CENTRAL MEDICAL SERVICES SOCIETY

(An Autonomous Body under Ministry of Health & Family Welfare, Govt. of India)
2nd Floor, Vishwa Yuvak Kendra, Teen Murti Marg,
Chanakyapuri, New Delhi-110021.

सत्यमेव जयते

Date: 19.10.2026

Minutes of Pre-bid meeting held on 17.09.2026 at 11:00 AM regarding Tender No.: CMSS/PROC/2026-27/NTEP/034 dated 10.09.2026 for procurement of Second-Line Anti-TB Drugs for NTEP

Pre-bid queries raised by the bidder and Clarifications / Amendments by CMSS:

Sr. No.	Tender Clause No. & Page No.	As per Tender	Bidder's Query	Clarifications / Amendments
1.			We wish to submit a formal representation regarding the procurement terms, eligibility, and Make in India /local content criteria for Cycloserine. While our manufacturing operations are based overseas and do not meet the prescribed local value-addition thresholds under the Public Procurement (Preference to Make in India) guidelines, we submit the following considerations for your evaluation: Global Standing & Comprehensive Anti-TB Capabilities Dong-A ST is an established global pioneer in the research, development, and manufacturing of Second-Line and Novel Anti-TB Drugs (both Active Pharmaceutical Ingredients and Finished Formulations). Cycloserine: WHO Pre-Qualified (WHO-PQ) for both API and Finished Formulations. • Clofazimine: WHO Pre-Qualified (WHO-PQ) for both API and Formulations. • Bedaquiline: Under finalization / filing for WHO-PQ (API & Formulations). • Pretomanid & Delamanid: Advanced manufacturing pipelines aligning with next-generation BPaL/M regimens. • Terizidone: Dedicated manufacturing infrastructure for both API and Formulations. Cycloserine: Clinical Validation & Technical Merits Our Cycloserine formulation delivers distinct clinical, operational, and supply-chain advantages directly relevant to India's public health network: • WHO Prequalification (WHO-PQ): Both API and Formulations comply fully with stringent global cGMP, bioequivalence, and safety standards verified by the World HealthOrganization. • Clinical Trial Parity with Innovator: Our finished formulation has completed comprehensive clinical trials and	**Clarified as:** No change.

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<table>
<tr><td></td><td></td><td></td><td>bioequivalence comparisons against the Innovator brand, confirming bio-availability and therapeutic equivalence.
• Extended 4-Year Shelf Life: Validated by stability studies, our formulation offers a 4-yearshelf life—a critical operational advantage that minimizes supply-chain expiry waste, simplifies central/state buffer warehousing, and preserves potency across diverse storage conditions.
• Proven Global Supply Record: We have an established, continuous track record of supplying multilateral health programs, Stop TB Partnership / Global Drug Facility (GDF), and national health ministries across the globe.</td><td></td></tr>
<tr><td>2.</td><td>SECTION I. NOTICE INVITING TENDER (NIT) & Pg No. 3</td><td></td><td>The Unit of Measurement should be amended in tender documents as well as BOQ as follows in line with technical specification;
<table><tr><th>Sch No.</th><th>Name of the Item</th><th>Unit</th></tr><tr><td>II</td><td>Clofazimine Tablet -100mg</td><td>Strip of 10 Capsule/Tablets</td></tr><tr><td>III</td><td>Cycloserine-250mg</td><td>Strip of 10 Capsule</td></tr></table>
Note-
For Sch. II- Technical Specification allows for Tablets/Capsules.
For Sch. III- Technical specification allows only Capsules.</td><td>Clarified as:

Refer Amendment No. 3</td></tr>
<tr><td>3.</td><td>SECTION VI & Page No. 69
Para J. Packing</td><td>A strip consisting of individual blister of the drugs duly identified should be packed in an Aluminum PVC – Blister pack. The Blister should be tropicalized with regard to moisture barrier properties for drugs stability under field conditions.
Aluminum PVC Blister:
PVC Film: Transparent, clear /amber, food grade, blister forming PVC film, film gauge – 200 microns, PE coating: 25 microns PVdC coating: 60gsm.</td><td>We request CMSS to accept the Product Moxifloxacin 400mg in Alu Alu Strip as per last supplied to CMSS.

