ONLINE TENDER
FOR PROCUREMENT OF FIRST LINE ANTI TB DRUGS
FOR NTEP FOR THE YEAR 2021-22

Tender No: CMSS/PROC/2020-21/NTEP/010
(National Competitive Bidding)
(FOR CLASS-1 LOCAL SUPPLIERS ONLY)

CENTRAL MEDICAL SERVICES SOCIETY
Ministry of Health & Family Welfare (Government of India)
2nd Floor, Vishwa Yuvak Kendra, Pandit Uma Shankar Dikshit Road,
Chanakyapuri, New Delhi-110021
Ph -: +91-11-21410905, +91-11-21410906
Email: - gmproc.cmss@gmail.com, aginderjeetyadav.cmss@gmail.com
ONLINE BIDS ARE INVITED IN TWO PACKET BID SYSTEM FOR PROCUREMENT OF FIRST LINE ANTI TB DRUGS FOR NTEP
Manual bids shall not be accepted.

BID DOCUMENTS MAY BE DOWNLOADED FROM CPPP WEBSITE: https://eprocure.gov.in/eprocure/app
AS PER THE SCHEDULE AS GIVEN IN CRITICAL DATE SHEET AS UNDER:

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<td>Bid Submission Start Date and Time</td>
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Bids shall be submitted online only at CPPP website: https://eprocure.gov.in/eprocure/app.
Bidder/Contractor is advised to follow the instructions provided in the ‘Instructions to the Contractors/Bidder for the e-submission of the bids online through the Central Public Procurement Portal for e Procurement at https://eprocure.gov.in/eprocure/app’.

Bid documents may be scanned with 100 dpi with black and white option which helps in reducing size of the scanned document. Not more than one bid shall be submitted by one contractor or contractors having business relationship.

Address for Communication : Central Medical Services Society,
2nd Floor, Vishwa Yuvak Kendra,
Pandit Uma Shankar Dikshit Road,
Chanakyapuri, New Delhi-110021
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ONLINE TENDER FOR THE SUPPLY OF FIRST LINE ANTI TB DRUGS FOR THE YEAR 2021-22

The CMSS, an autonomous Society of Ministry of Health & Family Welfare (Govt. of India), is responsible for procuring quality drugs, vaccines, contraceptives, medical devices, diagnostic kits and other health sector goods.

Tender Inviting Authority: DG&CEO, Central Medical Services Society, Ministry of Health & Family Welfare (Government of India) 2nd floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Road, Opposite Police Station Chankaya Puri, New Delhi-110021 (hereinafter referred as Tender Inviting Authority unless the context otherwise requires).

Tender Accepting Authority: Governing Body, Central Medical Services Society (hereinafter referred as CMSS, unless the context otherwise requires)

Tender Inviting Authority invites tender through online bid submission at CPPP website: https://eprocure.gov.in/eprocure/app for supply of Drugs to Central Medical Services Society for the year 2021.

The list of items to be quoted and their specifications are given in Annexure- I and the amount of EMD to be submitted is given in Annexure– III, Bidder may quote for any schedules or any combination of schedules or all schedules and the EMD may be submitted accordingly as specified in Annexure –III.

Bidders are requested to submit all documents with the bid as shown as checklist (Annexure - VII). NO CLARIFICATIONS may be sought from bidders and incomplete bid may be summarily rejected at sole responsibility of bidder(s). CMSS decision in this regard will be final and binding.
1. **LAST DATE FOR RECEIPT OF TENDER**

   Online Tenders (in two separate packets {Technical bid “Packet 1” and Price Bid “Packet 2”}) will be submitted online at CPPP website: [https://eprocure.gov.in/eprocure/app](https://eprocure.gov.in/eprocure/app) as per critical date sheet. The list of items along with their Technical Specifications are attached here as Annexure-I.

2. **BID VALIDITY:**

   i) The bid shall be valid for a period of 150 days from the date of opening of Packet 1 (Technical Bid).

   ii) In exceptional circumstances, the purchaser may request the consent of the bidder for an extension to the period of bid validity. The request and the responses thereto shall be made in writing. The bid security provided under clause 9 shall also be suitably extended. A bidder may refuse the request without forfeiting his bid security. A bidder accepting the request and granting extension will not be permitted to modify his bid.

