add additional details not covered elsewhere in your bid in this regard.
We shall comply with, abide by, and accept without variation, deviation, or reservation of the entire terms & conditions of tender document including all Corrigendum, Pre-bid Minutes of the Tender Document etc, except those mentioned below.

a) ……
b) ……..

We understand that if contrary terms and conditions are mentioned elsewhere in our bid, same shall not be recognised and shall be null and void.
……..
(Signature with date)
……..
(Name and designation)
Duly authorized to sign bid for and on behalf of
…….
…….
[name & address of Bidder and seal of company]
DA: If any, at the option of the Bidder.

Form6: Bid Summary

Bid Summary : M/s…….
CMSS Tender No. : ……
Tender Name : ……...
CPP/GeM Id No. : ……...
Tender Opening Date : ……

S. No.	Description
1.	**Bidder Information**

S. No.	Item Description	Details
1(a)	Name of Bidder	
1(b)	PAN No.	
1(c)	GST No.	
1(d)	Registered Address	
1(e)	Operating Address	
1(f)	Telephone No.	
1(g)	Emails	
1(h)	Name of Person Signing the Bid	
1(i)	Designation	

Attached Documents

S. No.	Documents	Reference Bid page No.
1(j)	Bidder Information Form (Form 1.1 of Bid Document)	
1(k)	Copy of PAN	
1(l)	Copy of GST	
1(m)	Copy of Power of Attorney	

2. **Quoted Items**

S. No.	Schedule No.	Item Name
2 (a)		
2 (b)		
2 (c)		
2 (d)		

Attached Documents

S. No.	Documents	Reference Bid page No.
2 (e)	Bid Form (Form 1 of Bid Document)	

3 **Bid Security/ Bid Securing Declaration**

S. No.	Schedule No.	Bid Security/ Bid Securing Declaration Details (Bank Guarantee Number & Date/ NEFT/ RTGS/ Bid Securing Declaration Details)
3 (a)		
3 (b)		
3 (c)		
3 (d)		

Attached Documents

S. No.	Documents	Reference Bid page No.
3 (e)	Bid Security/ Bid Securing Declaration	

4. **Eligibility Requirement**

S. No.	Item Description	Yes/No	If Yes, Details thereof
4 (a)	Blacklisted/Debarred/Banned		
4 (b)	Relation with Officials of Procuring Entity		
4 (c)	Conflict of Interest		
4 (d)	Beneficial Ownership in Land Boarder Sharing Country [GFR Rule 144 (xi)]		DPIIT Registration No. : _____ Dated :_____ Valid Till :_____
4 (e)	MSME Status		Class: Micro/Small/Medium MSME Udhyam Reg. No. : _____ Dated : _____ Valid Till : _____ Udhyam Registration Classification S. No. | Classification Year | Enterprise Type | Classification Date | | | | | | | | | | | | | | | |
4 (f)	Startup		DPIIT Startup Reg. No. :_____

			Dated :_____ Valid Till :_____
4(g)	Integrity Pact		

4 (h) Local Content for Item Quoted

Schedule No.	Name of Item	Percentage Local Content	Location of Value Addition

Attached Documents

S. No.	Documents	Reference Bid page No., If Applicable
4 (i)	Eligibility Declaration (Form 1.2 of Bid Document)	
4 (j)	Blacklisting / Debarring/ Banning Order, If Any.	
4 (k)	Details of relationship with procuring entity, If Any.	
4 (l)	Details of Conflict of Interest, If Any.	
4 (m)	Copy of DPIIT Registration Certification under GFR Rule 144 (xi), if Beneficial Ownership in Land Boarder Sharing Country	
4 (n)	MSME Udhyam Registration Certificate, If MSE	
4 (o)	DPIIT Startup Registration Certificate, If Startup.	
4 (p)	Statutory Auditors Certificate for Local Content, If Purchase Value More than INR 10 Crore. Local Content Declaration Compliance. (Form 1.3 of Bid Document)	
4(q)	Integrity Pact (Form 1.4 of Bid Document)	

Note: Details in respect of Para 4 to 7 below are to be filled up separately for each of the schedule quoted.