Referring to your packing requirement for the aforementioned products in Alu-PVC; this is to inform you that Alu-PVC & Alu-Alu doesn't make any difference in term of delivery of product to the patient. Both products are equally patient friendly packaging, in fact Alu-Alu strip pack is a better pack than Alu-PVC blister pack considering the following points:
➢ Strip pack is of Aluminum based material which has a good resistance to temperature changes than Alu-PVC pack which is a plastic base material with limited heat resistance.
➢ Alu-Alu strip pack has excellent barrier properties than Alu-PVC with respect to humidity, oxygen and U.V rays.
➢ Alu-Alu strip pack has better thermal stability than Alu-PVCmaterial.</td><td>Clarified as:

<u>For Schedule I & XIV:</u>

Both Aluminium-PVC Blister pack or Alu-Alu Strip pack are acceptable.</td></tr>
<tr><td>4.</td><td>SECTION VI & Page No. 76
Para J. Packing</td><td>A strip consisting of individual blister of the drugs duly identified should be packed in an
Aluminum PVC – blister pack. The blister should be tropicalized with regard to</td><td>We request CMSS to accept the Product Clofazimine 100mg in Alu Alu Strip.

Referring to your packing requirement for the aforementioned products in Alu-PVC; this is to inform you that Alu-PVC& Alu-Alu doesn't make any difference in term of delivery of</td><td>Clarified as:

<u>For Schedule II & XV:</u>

Both Aluminium-PVC Blister pack or Alu-Alu Strip pack are acceptable.</td></tr>
</table>

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		moisture barrier properties for drugs stability under field conditions. Aluminum PVC Blister: PVC film: Transparent, clear /amber, food grade, blister forming PVC film, film gauge – 200 microns, PE coating: 25 microns PVdC coating: 60gsm.	product to the patient. Both products are equally patient friendly packaging, in fact Alu-Alu strip pack is a better pack than Alu-PVC blister pack considering the following points: ➢ Strip pack is of Aluminum based material which has a good resistance to temperature changes than Alu-PVC pack which is a plastic base material with limited heat resistance. ➢ Alu-Alu strip pack has excellent barrier properties than Alu-PVC with respect to humidity, oxygen and U.V rays. ➢ Alu-Alu strip pack has better thermal stability than Alu-PVCmaterial.	
5.	SECTION VI & Page No. 82 Para J. Packing	The drug is initially packed in a Strip containing 10 capsules. 10 such strips would be further packed in white coloured Millboard/Grey board boxes and 20 such Boxes are ultimately packed in 5-Ply Shipper. Individual capsules duly identified should be packed in an Aluminium /Aluminium strip. The strip should be tropicalized with regard to moisture barrier properties for drug stability under field conditions. Quality Assurance is according to Norm ISO 9001 for all the packaging material. Aluminum foil: Hard tempered foil, VMCH coated, Thickness: 0.025mm. Spacing between capsules should be enough so as to allow removal by patients with finger deformities.	**We request CMSS to accept the product Cycloserine 250mg in Alu- Alu Blister.** This is to inform you that both Alu-Alu blister and Alu-Alu strip are patient friendly packing. However, Alu-Alu blister packaging offers the advantage of individual unit-dose packaging, where each dose is isolated and protected, maintaining its integrity of the soft gelatin capsule. Also, blister packaging provides excellent protection against various environmental factors, including moisture, light, and air. The blister compartments create a barrier that shields the medication from external elements, preserving its stability and efficacy throughout its shelf life which give the stability data throughout its shelf life for 36 months. So, this packaging shelf life gives as 36months. Therefore, considering the characteristic features of Alu-Alu blister, it assures that there is no impact on product quality when packed in Alu-Alu blister.	**Clarified as:** **<u>For Schedule III:</u>** Both Aluminium–strip pack or Aluminium –blister packaging are acceptable.
6.	SECTION VI & Page No. 99 Para J. Packing	A strip consisting of individual blister of the drugs duly identified should be packed in an Aluminum PVC – blister pack. The blister should be tropicalized with regard to moisture barrier properties for drugs stability under field conditions. Aluminium-PVC Blister: PVC Film: Transparent, clear /amber, food grade, blister forming PVC film, film gauge – 200microns, PE coating: 25 microns, PVdC coating: 60gsm.	**We request CMSS to accept the Product Ethambutol 800mg in Alu Alu Strip.** Referring to your packing requirement for the aforementioned products in Alu-PVC; this is to inform you that Alu-PVC& Alu-Alu doesn't make any difference in term of delivery of product to the patient. Both products are equally patient friendly packaging, in fact Alu-Alu strip pack is a better pack than Alu-PVC blister pack considering the following points: ➢ Strip pack is of Aluminum based material which has a good resistance to temperature changes than Alu-PVC pack which is a	**Clarified as:** **<u>For Schedule VI:</u>** Both Aluminium-PVC Blister pack or Alu-Alu Strip pack are acceptable.