3. **PRE BID MEETING/CLARIFICATIONS:**

   i) A prospective bidder, requiring any clarification of the bid documents may notify the purchaser in writing or email at the purchaser’s mailing address indicated in the Invitation of bid. The purchaser shall respond in writing (to be uploaded on CPPP and on e-procurement website) to any request for clarification of bid documents, which it receives not later than date mentioned in critical date sheet and prior to the pre-bid meeting. **Queries received after the pre-bid date mentioned in the critical date sheet will not be entertained.**

   ii) The Tenderers or their Official Representatives are invited to attend a pre-bid meeting which will take place as specified in critical date sheet.

   iii) Any clarification issued by CMSS in response to query raised by prospective bidders shall form an integral part of bid documents and it may amount to an amendment of the relevant clauses of the bid documents.
iv) The clarification if any will be uploaded at CPPP and on e-procurement website and bidder is expected to see the CMSS website for clarification before submitting the bid.

4. ELIGIBILITY CRITERIA

(a) Only Class- I Local supplier shall eligible for participation. Bids from Class- I Local supplier (MSE/Non MSE) as defined in DPIIT order no. P-45021/2/2017-PP (BE-II) dt. 04.06.2020 i.r.o Public Procurement (Preference to Make in India) shall be accepted. Bids from firms/vendors other than Class-I Local Supplier (MSE/Non MSE) shall be summarily rejected.

(b) Tenderer shall be a manufacturer of quoted product and having valid own manufacturing license in the indicated pharmacopeia (in technical specification at Annexure IA) and Certificate of Pharmaceutical Product (COPP) as recommended by WHO in any of the pharmacopeia IP/BP/USP. The manufacturing license & COPP should be valid on the date of tender opening packet 1.

(c) For all regulated products, the bidder should have at least two years of manufacturing and marketing experience of the particular items as a manufacturer for each regulated product quoted in the tender. However, this would not apply to regulated products which have been licensed by DCG (I) less than two years ago. DCG(I) is permission shall be required for all new regulated products to this effect.

(d) Average Annual turnover for Tenderers in the last two years i.e. 2017-18 and 2018-19 shall not be less than the following:

<table>
<thead>
<tr>
<th>Schedule</th>
<th>Amount (in Rs.)</th>
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<tr>
<td>I</td>
<td>80 Cr.</td>
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<tr>
<td>II</td>
<td>100 Cr.</td>
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<td>III</td>
<td>4 Cr.</td>
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The turnover benchmark will not apply to Micro and Small Enterprises (MSE).

(e) Tender should not be submitted by the firm/company for the Product(s) for which the firm/Company has been blacklisted/banned/debarred by CMSS/State Governments/Central Government/its Drug procurement agencies or if the Firm/Company is debarred as a whole by these agencies.

(f) Tenderer should quote at least for 50% of the tendered quantity of each items quoted and the Tenderer shall have an annual production capacity not less than one and half times the quantity quoted for each schedule.

(g) Tenderer should have supplied 25% (For Sch. I & II) & 50% (For Sch. III, IV & V) of the quoted quantity of same or similar items during the last three financial years. Bidder should submit Purchase order copies and certificate duly issued by statutory auditor of the company on his letter head by certifying the quantities manufactured and marketed in trade, export, open market, sold to government institutions, private bodies etc. and the marketed quantities are not less than atleast 25% (For Sch. I & II) & 50% (For Sch. III, IV & V) of the quoted/similar item. Similar item is defined as below:

For Sch I to V – Any Anti TB Drugs

5. GENERAL CONDITIONS

(i) A complete set of tender document may be downloaded by any interested eligible bidder from website: https://eprocure.gov.in/eprocure/app as per the schedule given in Critical Date Sheet. No cost for the Tender document shall be
charged for the Tender documents downloaded by the Tenderers.

(ii) All tenders must be accompanied with Earnest Money Deposit as specified against each schedule in Annexure-III of the Tender document.

(iii) Tenders will be opened online therefore, the presence of tenderers/authorized representatives of the Tenderers is not necessary.

(iv) Bidders are advised to watch for amendments, if any, which may be issued prior date of submission of bids by tender inviting authority on the website: www.cmss.gov.in and https://eprocure.gov.in/eprocure/app for which CMSS will not issue any separate communication to individual bidders.