5. **Schedule of Requirement Compliance**

S. No.	Complies with schedule of Requirement	Yes/No	If No, Details thereof
5 (a)			

Attached Documents

S. No.	Documents	Reference Bid page No.
5 (b)	Schedule of Requirement- Compliance & Deviation (Form 2 of Bid Document)	

6. **Technical Specification Compliance**

S. No.	Compliance with Technical Specification as Indicated in the Tender Documents	Yes/No	If No, Details thereof
6 (a)			

Attached Documents

S. No.	Documents	Reference Bid page No.
6 (b)	Technical Specifications & Quality Assurance- Compliance & Deviation (Form 3 of Bid Document)	
6 (c)	Long Term Stability Data in accordance with ITB Clause 9.2.1 (5)	

7. **Terms & Conditions Compliance**

S. No.	Compliance with Tender Terms & Conditions	Yes/No	If No, Details thereof
7 (a)			

Attached Documents

S. No.	Documents	Reference Bid page No.
7 (b)	Terms & Conditions Compliance (Form 5 of Bid Document)	

8. **Qualification Criteria Compliance**

S. No.	Description	Details
8 (a)	Bidder is Manufacturer	If No, Details thereof
8 (b)	Manufacturing License Details	License No. : _____ License Date : _____ License Validity : _____ Mfg. Address : _____ Issuing Authority: _____
8 (c)	WHO GMP Details	WHO GMP Certificate No. : _____ Date : _____ Valid Till : _____ License for which WHO GMP has been Issued : _____ Manufacturing Premises for which WHO GMP is Applicable : _____ Issuing Authority : _____
8 (d)	COPP Certificate Details	COPP Certificate No. : _____ Date : _____ Valid Till : _____ Item for which COPP Certificate has been Issued : _____ License for which COPP has been Issued : _____ Issuing Authority : _____
8 (e)	Market Standing Certificate	MSC valid for the F.Y. : _____&_____ MSC Certificate No. : _____ Date : _____ Valid Till : _____ License for which MSC has been Issued : __ Issuing Authority : _____
8 (f)	Non-Conviction Certificate	Non-Conviction Certificate Valid for F.Y. : ____&____ Non-Conviction Certificate No. : _____ Date : _____ Valid Till : _____ License for which Non Conviction Certificate has been Issued : _____ Issuing Authority :_____

8 (g)	Past Supplies Details	<table><tr><td>F.Y.</td><td>Quantity of Similar Items Supplied</td></tr><tr><td>2023-24</td><td></td></tr><tr><td>2024-25</td><td></td></tr><tr><td>Total</td><td></td></tr></table> Chartered Accountant Name : _____ Membership No. : _____ UDIN No. : _____ Date : _____
8 (h)	Manufacturing Capacity	Annual Production Capacity : _____ Mfg. License No. : _____ Licensing Authority Certificate No.: _____ Date : _____ Issuing Authority : _____
8 (i)	Turnover	<table><tr><td>F.Y.</td><td>Annual Turnover (Rs.)</td></tr><tr><td>2021-22</td><td></td></tr><tr><td>2022-23</td><td></td></tr><tr><td>2023-24</td><td></td></tr><tr><td>Average Annual Turnover</td><td></td></tr></table> Chartered Accountant Name : _____ Membership No. : _____ UDIN No. : _____ Date : _____
8 (j)	Successful Past Supplier of Quoted Item	Yes/No If Yes, details thereof

Attached Documents

S. No.	Document	Reference Bid Page No.
8 (k)	Manufacturing License	
8 (l)	If the item is not available in IP, Bidder's undertaking that the drug is not available in IP OR any other approve Pharmacopoeia	
8 (m)	WHO GMP Certificate	
8 (n)	COPP Certificate	
8 (o)	Market Standing Certificate	
8 (p)	Non-Conviction Certificate	
8 (q)	**Past Supplies Details**	
	Past Supplies POs	
	GST Invoices	

		E-way Bills	
		Document issued by Custom Authority, If Applicable	
		Affidavit, If Applicable	
		Past Performance Details in the Prescribed Proforma (Form 4.1 of Bid Document)	
	8 (r)	Manufacturing Capacity Certificate	
	8 (s)	Annual Turnover Statement in the Prescribed Proforma (Form 4.2 of Bid Document)	
	8 (t)	Audited Annual Report	
	8 (u)	CMSS P.O. Copy Executed Successfully	

……..
(Signature with date)
……..
(Name and designation)
Duly authorized to sign bid for and on behalf of…….

[name & address of Bidder and seal of company]

Form 7: Documents relating to Bid Security.