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			plastic base material with limited heat resistance. ➢ Alu-Alu strip pack has excellent barrier properties than Alu-PVC with respect to humidity, oxygen and U.V rays. ➢ Alu-Alu strip pack has better thermal stability than Alu-PVCmaterial.	
7.	SECTION VI & Page No. 117 Para J. Packing	A strip consisting of individual blister of the drugs duly identified should be packed in an Aluminium-PVC blister pack. The blister should be tropicalized with regard to moisture barrier properties for drugs stability under field conditions. Aluminum-PVC Blister: PVC Film: Transparent, clear /amber, food grade, blister forming PVC film, film gauge – 200microns, PE coating: 25 microns, PVdC coating: 60gsm.	**We request CMSS to accept the Product Pyrazinamide 500mg in Alu Alu Strip.** Referring to your packing requirement for the aforementioned products in Alu-PVC, this is to inform you that Alu-PVC& Alu-Alu doesn't make any difference in term of delivery of product to the patient. Both products are equally patient friendly packaging, in fact Alu-Alu strip pack is a better pack than Alu-PVC blister pack considering the following points: ➢ Strip pack is of Aluminum based material which has a good resistance to temperature changes than Alu-PVC pack which is a plastic base material with limited heat resistance. ➢ Alu-Alu strip pack has excellent barrier properties than Alu-PVC with respect to humidity, oxygen and U.V rays. ➢ Alu-Alu strip pack has better thermal stability than Alu-PVCmaterial.	**Clarified as:** **<u>For Schedule X:</u>** Both Aluminium-PVC Blister pack or Alu-Alu Strip pack are acceptable.
8.	SECTION VI & Page No. 141 Para J. Packing	A strip consisting of individual blister of the drugs duly identified should be packed in an Aluminium-PVC blister pack. The blister should be tropicalized with regard to moisture barrier properties for drug stability under field conditions. Aluminum-PVC Blister: PVC Film: Transparent, clear /amber, food grade, blister forming PVC film, film gauge – 200microns, PE coating: 25 microns PVdC coating: 60gsm.	**We request CMSS to accept the Product Rifampicin 450mg in Alu Alu Strip.** Referring to your packing requirement for the aforementioned products in Alu-PVC, this is to inform you that Alu-PVC& Alu-Alu doesn't make any difference in term of delivery of product to the patient. Both products are equally patient friendly packaging, in fact Alu-Alu strip pack is a better pack than Alu-PVC blister pack considering the following points: ➢ Strip pack is of Aluminum based material which has a good resistance to temperature changes than Alu-PVC pack which is a plastic base material with limited heat resistance. ➢ Alu-Alu strip pack has excellent barrier properties than Alu-PVC with respect to humidity, oxygen and U.V rays. ➢ Alu-Alu strip pack has better thermal stability than Alu-PVCmaterial.	**Clarified as:** **<u>For Schedule XIII & XX:</u>** Both Aluminium-PVC Blister pack or Alu-Alu Strip pack are acceptable.
9.	SECTION VI-TECHNICAL SPECIFICATIONS AND QUALITY ASSURANCE	Protocols & Testing: Microbial Count: Each Batch should be accompanied with a certificate from the manufacturer that the drugs meet the specified requirements.	**For All Schedules** Request to allow Skip Test of Microbial test. So please remove the clause to mention Micro test in each batch. As per WHO guideline Microbial test is done on first five Commercial batches & then after	**Clarified as:** No Change.