(v) All notices or communications relating to and arising out of this tender and any consequent agreement or any of the terms thereof shall be considered duly served on or given to the Tenderer if delivered to it or left at the premises, places of business or abode or sent at official email as provided by the Tenderer.

(vi) **FORGERY/FRAUD BY BIDDERS/SUPPLIER:**

(a) Genuineness of the papers/documents/certificates/declaration submitted with bid is the responsibility of the bidder. If at any stage it is found that the papers/documents/certificates/declaration submitted by the bidder are not in order, are forged, manipulated, fabricated or altered, the bid or purchase order issued to the bidder is liable to be cancelled and further necessary action including forfeiture of its EMD/Security Deposit, debarring/blacklisting against the bidder will be taken. Purchaser may also initiate police/legal action and request concerned statutory
authority for cancellation of license issued to supplier for tendered items.

(b) If any fraud, short supply of goods is detected on part of the bidder at any stage, the bid or work order/ Purchase order issued to the bidder is liable to be cancelled and further necessary action against the bidder including debarring/blacklisting will be taken.

(c) In any of above two cases, the CMSS is at liberty to make alternative purchase of the tendered items 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.

(vii) **PATENT RIGHTS:**
The supplier shall indemnify the purchaser against all third-party claims of infringement of patent, trademark or industrial design rights arising from use of the goods or any part thereof.
In event of any such claim in respect of alleged breach of patent, registered designs, trademarks etc. being made against TIA, the TIA shall notify the supplier of the same and the supplier shall at its own expenses take care of the same for settlement without any liability to the TIA.

(viii) **TERMINATION FOR DEFAULT:**
1. The purchaser may, without prejudice to any other remedy for breach of contract, by written notice of default, sent to the supplier, terminate this contract in whole or in part.
   (a) If the supplier fails to deliver any or all of the goods within the time period(s) specified in the contract, or any extension thereof granted by the purchaser.
(b) If the supplier fails to perform any other obligation(s) under the contract, and

(c) If the supplier, in either of the above circumstances, does not remedy his failure within a period of 15 days (or such longer period as the purchaser may authorize in writing) after receipt of the default notice from the purchaser.

2. In the event the purchaser terminates the contract in whole or in part, pursuant to above the purchaser may procure; upon such terms and in such manner, as it deems appropriate, tendered goods undelivered and the supplier shall be liable to the purchaser for any excess cost for such similar goods. However, the supplier shall continue performance of the contract to the extent not terminated.

(ix) **TERMINATION FOR INSOLVENCY:**

The purchaser may, at any time, terminate the contract by giving written notice to the supplier, without compensation to the supplier, if the supplier becomes bankrupt or otherwise insolvent, as declared by the competent court provided that such, termination will not prejudice or affect any right of action or remedy which has accrued or will accrue thereafter to the purchaser.

(x) **SET OFF:**

Any sum of money due and payable to the supplier (including security deposit refundable to him) under this contract may be appropriated by the purchaser and set off the same against any claim of the purchaser for payment of a sum of money arising out of this contract or under any other contract made by the supplier with the Purchaser.
(xi) Purchaser reserves the right to debar/ blacklist a bidder for a suitable period in case he fails to honour his bid/contract without sufficient grounds.

(xii) **BID SUBMISSION:**

(a) Bidders are hereby cautioned that any attempt of cartel formation will be viewed seriously and may at the discretion of purchaser, lead to cancellation of tender. Purchaser in its discretion may decide to forfeit EMD of such bidders and blacklist or debar these bidders for suitable period besides taking other punitive measures. Decision of purchaser in this regard shall be final and binding.

(b) (i) Different firms or companies having any common partner(s) or Director(s) are not permitted to quote for more than one tender offer. In case more than one offer is received from such bidders, then all such offers except with the lowest quote shall be rejected summarily.

(ii) In case more than one offer for any tendered item is received from the same bidder, then all such offers except with the lowest quote shall be rejected summarily.