(Ref ITB-clause 9.2)

Note: To be submitted as part of Technical bid, along with supporting documents, if any. Submit as Form 7 as part of Technical bid, a Bid Securing Declaration In lieu of bid security in the following format. Bidders exempted from submission of bid security are also required to submit this.

Bid Securing Declaration ***(Should be notarised on Rs. 100 stamp papers)***

(on Company Letter-head)

Bidder's Name_____

[Address and Contact Details]

Bidder's Reference No._____ Date…….

To

DG & CEO, Central Medical Services Society, Ministry of Health and Family welfare, Government of India, New Delhi

Address: 2nd floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Road, Opposite Police Station Chanakaya Puri,

New Delhi-110021

Telephones: 011-21410905, 21410906

Ref: Your Tender Document No. Tender No./ xxxx; Tender Title: GOODS

Sir/ Madam

We, the undersigned, solemnly declare that:

We understand that according to the conditions of this Tender Document, for MSEs and Startups bidders, the bid must be supported by a Bid Securing Declaration in lieu of Bid Security.

We confirm that we are MSE/Startups and unconditionally accept the conditions of this Bid Securing Declaration. We understand that we shall stand automatically suspended from being eligible for bidding in any tender in Procuring Organisation for 2 years from the date of opening of this bid if we breach our obligation(s) under the tender conditions if we:

1) withdraw/ amend/ impair/ derogate, in any respect, from our bid, within the bid validity; or

2) being notified within the bid validity of the acceptance of our bid by the Procuring Entity:

a) refused to or failed to produce the original documents for scrutiny or the required Performance Security within the stipulated time under the conditions of the Tender Document.
b) Fail or refuse to sign the contract.

We know that this bid-Securing Declaration shall expire if the contract is not awarded to us, upon:

1) receipt by us of your notification

a) of cancellation of the entire tender process or rejection of all bids or
b) of the name of the successful bidder or

2) forty-five days after the expiration of the bid validity or any extension to it.

(Signature with date)
……..
(Name and designation)
Duly authorized to sign bid for and on behalf of…….
[name & address of Bidder and seal of company]
Dated on ……. day of …….. [insert date of signing]
Place……[insert place of signing]
DA:……

Form 7A: **Bank Guarantee for EMD (Format)**

Instruction to BG Issuing Bank – The Bank Guarantee should be through SFMS (Structured Financial Messaging System) & the following fields should be filled with the details given below.

FMS Field Number	SFMS Field Details	Details to be filled
7034	Name of Beneficiary and his Details	**CENTRAL MEDICAL SERVICES SOCIETY** 2ND FLOOR, VISHWA YUVAK KENDRA CHANKAYA PURI, NEW DELHI-110021
7035	Beneficiary IFSC	**HDFC0000003**
7036	Beneficiary Branch Name and Address	HDFC Bank Ltd 209-214 KAILASH BUILDING 26 KASTURBA GANDHI MARG NEW DELHI 110001
7037	Sender To Receiver Information	**CENTRALYCX**

This is captured in both IFN760 COV (BG Issuance) / IFN767 COV (BG Amendment, if any).

[The Bank shall fill in this Bank Guarantee Form in accordance with the instructions indicated.]

_____
*[insert **Bank's Name**, and **Address** of Issuing Branch or Office]*
Beneficiary: *[insert **Name and Address of Purchaser]***
Date: _____
BID GUARANTEE No.: _____

We have been informed that*[insert **name of the Tenderer**]* (hereinafter called "the Tenderer ") has submitted to you its bid dated (hereinafter called "the Bid")for the execution of *[insert **name of contract]*** under Tender No……
Furthermore, we understand that, according to your conditions, bids must be supported by a EMD.

At the request of the Tenderer, we *[insert **name of Bank]*** hereby irrevocably under take to pay you any sum or sums not exceeding in total an amount of *[insert **amount in figures]*** (*[insert **amount in words]***) upon receipt by us of your first demand in writing accompanied by a written statement stating that the Tenderer is in breach of its obligation(s) under the bid conditions, because the Tenderer:

a) has withdrawn its Bid during the period of bid validity specified by the Tenderer in the Form of Bid; or
b) having been notified of the acceptance of its Bid by the Purchaser during the period of bid validity, (i) fails or refuses to execute the Contract Form, if required, or(ii)fails or refuses to furnish the security deposit, in accordance with the Instructions to Tenderer s.
c) does not accept the correction of the Bid Price

d) This guarantee will expire: (a) if the Tenderer is the successful tenderer ,upon our receipt to copies of the contract signed by the Tenderer and the performance security issued to you upon the instruction of the Tenderer ; or(b) if the Tenderer is not the successful tenderer ,upon the earlier of (i) our receipt of a copy of your notification to the Tenderer of the name of the successful tenderer ;or (ii) Twenty Eight days after the expiration of the Tenderer 's Bid.