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			on first and every 10th batch of the year whichever is earlier.	
10.	SECTION VIII – SPECIAL CONDITIONS OF CONTRACT & Page No. 208 Para GCC 7.1.7	The goods supplied under the contract shall be subjected to Pre-Delivery Inspection at manufacturer's manufacturing premises before dispatch.	We request to do the PDI for Tranche I – Lot 1 and rest consider as NON PDI. This is because after the completion of PDI by QA/QC department, and then until the Lab result are not received to CMSS by their irrespective Lab, we are unable to dispatch the goods until we get dispatch confirmation by QA/QC team. We are not getting green light for dispatch more than 1 month after the completion of Pdi procedure. After receiving dispatch confirmation, transportation itself takes additional days to get the goods delivered. This makes us more challenging to get the delivery done on time to avoid LD charges or product short shelf-life issues. So to avoid such circumstances, we request to consider Tranche I as PDI & rest orders as NON PDI for smooth dispatches and deliveries.	**Clarified as:** No Change.
11.	SECTION VIII – SPECIAL CONDITIONS OF CONTRACT & Page No. 208 Para GCC 8.7.5	The contractor shall ensure that at least 5/6th of shelf-life remains balance on delivery date.	Please refer to this condition; instead of 5/6th (83%), we ask that the consignee be given a minimum of 75% shelf life at the time of delivery. This is because we manufacture in lots at once, and it takes time for those batches to get released, followed by PDI and further dispatches post CMSS's clearance. As a result of this drawn-out process, approximately one-fifth of the shelf life is lost.	**Clarified as:** No Change.
12.	SECTION IX-BIDDING FORMS & Page No. 227 Form 4.1: PROFORMA FOR PERFORMANCE STATEMENT:		Refer to this format, we request you to remove Unit price all inclusive & total value details, as those details are confidential, so we would not like to share the said details.	**Clarified as:** Bidder may mask the unit price all inclusive & total value details.
13.	SECTION V-SCHEDULE OF REQUIREMENTS & Page No. 64 Delivery Terms: (b) Delivery Schedule:	The bidder shall deliver the following quantities within 90 days of issue of Purchase Order:	We understand 20% - 35% of the tender quantities have been asked to deliver in 90 days. It takes time for arranging the raw materials, packing materials, excipients itself will take 40 to 45 days. Once all the materials are available further 10-15 days for granulation, compression, coating, packing and additional 15 days batch release by QA/QC. Once the goods are additional time for PDI. We cannot anticipate in how many days we will receive the greenlight from NTEP/CMSS to ship the goods to the warehouses. Thus, delivering the goods to the destination within 90 days is not possible. Request you to either decrease the quantities to 5% to deliver in 90 days or increase the lead-time to 120 days for delivering the goods.	**Clarified as:** No Change.

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14.	SECTION VII: GENERAL CONDITIONS OF CONTRACT (GCC) & Page No. 181 9.12 Liquidated damages	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.	We have been supplying several medicines to CMSS/NTP since past many years without defaulting. Considering the long-term association and proving our reliability, we request you to remove the liquidated damages clause from the tender.	**Clarified as:** No Change.
15.	SECTION-IV - QUALIFICATION CRITERIA & Page No. 62 Para k)	Copies of the audited Annual reports including the Balance Sheet and Profit and Loss Account for the last three years i.e. 2022-23, 2023-24 and 2024-25 OR 2023-24, 2024-25 and 2025-26 duly certified by a practicing Chartered Accountant, where ever applicable.	Regarding Annual Audited documents, we request you to allow us to submit Annual Turnover Statement, Balance Sheet & Profit Loss account details only of last 3 years instead of full Audited Annual reports. As our audited balance sheet copies for 3 years are, approximately 500 pages (Total), due to which we have to compress the pdf file until its gets below 40MB limit to uploaded it on the portal. In many cases due to this compression of the PDF file, several pages are not legible, on which we keep on receiving queries during technical evaluation. Alternatively, we request you to increase the total limit to upload the documents on the portal.	**Clarified as:** Bidder may submit Annual Turnover Statement, Balance Sheet & Profit Loss account details of last 3 years instead of full Audited Annual reports.



<table>
<tr><td>16.</td><td></td><td></td><td>We hereby request you to allow 2nd round to ask clarifications about the said tender, as this tender – RATE CONTRACT is new for us and we may have more queries along the way while preparing for the tender.</td><td>Clarified as:

As per tender terms & conditions.</td></tr>
<tr><td>17.</td><td></td><td></td><td>Refer to Sch – XI, XII, XIII, XVIII, XIX, XX

Due to fluctuation of Rifampicin API and increase in price, so request you not to consider NPPA rates.</td><td>Clarified as:

No Change.</td></tr>
<tr><td>18.</td><td>SECTION VII: GENERAL CONDITIONS OF CONTRACT (GCC) & Page No. 178
8.7.5 Perishable Goods</td><td>For Goods with a limited shelf life, the contractor shall ensure that at least 5/6th (or any other period/criteria stipulated in the SCC) of shelf-life remains balance on delivery date. The Procuring Entity reserves rights to reject expired or products with less than such specified shelf life.</td><td>We kindly request that the residual shelf-life requirement for Delamanid 50 mg (Product Code: 63) be revised from 5/6th to 3/4th of the total approved shelf life, considering its product-specific manufacturing requirements:

Complex manufacturing: Specialized API synthesis and solid dispersion formulation, with stringent controls for oxygen, light and moisture, including nitrogen-purged packaging.

Extended lead time: End-to-end manufacturing cycle requires approximately 10?12 months lead time
(from API manufacturing to FPP), including 2?3 months for API-to-FPP conversion.

Shelf-life methodology: Shelf life is calculated from the API manufacturing date, meaning a significant portion is utilized during manufacturing and FPP conversion, while the product maintains its approved stability through the stated expiry.