(xiii) **NEAR RELATIVE CERTIFICATE:**

The bidder should give a certificate that none of his/her near relative as defined below is working in CMSS where he is going to apply for the tender. In case of Proprietorship firm certificate will be given by the proprietor. For partnership firm certificate will be given by all the partners and in case of limited company by all the Directors of the company excluding Govt. of India/Financial Institutions nominees and independent non-
official part time directors appointed by Govt. of India or the Governor of the state. Authorised signatory of bid may also sign this bid on behalf of the entire directors/ partners/ proprietor. Due to any breach of conditions by the company or firm or any other person the tender will be cancelled and bid security will be forfeited at any stage whenever it is noticed and CMSS will not pay any damage to the company or firm or the concerned person. The company or firm or the person will also be debarred for further participation for quoted item in the concerned unit.

The near relatives for this purpose are defined as:

(a) Members of a Hindu undivided family.
(b) They are husband and wife.
(c) The one is related to the other in the manner as father, mother, son(s) & son’s wife (Daughter in law), daughter(s) and daughter’s husband (son in law), brothers(s) and brother’s wife, sister(s) and sister’s husband (brother in law).

An undertaking as specified in Annexure XVIII is to be submitted.

6. **TECHNICAL BID – “PACKET1”**

Those intending to participate in the tender (herein called Tenderer) should first ensure that they fulfil all the eligibility criteria and all documents should be valid on the date of tender opening packet 1:

6.1 The Tenderer should electronically submit the soft copies of following documents in Technical Bid “Packet 1”. (All the documents submitted should bear signature and stamp of the Tenderer)."
(a) DD/FDR/RTGS/NEFT e-receipt or Bank Guarantee (if applicable) in respect of EMD as per Clause 9 of this Tender document or in case of MSE, a copy of their valid registration certificate in support of their being an MSE and a notarised undertaking given in Annexure VIII.

(b) Tender Forwarding letter as per Annexure-II.

(c) The Tenderer should furnish the Manufacturing License valid on tender opening for each items quoted been duly renewed up to date and the items quoted shall be clearly highlighted in the license. Original documents should be produced for verification when demanded. If the tendered drug is in Indian Pharmacopoeia (IP), then the manufacturing license has to be submitted in IP only.

(d) Duly notarized general power of Attorney (on non-judicial stamp paper of worth Rs. 50/-) in favour of authorized signatory in case of partnership firm (to be signed by all partners) / proprietorship firm or board resolution in case of a company to sign the bid and bind the bidder. The signature of authorized signatory should be duly attested. In case of proprietorship on its letter head, the proprietor of firm declares himself as proprietor with specimen signature.

(e) Market Standing Certificate issued by the Licensing Authority as a Manufacturer for each item quoted for the last 2 years i.e. 2017-18 and 2018-19.

(f) Capacity certificate issued by the licensing authority.

(g) Tenderer should have supplied 25% (For Sch. I & II) & 50% (For Sch. III, IV & V) of quoted or similar item (as per clause 4g) during the last 3 financial years (Copies of P.O’s to be submitted along with CA certificate). Similar items are defined at 4 (g).

(h) Non-Conviction Certificate issued by the FDA/ Drugs Controller of the State certifying that the firm/company has not been
convicted and the products quoted have not been cancelled during last two years i.e. 2017-18 and 2018-19.

(i) A valid Certificate of Pharmaceutical Product (COPP) as recommended by WHO in any pharmacopeia IP/BP/USP and a valid WHO-GMP.

(j) Annual turnover statement for 2 years i.e., 2017-2018 and 2018-19 should be furnished in the format given in Annexure-V duly certified by the Chartered Accountant.

(k) Copies of the audited Annual reports including the Balance Sheet and Profit and Loss Account along with all the annexure for the last two years i.e. 2017-18 and 2018-19 duly certified by a practicing Chartered Accountant.

(l) List of items quoted (the name and Item Code of the items quoted) and relevant pharmacopoeia annual production for the last 2 years as per the Annexure-VI.

(m) Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life.

(n) A Checklist (Annexure-VII) indicating the documents submitted with the tender document and their respective page numbers shall be enclosed with the tender document. The documents should be serially arranged.

(o) Each page of submitted bid (along with tender document) be properly page numbered and shall be signed by the authorized signatory of the Tenderer with office seal.

(p) All the documents enclosed with the tender document should also be signed by the authorized signatory of the Tenderer.

(q) No Deviation Certificate as per Annexure-XVII.

(r) Near Relative Certificate as per Annexure-XVIII.

(s) Draft artwork is to be submitted in technical bid.