Consequently, any demand for payment under this guarantee must be received by us at the office on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No. 758.

_____

[signature(s)

FORMATS

Format 1: Letter of Acceptance
(Ref Clause 13.2.5 of ITB)

LETTER OF ACCEPTANCE

No: CMSS/PROC/2024-25/___/___ Date _____

To,
M/s _____
Address: _____
Attn: _____
Phone: _____
Email _____

(Kind Attn: _____(Name), _____ Designation)

Sub: Acceptance of Tender for supply of _____

Ref: 1) CMSS Tender No. **CMSS/PROC/2024-25/____/____** opened on _____
2) Your Ref. No. _____ dated _____ in response to above mentioned tender.

Dear Sir,
I am pleased to inform you that your offer in response to above mentioned tender for supply of _____has been accepted for following items:

Sch No.	Items Description	Quantity	Unit	Ex-Works per Unit (Rs.)	GST (%)	GST (Rs)	Transport & any other charges (Rs.)	Total unit price (all incl) (Rs.)	Grand Total (Rs.)
1									
2									
								Grand Total	

2. You are requested to deposit Security Deposit @ 3% of the total value by NEFT/ RTGS/ Bank Guarantee/Demand Draft/ Banker's Cheque and enter into an Agreement, as per the format given in **Annexure-X** of the Tender document, within 15 days from the date of receipt of this letter. The Security Deposit shall be valid for 1260 days from the date of commencement.

3. Please convey your acceptance to this LOA within 03 days of issue, else it will be presumed that you are not keen to accept the LOA and CMSS may proceed for allocation of quantity to other bidder and with other actions stipulated in referred Tender document.

4. All other terms and conditions will be applicable as per Tender document no. CMSS/PROC/2023-24/___/____ and subsequent amendments to it.

GM/Procurement

Annexure A to LOA No:
Supplier: M/s _____

Annexure-A

LIST OF MANUFACTURING LICENSES & SITE ADDRESSES					
Sr. No.	**Item Code**	**Item Description**	**Manufacturing Site Address**	**Manufacturing License No.**	**Remarks**
1					
2					
3					

Format 1A: Long Term Agreement (LTA)
(Ref Clause 13.2.5 of ITB)

LONG TERM AGREEMENT (LTA) NO.: CMSS/PROC/2024-25/____/LTA/_____
E- STAMP CERTIFICATE NO.:
LTA Validity: From _____ to _____

TERMS OF AGREEMENT

THIS AGREEMENT made the..... day of ....., year between **Central Medical Services Society, 2nd Floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Marg, Opposite Police Station Chankaya Puri, New Delhi-110021** (here in after "the Purchaser") of the one part and ..... (Name of Supplier) of..... (Address and Country of Supplier) (Here in after called "the Supplier") of the other part:

WHEREAS the Purchaser is desirous that certain Goods and ancillary services viz;
Procurement of _____

in the Tender Reference No. **CMSS/PROC/2024-25/___/____, Dt**_____(Brief Description of Goods and Services) and has accepted a bid by the Supplier for the supply of those goods and services for the sum of..... (Contract Price in Words and Figures) (Hereinafter called "the Contract Price").

WHEREAS the Supplier confirms that it is qualified, ready, willing and able to supply/services the **Procurement of** _____, in accordance with the terms and conditions of this Agreement.

1. DEFINITIONS

Commencement Date means _____

Expiry Date means _____

Products, in singular form Product, means the item(s), as described and detailed above, provided by the Supplier to CMSS from time to time pursuant to this agreement.

Tender means Tender No. Tender No: **CMSS/PROC/2024-25/____/____** from CMSS to the Supplier, to quote for the cost of supply of the Products to CMSS.

Long Term Agreement, as abbreviated to Agreement or LTA, means this Agreement between the Parties, to provide Products, including its Annexure, however with due consideration of the order of precedence among the LTA and individual Annexure.
Parties means CMSS and the Supplier, their successors and assigns and where not repugnant to the context, their servants or agents.