In view of these factors, we request acceptance of 3/4th of the total approved shelf life as the minimum residual shelf life at delivery.</td><td>Clarified as:

No Change.</td></tr>
<tr><td>19.</td><td>SECTION V SCHEDULE OF REQUIREMENTS & Page No. 63</td><td></td><td>Please clarify whether both schedule requirements are different.

<table><tr><td>Schedule</td><td>Requirement (Tablets)</td></tr><tr><td>IV Delamanid-50mg</td><td>70,26,200</td></tr><tr><td>XVI Delamanid-50mg (Developmental Tender Schedule)</td><td>17,56,550</td></tr></table></td><td>Clarified as:

Refer Tender Clause ITB 9.2.1.3 of Section II: Instructions To Bidders (ITB).</td></tr>
<tr><td>20.</td><td>SECTION VI TECHNICAL SPECIFICATIONS AND QUALITY ASSURANCE & Page No. 87
Para K.</td><td>Labelling on Millboard/Grey board Box</td><td>Please confirm whether the labelled texts mentioned are correct.

DR-TB TREATMENT DRUG CONTAINS DELAMANID50mg
(Product Code 63)
?Central Government supply not for sale?</td><td>Clarified as:

DR-TB TREATMENT DRUG CONTAINS DELAMANID 50mg
(Product Code 63)
Central Government Supply – Not for Sale</td></tr>
<tr><td>21.</td><td>SECTION VI TECHNICAL SPECIFICATIONS</td><td>Labelling on 5-Ply Shipper</td><td>Please confirm whether the labelled texts mentioned are correct.</td><td>Clarified as:</td></tr>
</table>

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	AND QUALITY ASSURANCE & Page No. 88 Para L.		TB TREATMENT DRUG CONTAINS DELAMANID50mg (Product Code 63) ?Central Government supply not for sale?	DR-TB TREATMENT DRUG CONTAINS DELAMANID 50mg (Product Code 63) Central Government Supply – Not for Sale
22.	SECTION VI & Pg No. 66		**Moxifloxacin-400mg (Strip of 10 Tablets)** **Clauses (J) relating to packing of millboard/grey board boxes/ nit) is mentioned that the drug is initially packed in blister strips, each strip containing 10 tablets, IO such strips would be further packed in white coloured Millboard/Grey Board boxes and 20 such boxes are further packed in 5-ply shipper.** In this regard, we would like to submit that the box containing 10 blister strips may appropriately be fabricated entirely from 400 GSM Millboard/Grey Board, instead of using 3 mm corrugated cardboard with inner and outer coverings. This construction would provide adequate strength, durability, and overall suitability for the intended packaging requirements. Further, 20 such boxes may be packed in one 3-ply shipper. Subsequently, four such 3-ply shippers, each containing 20 boxes of 10 X 10strips, may be packed into one final 5-ply outer shipper. This configuration would ensure that the total weight of each shipping carton remains within approximately 12–15 kg, thereby facilitating safe handling, transportation, and storage.	**Clarified as:** No Change.
23.	SECTION VI & Pg No. 79		**Cap Cycloserine- 250mg (Strip of 10 Tablets)** **Technical Specification and Quality Assurance, Individual Capsules duly identified should be packed in an Aluminium Aluminium Strip.** We would like to submit that Aluminium-PVC blister packaging is a feasible and suitable packaging, considering its stability and practical handling requirements. Further, the cost of Aluminium/Aluminium Strip packaging is considerably higher, which may have a direct impact on the overall cost of the product and the production capacity of Aluminium/Aluminium Strip is lower due to slower packing process. We kindly request that the packaging specification may be amended to permit Aluminium-PVC blister packaging in addition to Aluminium/Aluminium Strip packaging. In this regard, we would like to submit that the box containing 10 blister strips may appropriately be fabricated entirely from 400 GSM Millboard/Grey Board, instead of using 3	**Clarified as:** Both Aluminium–strip pack or Aluminium –blister packaging are acceptable. No Change in packaging requirement