(t) Tenderer should submitted an undertaking by the firm/company for the Product(s) for which the firm/ Company has not been blacklisted/ banned/ debarred by CMSS/ State Governments/ Central
Government/ its Drug procurement agencies or if the Firm/Company is not debarred as a whole by these agencies.

(u) Tenderer should submit a certificate from the statutory auditor or cost auditor of the company (in the case of companies) or from a practicing cost accountant of practicing chartered accountant (in respect of suppliers other than companies) giving the percentage of local content as per clause 10.4 of this tender at the time of submission of bid.

6.2 (a) The above mentioned documents are to be submitted in soft copy electronically on the CPPP portal https://eprocure.gov.in/eprocure/app as Technical Bid “Packet 1” as per date prescribed in critical date sheet and as per instructions of online bid submission given in Annexure-XVI.

(b) Original Bank Guarantee or notarized undertaking by MSE companies in the format given in Annexure VIII for exemption of EMD in physical form is to be deposited with the Tender Inviting Authority as per date prescribed in the critical date sheet. If the last date of deposit of original Bank Guarantee notarised undertaking by MSE companies happens to be a central government holiday for offices located in New Delhi, next working day shall be treated as the last date of deposit. The original Bank Guarantee or notarized undertaking by MSE companies may be either deposited in person or by courier. If sent by courier, the tenderer has to send it in advance so as to make sure that the original Bank Guarantee or notarized undertaking by MSE companies is delivered to the Tender Inviting Authority by the date specified in critical date sheet. Failure to deposit the original Bank Guarantee or notarized
undertaking by MSE companies by the specified last date shall result in rejection of bid summarily.

7. **PRICE BID-“Packet 2”**

7.1 “Packet 2” is for the Price Bid of the Tenderer.
   i) Bid should be uploaded online in the form of BOQ.XXXX.xls.
   ii) Format of the Schedules of price bid is available in Annexure-XIII.
   iii) The supplier shall quote as per price schedule given in Annexure-XIII for all the items quoted by him as per schedule of requirement.
   iv) The price quoted shall be the landed price per unit at the specified locations on DDP basis and shall include all taxes and duties including transportation and other incidental expenditure for delivery at CMSS warehouses.
   v) The rate quoted in Price Schedule Annexure-XIII should be for a unit as given in specifications as detailed in the tender document. The bidder is not permitted to change / alter specification or unit size in the box.

7.2 **GST (Goods and Service Tax)/other statutory Taxes/Levies**
   i) The bidder may quote for GST as per applicability in accordance with relevant Government notification.
   ii) Any variation upwards/downwards as a result of statutory variation in GST/ other taxes/duties/levies for supplies during original specified delivery schedule of goods shall be allowed.
   iii) Any upward/downward revision (only during scheduled delivery period) in statutory taxes, levies will be allowed and benefit will pass on to supplier/purchaser.
   iv) Any increase in taxes and other statutory duties/levies after the expiry of the delivery date shall be to the supplier’s accounts. However, the benefit of any decrease in these
taxes/duties shall be passed on to the purchaser by the supplier.

7.3 The basic unit price quoted by the bidder shall remain fixed during the entire period of contract and shall not be subject to variation on any account. A bid submitted with an adjustable price quotation will be treated as non-responsive and rejected.

8. OPENING OF “PACKET 1” i.e. ‘TECHNICAL BID AND “PACKET 2” i.e. FINANCIAL BID’ OF TENDER CLARIFICATION OF BIDS SUBMITTED:

8.1 To assist in the examination, evaluation and comparison of bids, the purchaser may, at his discretion ask the bidder for the clarification in its bid. The request for the clarification and response shall be in writing. However, no post bid clarification at the initiative of the bidder shall be entertained. Documents issued after the date of tender opening will not be accepted.

8.2 Tenderers are advised to submit all the required documents as per tender terms and conditions. Failure to submit shall result in rejection of bids. Clarifications (if required) to assist in the evaluation of bids will be asked by the purchaser only once. The tenderer is requested to reply in the given time by purchaser.

8.3 Presence of authorized official of the Tenderer is not necessary at the time of opening of Technical Bid - “Packet 1” as opening is online.

8.4 The purchaser shall evaluate the bids to determine whether they are complete, whether any computational errors have been made, whether required sureties have been furnished, whether the documents have been properly signed and whether the bids are generally in order.