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:

1. **LTA DOCUMENTS:**

The following documents shall be deemed to form and be read and construed as part of this Agreement, viz.:

(a) This LTA
(b) The Notice Inviting Tender
(c) Terms and Conditions of Tender Document as given in Tender No: **CMSS/PROC/2024-25/___/___,** dt. _____
(d) The Minutes of Pre-Bid meeting and corrigendum issued.
(e) Schedule of Requirement.
(f) The Technical Specification
(g) The Supplier's Offer including Enclosures, Annexure etc.
(h) Any other document listed in the supplier's bid and replies to queries, clarifications issued by the purchaser, such confirmations given by the tenderer which are acceptable to the purchaser and the entire Addendum issued as forming part of the contract.
(i) The Letter of Acceptance issued by the purchaser.
(j) Integrity Pact

2. **PURPOSE OF LTA:**

2.1 The Purchaser hereby covenants to pay the Supplier in consideration of the provision of the goods, the Contract Price at the times and in the manner prescribed by this Agreement.

2.2 Brief particulars of the Products or goods which shall be supplied / provided by the Supplier are as under.

Sch No.	Items Description	Quantity	Unit	Ex-Works per Unit (Rs.)	GST (%)	GST (Rs)	Transport & any other charges (Rs.)	Total unit price (all incl) (Rs.)	Grand Total (Rs.)
1									
2									
								Grand Total	

2.3 The supplier agrees that his supplies are subject to terms and conditions details contained in LTA documents mentioned above. The supplier appreciates that the supplies are meant for public health system in the country and hence will agree to supply the goods of good quality as per standards in a timely manner as specified as per tender terms and conditions. The supplier has already given its no deviation (clause-by-clause compliance) for the subject terms and conditions.

3. Manufacturing License and Site
License and Site Address: As per Annexure A.

IN WITNESS where of the parties here to have caused this Agreement to be executed in accordance with their respective laws the day and year first above written.

Signed, Sealed and Delivered by the said..... (For the Purchaser)
in the presence of .....

Signature
Name
Address

Signed, Sealed and Delivered by the Said ..... (For the Supplier)
in the presence of .....

Signature
Name
Address
Annexure A to LTA No:
Supplier: M/s

Annexure-A

Annexure A to LTA No:
Supplier: M/s

LIST OF MANUFACTURING LICENSES & SITE ADDRESSES					
Sr. No.	**Item Code**	**Item Description**	**Manufacturing Site Address**	**Manufacturing License No.**	**Remarks**
1					
2					
3					

Format 1B: Purchase Order (PO)
(Ref Clause 13.2.5 of ITB)

PURCHASE ORDER

PO No: CMSS/PROC/2024-25/___/____ **Dated: _____**

To,

M/s _____
Address: _____
Attn: _____
Phone: _____
Email _____

Subject: ***Purchase Order for supply of _____***
Ref: Long Term Agreement No: CMSS/PROC/2024-25/___/___ /LTA/..... dated_____

Dear Sir,

Please supply following quantities for the items specified as per the technical specifications and terms & conditions of the Long-Term Agreement referred above:

Sr. No.	Item Code	Item Description	Quantity Accepted by the Purchaser	Unit	Ex Works Price per Unit (Rs)	GST (%)	GST (Rs)	Transportation Charges (Rs)	Rate Per Unit (Landed Price) (Rs)	Total Value (Rs)	Destination
1											As per Annex 1
2											As per Annex-1

1. All the Terms & Conditions of the Agreement signed by you on acceptance of your tender are applicable.
2. Delivery Period: As per Annexure A of the tender document
3. Manufacturing license as per Annexure A and site address as per Annexure B.
4. Payment Terms: Within 75 days of supplies in respect of items requiring sterility tests and within 60 days of supplies for other items.

General Manager (Procurement)

Copy to:

1. *General Manager (LSC), CMSS*
2. *General Manager (QA), CMSS*
3. *General Manager (Finance), CMSS*
4. *All Consignees (CMSS Warehouses) concerned.*

Annexure-A

Annexure A to PO No:
Supplier: M/s

CONSIGNEE-LIST						
Sr. No.	**Item Description**	**Consignee Location**	**Consignee Address**	**Quantity**	**UOM**	**Remarks**
1						
2						
3						

Annexure-B

Annexure B to PO No:
Supplier: M/s

LIST OF MANUFACTURING LICENSES & SITE ADDRESSES					
Sr. No.	**Item Code**	**Item Description**	**Manufacturing Site Address**	**Manufacturing License No.**	**Remarks**
1					
2					
3					

Format 1.1: **Bank Guarantee Format for Performance Security**

Instruction to BG Issuing Bank – The Bank Guarantee should be through SFMS (Structured Financial Messaging System) & the following fields should be filled with the details given below.