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			mm corrugated cardboard with inner and outer coverings. This construction would provide adequate strength, durability, and overall suitability for the intended packaging requirements. Further, 20 such boxes may be packed in one 3-ply shipper. Subsequently, four such 3-ply shippers, each containing 20 boxes of 10 X 10strips, may be packed into one final 5-ply outer shipper. This configuration would ensure that the total weight of each shipping carton remains within approximately 12–15kg, thereby facilitating safe handling, transportation, and storage.	
24.	SECTION VI & Pg No. 90		**Ethambutol- 400mg Tablet & Ethambutol 800mg Tablet (Strip of 10 Tablets)** Section VI Clauses (l) relating to packing of millboard/grey board boxes, it is mentioned that the drug is initially packed in blister strips containing IO tablets, IO such strips would be further packed in white coloured Millboard/Grey Board boxes and 20 such boxes are further packed in 5-Ply shipper. In this regard, we would like to submit that the box containing 10 blister strips may appropriately be fabricated entirely from 400 GSM Millboard/Grey Board, instead of using 3 mm corrugated cardboard with inner and outer coverings. This construction would provide adequate strength, durability, and overall suitability for the intended packaging requirements. Further, 20 such boxes may be packed in one 3-ply shipper. Subsequently, four such 3-ply shippers, each containing 20 boxes of 10 X 10strips, may be packed into one final 5-ply outer shipper. This configuration would ensure that the total weight of each shipping carton remains within approximately 12–15kg, thereby facilitating safe handling, transportation, and storage.	**Clarified as:** No Change.
25.	SECTION VI & Pg No. 102		**Levofloxacin-250mg & Levofloxacin- 500mg (Strip of 10 Tablets)** Section VI Clauses (J) relating to packing of millboard/grey board boxes, it is mentioned that the drug is initially packed in blister strips containing 10 tablets, 10 such strips would be further packed in white coloured Millboard/Grey Board boxes and 20 such boxes are further packed in 5-Ply Shiper. In this regard, we would like to submit that the box containing 10 blister strips may appropriately be fabricated entirely from 400 GSM Millboard/Grey Board, instead of using 3 mm corrugated cardboard with inner and outer coverings. This construction would provide adequate strength, durability, and overall	**Clarified as:** No Change.

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			suitability for the intended packaging requirements. Further, 20 such boxes may be packed in one 3-ply shipper. Subsequently, four such 3-ply shippers, each containing 20 boxes of 10 X 10strips, may be packed into one final 5-ply outer shipper. This configuration would ensure that the total weight of each shipping carton remains within approximately 12–15kg, thereby facilitating safe handling, transportation, and storage.	
26.	SECTION VI & Pg No. 114		**Pyrazinamide- 500mg & Pyrazinamide-750mg (Strip of 10 tablets)** Section VI Clauses (J) relating to packing of millboard/grey board boxes, it is mentioned that the drug is initially packed in blister strips containing 10 tablets, 10 such strips would be further packed in white coloured Millboard/Grey Board boxes and 20 such boxes are further packed in 5-Ply shipper. In this regard, we would like to submit that the box containing 10 blister strips may appropriately be fabricated entirely from 400 GSM Millboard/Grey Board, instead of using 3 mm corrugated cardboard with inner and outer coverings. This construction would provide adequate strength, durability, and overall suitability for the intended packaging requirements. Further, 20 such boxes may be packed in one 3-ply shipper. Subsequently, four such 3-ply shippers, each containing 20 boxes of 10 X 10strips, may be packed into one final 5-ply outer shipper. This configuration would ensure that the total weight of each shipping carton remains within approximately 12–15kg, thereby facilitating safe handling, transportation, and storage.	**Clarified as:** No Change.
27.	SECTION VI & Pg No. 126		**Capsule Rifampicin-150mg & Capsule Rifampicin- 450mg (Strip of 10 Capsules)** Section VI Clauses (J) relating to packing of millboard/grey board boxes, it is mentioned that the drug is initially packed in blister strips containing 10 capsules, 10 such strips would be further packed in white coloured Millboard/GreV Board boxes and 20 such boxes are further packed in 5-Ply shipper. In this regard, we would like to submit that the box containing 10 blister strips may appropriately be fabricated entirely from 400 GSM Millboard/Grey Board, instead of using 3 mm corrugated cardboard with inner and outer coverings. This construction would provide adequate strength, durability, and overall suitability for the intended packaging requirements. Further, 20 such boxes may be packed in one 3-ply shipper. Subsequently, four	**Clarified as:** No Change.