FMS Field Number	SFMS Field Details	Details to be filled
7034	Name Of Beneficiary and His Details	**CENTRAL MEDICAL SERVICES SOCIETY** 2ND FLOOR, VISHWA YUVAK KENDRA CHANKAYA PURI, NEW DELHI-110021
7035	Beneficiary IFSC	**HDFC0000003**
7036	Beneficiary Branch Name and Address	HDFC Bank Ltd 209-214 KAILASH BUILDING 26 KASTURBA GANDHI MARG NEW DELHI 110001
7037	Sender To Receiver Information	**CENTRALYCX**

This is captured in both IFN760 COV (BG Issuance) / IFN767 COV (BG Amendment, if any).

(Ref Clause 9.4 of ITB and clause 5.8 of GCC)

To
DG & CEO, Central Medical Services Society, Ministry of Health and Family welfare, Government of India, New Delhi
Address: 2nd floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Road, Opposite Police Station Chanakaya Puri,
New Delhi-110021
Telephones: 011-21410905, 21410906
Ref: Your Tender Document No. Tender No./ xxxx; Tender Title: GOODS

Whereas…… (name and address of the contractor) (hereinafter called "the contractor") has undertaken, in pursuance of contract no …….. date……. to supply …… (description of goods and Works/ Services) (hereinafter called "the contract").
And Whereas you have stipulated it in the said contract that the contractor shall furnish you with a bank guarantee by a Commercial bank for the sum specified therein as security for compliance with its obligations as per the contract;

And Whereas we have agreed to give the contractor such a bank guarantee.

Now Therefore we hereby affirm that we are guarantors and responsible to you, on behalf of the contractor, up to a total of …….(amount of the guarantee in words and figures), and we undertake to pay you, upon your first written demand declaring the contractor to be in default under the contract and without cavil or argument, any sum or sums within the limits of (amount of guarantee) as aforesaid, without your needing to prove or to show grounds or reasons for your demand or the sum specified therein.

We hereby waive the necessity of your demanding the sail debt from the contractor before presenting us with demand.

We further agree that no change or addition to or other modification of the terms of the contract to be performed there under or of any of the contract documents which may be made between you and the contractor shall in any way release us from any liability under this guarantee, and we hereby waive notice of any such change, addition, or modification.

This guarantee shall be valid until the …….day of …….20……

Our…….branch at……*(Name & Address of the ……..……..*(branch) is liable to pay the guaranteed amount depending on the filing of a claim and any part thereof under this Bank Guarantee only and only if you serve upon us at our ……* branch a written claim or demand and received by us at our ……..* branch on or before Dt…….. otherwise, the bank shall be discharged of all liabilities under this guarantee after that.

(Signature of the authorized officer of the Bank)
…….
…….
Name and designation of the officer
……
Seal, name & address of the Bank and address of Branch

*Preferably at the headquarters of the authority competent to sanction the expenditure for the procurement of goods or at the concerned district headquarters or the state headquarters.

Format 1.2: No Claim Certificate
(Refer Clause 12.3.1 of GCC)
(On company Letter-head)
Contractor's Name_____
[Address and Contact Details]
Contractor's Reference No._____ Date…….
To

DG & CEO, Central Medical Services Society,
Ministry of Health and Family Welfare,
Government of India, New Delhi
Address: 2nd floor, Vishwa Yuvak Kendra,
Pt. Uma Shankar Dikshit Marg, Teen Murti Road, Opposite Police Station Chanakaya Puri,
New Delhi-110021
Telephones: 011-21410905, 21410906

No Claim Certificate

Sub: Contract Agreement no. ---------- dated ----------for the supply of ----------

We have received the sum of Rs. (Rupees _____only) as final settlement due to us for the supply of_____
under the abovementioned contract agreement.

We have received all the amounts payable to us with this payment and have no outstanding dispute of any description whatsoever regarding the amounts worked out as payable to us and received by us.

We hereby unconditionally and without any reservation whatsoever, certify that we shall have no further claim whatsoever, of any description, on any account, against the Procuring Entity, under contract above. We shall continue to be bound by the terms and conditions of the contract agreement regarding its performance.