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			such 3-ply shippers, each containing 20 boxes of 10 X 10strips, may be packed into one final 5-ply outer shipper. This configuration would ensure that the total weight of each shipping carton remains within approximately 12–15kg, thereby facilitating safe handling, transportation, and storage.	
28.			There are two parts of tender, one is regular and the other is developmental tender. We would like to know if we can participate and quote for both the quantities for the same item in the tender for the same company as the company may or may not have requisite performance certificate for the said quantity as desired in the tender. If we can quote for both quantities, it gives the manufacturer to at least participate and qualify in one of the groups.	**Clarified as:** Refer Tender Clause ITB 9.2.1.3 & 13.1.3 (5) & 13.1.3 (6) of Section II: Instructions To Bidders (ITB).
29.			We would like to know that subsequent to the first order placed by the department, the total quantity shall be ordered / procured in how many parts. Whether the order is on quarterly basis.	**Clarified as:** Refer Tender Clause ITB 9.2.1.3 & 13.1.3 (5) & 13.1.3 (6) of Section II: Instructions To Bidders (ITB).
30.		As per Technical specifications, Rifampicin-150mg, Rifampicin-300mg and Rifampicin-450mg are to be supplied in capsule formulation.	Acceptance of Tablet dosage as well for Rifampcin-150mg, Rifampcin-300mg and Rifampcin-450mg, i.e. Rifampicin-150mg (Tablet / capsule) Rifampicin-300mg (Tablet / capsule) Rifampicin-450mg (Tablet / capsule)	**Clarified as:** No Change.
31.	SECTION VI TECHNICAL SPECIFICATIONS AND QUALITY ASSURANCE Schedule I & XIV – Tab Moxifloxacin-400mg and Schedule VIII – Tab Levofloxacin-500mg	Each 5 ply shipper shall contain 20 millboard / Greyboard boxes	Consider increasing the tertiary shipper size as was done in recent tender for Anti-TB Drugs. (Tender No. CMSS/PROC/2024-25/NTEP/039). We request that the clause may be amended to accommodate 20 to 50 secondary boxes in 5-Ply Shipper.	**Clarified as:** No Change.
32.	SECTION III: BID DATA SHEET 9.2.1.3 Para 5 & Page No.54, 55	However, for Schedule XIV to Schedule XX (Developmental Tender Schedule), the technical bid shall include the following document(s): - a) Valid Manufacturing license b) Valid WHO GMP with CoPP Certificate c) Self- declaration certificate for compliance of non-conviction for last 02 years d) Certificate of Analysis e) Certificate of Annual Production Capacity	Refer to point on COA- As this pertains to developmental tender which means manufacturer might not have produced same drug in the recent past for domestic supply but only similar drug's and therefore COA can't be produced. If this clause can't be removed we request you to submit COA pertaining to export supplies.	**Clarified as:** No Change.

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		f) Annual Turnover Statement of previous years in the Form 4.2 g) Audited Annual Reports of previous years Any other document stipulated in Section-IV: Qualification Criteria except "Market Standing Certificate" & "Past Supply Certificate"		

Note: Above changes will be part of the tender document.

19/10/26

(Manish Kumar Bhaskar)
Joint Director (Procurement)

मनीष कुमार भास्कर/Manish Kumar Bhaskar
संयुक्त निदेशक (प्राप्तण) / Joint Director (Procurement)
केन्द्रीय चिकित्सा सेवा सोसाइटी / Central Medical Services Society
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
भारत सरकार / Government of India

Approved vide Technical Specification Committee meeting dt 03.09.2026

(Product Code-40) : Clofazimine 100mg Capsule / Tablet (Scored/ unscored)

A. Specific requirements

Item:

Product Code 40 (PC 40) consists of blister strips of Clofazimine in Capsule / Tablet (Scored/ unscored) form. The drug contained in the product shall have valid registration in the country of manufacture and shall meet all requirements of the licensing authority of the country of manufacture. The drug contained in the product shall also have valid registration in India and shall meet all the requirements of the licensing authority in India.

Description:

Clofazimine Capsules or tablets (scored / unscored) contained in blisters of the strip shall conform to the general requirements of Capsules /Tablets (Scored/ unscored) and the requirements under individual monograph given in IP or other Pharmacopoeia of equivalent accuracy in case of international transactions.

Each Capsule or Tablet (scored / unscored) shall contain - Clofazimine 100mg, Pharmacopeia* (IP/ BP/USP/Other International Pharmacopeia

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

Protocols and Testing:

For manufacturers outside India:

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

For Indian manufacturers:

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

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

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Package Integrity Test:

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

Microbial Count:

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

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

B. Labelling:

General requirements of the labels:

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

Labelling on Strip of Blisters:

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

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

Labelling on Millboard/Greyboard Box:

The label shall indicate the content of Clofazimine IP in each capsule / tablet.

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

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

MILLBOARD/GREYBOARD BOX

National Tuberculosis Elimination Programme (NTEP)

MDR-TB TREATMENT DRUG CONTAINS PRODUCT CODE 40
CLOFAZIMINE 100mg (CAPSULES / TABLET) (10 x 10 Caps)

Each Blister Strip Contains 10 Capsules / Tablets of Clofazimine (100mg)

Batch Nos:

Mfg. Date:

Exp. Date:

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

"Central Government Supply
– Not for Sale"

Manufacturer's Name

Manufacturing Lic. No.