Yours faithfully,

Signatures of contractor or
officer authorised to sign the contract documents.
on behalf of the contractor

(company Seal)

Date:_____
Place:_____

Format 1.3: Certification by Prospective Arbitrators
(Ref Clause 11.5.4 of GCC)
To
DG & CEO, Central Medical Services Society,
Ministry of Health and Family welfare, Government of India, New Delhi
Address: 2nd floor, Vishwa Yuvak Kendra,
Pt. Uma Shankar Dikshit Marg, Teen Murti Road,
Opposite Police Station Chanakaya Puri,
New Delhi-110021
Telephones: 011-21410905, 21410906

Certification by Prospective Arbitrators

1. Name: _____
2. Contact Details: _____
3. I hereby certify that I am retired officer of *[Name of Organisation]* retired as_____in_____grade.
4. I have no past or present relationship concerning the subject matter in dispute, whether financial, business, and professional or another kind.

Or

I have past or present relationships concerning the subject matter in dispute, whether financial, business, professional or another kind. The list of such interests is as under:------

5. I have no past or present relationship/ interest financial, business, professional or other, in any of the parties, which may raise justifiable doubts about my independence or impartiality in terms of the Arbitration and Conciliation Act 1996 amended from time to time.

Or

I have past or present relationship/ interest financial, business, professional or other, in any of the parties, which may raise justifiable doubts about my independence or impartiality in terms of the Arbitration and Conciliation Act 1996 as amended from to time. The details of such relationship or interest are as under:----------

6. There are no concurrent circumstances that are likely to affect my ability to devote sufficient time to the arbitration and finish the entire arbitration within twelve months.

Or

Some circumstances are likely to affect my ability to devote sufficient time to the arbitration and finish the entire arbitration within twelve months. The list of such circumstances is as under:----------

Signature)
(Name & Designation)

Format 2: Authorization for Attending Pre-bid Conference

(Refer ITB-Clause 8)

(on Company Official Letter Head)

Bidder's Name_____

[Address and Contact Details]

Bidder's Reference No._____ Date…….

To

DG & CEO, Central Medical Services Society, Ministry of Health and Family welfare, Government of India, New Delhi

Address: 2nd floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Road, Opposite Police Station Chanakaya Puri,

New Delhi-110021

Telephones: 011-21410905, 21410906

Ref: Your Tender Document No. Tender No./ xxxx; Tender Title: GOODS

Subject: Authorization for attending Pre-bid Conference on _____ (date).

Following persons are hereby authorized to attend the Pre-bid Conference for the tender mentioned above on behalf of _____ (Bidder) in order of preference given below.

Sr.	Name	Government Photo ID Type/ Number
I.		
II.		
Alternate Representative		

Note:

1. Maximum of two representatives (carrying valid Government photo IDs) shall be permitted to attend the Pre-bid opening. An alternate representative shall be permitted when regular representatives are not able to attend.

2. Permission to enter the hall where the pre-bid conference is conducted may be refused if authorization as prescribed above is not submitted.

Signatures of bidder

or

Officer authorized to sign the bid.

Documents on behalf of the bidder

[name & address of Bidder and seal of company]

Format 3: CONSIGNEE RECEIPT CERTIFICATE

(To be issued by consignee's authorized representatives upon receipt of goods)
The material of below mentioned consignment has been received in good condition:

1) Name of the items supplied: _____

2) Quantity of items Supplied: _____

3) Supplier's Name: _____

4) P.O No. & date: _____

5) Tranche No: _____

6) Invoice No. & Invoice Date_____

7) Batch No._____

8) (i) Consignee's Name & Address _____

_____

(ii) Email ID of consignee _____

(iii) Telephone/Mobile No. of Consignee _____

9) Date of Receipt of items by consignee: _____

10) Name and designation of Authorized Representative of Consignee: _____

_____

11) Signature of Authorized Representative of Consignee with date: _____

CERTIFICATE

We confirm having received material as detailed above in good condition on Dt._____ in accordance with the contract and entered in the stock ledger: - _____

Counter Signed by Head /Director/ MS/ Dean/ of the concerned Hospital/ Institute/ Organization:

Name: _____

Designation: _____

Signature: _____

Date: _____

Seal of the Consignee _____

Sample 1 of a BOQ

As per GeM format