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Labelling on 5-Ply Shipper:

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

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

5 – PLY SHIPPER

National Tuberculosis Elimination Programme (NTEP)

MDR-TB TREATMENT DRUG CONTAINS PRODUCT CODE 40
CLOFAZIMINE 100mg (CAPSULES / TABLETS)
20 Millboard/Greyboard Boxes

Batch No. :

Mfg. Date:

Exp. Date:

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

"Central Government Supply – Not for Sale"

Manufacturer's Name

Manufacturing Lic. No.

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Numbering of shipper packaging:

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

C. Quality Assurance:

Compliance:

The Supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of the specification and related documents; (b) meet the recognized standards for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller; (d) meet the requirements of manufacturing legislation and regulation of pharmaceuticals in the country of origin; (e) are free from defects in workmanship and in materials and (f)) the product has been manufactured as per WHO GMP requirements.

Evidence:

The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned.
The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment.
The Supplier shall provide to the Purchaser a copy of the approval of each source material, constituent material and component for each lot intended for shipment.
The Supplier shall provide evidence of basis for expiration dating and stability data concerning the commercial final package upon request.
The test data for raw materials, in-process, finished product and packaging material testing must be on record for each lot shipped and must be made available to Purchaser's representatives when requested.
Details of samples lifted for testing (such as quantity of strips, Millboard/Greyboard boxes, batch no. etc.) should be pasted on packing of 5 Ply Shipper and records to this effect be also made available to the purchaser.

Inspection:

The Purchaser may inspect and sample, or cause to be sampled, the product at the Supplier's factory and/or warehouse at a mutually agreeable time prior to the shipment of the product.
The successful Bidder will also be required to provide the Purchaser with access to its manufacturing facilities to inspect its facilities, quality control procedures for raw materials, test methods, in-process tests, and finished dosage forms.

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Testing:

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

D. Storage:

As per applicable Pharmacopoeia.

E. Shelf Life:

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

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

Study	Storage condition
Long Term Stability	25 °C ± 2 °C/60% RH ± 5% RH or 30 °C ± 2 °C/75% RH ± 5% RH

F. Qualification of the Manufacturer:

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

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G. Recalls:

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

H. Colour Coding:

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

I. Bar Coding

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

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

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

J. Packing

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

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

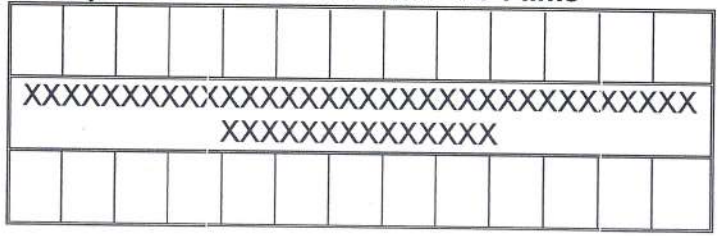
Aluminium-PVC Blister:

PVC Film: Transparent, clear /amber, food grade, blister forming PVC film, film gauge- 200microns, PE coating: 25 microns, PVdC coating: 60gsm.

Aluminium foil: Hard tempered Blister foil, VMCH coated, Thickness: 0.025mm.

Spacing between capsules / tablets should be enough so as to allow removal by patients with finger deformities.

Complex Constructions with PVC Films



TECHNICAL DATA FOR THE STANDARD COMPLEXES

Complex:

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

Water Vapour Transmission Rate (W V T R):

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

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Shrinkage longitudinally

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

Millboard/ Grey board Box:

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

5-Ply Shipper Package:

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

K. Markings

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

Millboard/Greyboard Box:

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

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

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- Logo of DOTS
- Place of manufacture (Made in_____)

5 – Ply Shipper:

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

- Generic name of the product
- Batch number of the drug
- Date of manufacture of the drug (month and year)
- Expiration date of the drug (month and year)
- Manufacturer's name and registered address
- Manufacturer's national registration number
- Destination country license or registration number
- Consignee's address and emergency phone number including mobile number
- Destination airport (if any)
- Contract number
- Number of Millboard/Greyboard Boxes contained in the carton (5 Ply Shipper)
- Gross weight of each carton (in kg)
- Instructions for storage and handling
- Logo of DOTS
- Place of manufacture (Made in____)

L. Documentation

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

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M. Dimensions of the logos

MILLBOARD/GREYBOARD BOX

MILLBOARD/GREYBOARD BOX

3.5x3cm	3.5x3cm
	

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5 – Ply Shipper

5.5x4.7 cm	5.5x4.7 cm
	

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