8.5 Prior to the detailed evaluation, pursuant to clause above, the purchaser will determine the substantial responsiveness of each bid to the bid documents for purposes of these clauses.
A substantially responsive bid is one, which confirms to all the terms and conditions of the bid documents without material deviations. The purchaser’s determination of bid’s responsiveness shall be based on the contents of the bid itself without recourse to extrinsic evidence.

8.6 A bid determined as substantially non-responsive will be rejected by the purchaser and shall not subsequent to the bid opening be made responsive by the bidder by correction of the non-conformity.

8.7 The purchaser may waive any minor infirmity or non-conformity or irregularity in a bid, which does not constitute a material deviation, provided such waiver does not prejudice or affect the relative ranking of any bidder. Such minor infirmity will be identified by the TEC and clarification in this regard may be called for.

8.8 Technical Evaluation Summary will be uploaded on CPPP Portal. The bidders are intimated that representations, if any, may be sent before price bid opening as per schedule indicated in uploaded summary. Any representations received after the indicated date and time would not be entertained under any circumstances. No new document would be allowed to be submitted at this stage.

8.9 “Packet 2” will be opened only for tenderers, who are found techno-commercially eligible on satisfying the criteria for technical evaluation and plant inspection (wherever necessary) based on the documents submitted in “Packet 1”. Presence of authorized official of Tenderers is not necessary in opening of “Packet 2” as opening is online.

8.10 Arithmetical errors shall be rectified on the following basis. If there is a discrepancy between the unit price and total price that is obtained multiplying the unit price and quantity, the unit price shall prevail and total price shall be corrected by the
purchaser. If there is a discrepancy between words and figures, the amount in words shall prevail.

9. **EARNEST MONEY DEPOSIT**

9.1. (a) The Earnest Money Deposit (EMD) is payable by all Tenderers, for an amount indicated in Annexure-III UNLESS EXEMPTED under clause 9.2. In case a Tenderer is quoting for more than one item, the Earnest Money Deposit payable by such Tenderer shall be the aggregate total of the Earnest Money Deposit for all the items quoted by such Tenderer. The Tenderers are required to furnish the breakup of the Earnest Money Deposit for the items quoted in the format as per Annexure-III. The earnest Money Deposit shall be paid by Account payee Demand Draft/ Fixed Deposit Receipt/ Banker's Cheque /Bank Guarantee or RTGS/NEFT in the following Bank Account:

**Beneficiary Name:** Central Medical Services Society  
**A/CNo.** : 32719062216  
**BankName** : SBIBank  
**Branch** : Nirman Bhawan, Maulana Azad Road, New Delhi  
**IFSCCode** : SBIN0000583

(b) Bank Guarantee (as per Annexure XIV) can also be accepted as a mode of payment and the named beneficiary shall be Central Medical Services Society. The Bank guarantee shall be issued by a bank (Nationalized or Scheduled Bank) in India to make it enforceable and acceptable to the purchaser. The Bank Guarantee shall be in the format as per Annex-XIV provided in the tender document.
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.

(c) The applicable EMD amount has been indicated in Annexure-III 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 by proportionately reducing the amount applicable to 100% quantity.

9.2 EXEMPTION FROM PAYMENT OF EARNEST MONEY DEPOSIT TO CLASS-I LOCAL SUPPLIER MSME (MICRO & SMALL ENTERPRISES)

(i) Vide Gazette no. CG-DL-E-26062020-220191 dt. 26.06.2020, Ministry of MSME have revised criteria for classifying the enterprises as Micro, small and Medium enterprises with effect from 1st July 2020 therefore following firms will be exempted from submission of EMD:

a) Micro and Small Enterprises as per classification given in MSME Notification dtd. 26.06.2020 registered under “Udyam Registration” w.e.f 01.07.2020 will be granted exemption from payment of Earnest Money Deposit. Udyam Registration Certificate has to be produced in support of above.

b) The existing Micro and Small Enterprises as per classification given in MSME Act 2006, registered till 30.06.2020 and holding Permanent Registration Certificate from the District Industries Centers or Khadi and Village Industries Commission or Khadi and Village Industries Board or Coir Board or National Small Industries Corporation or any other body specified by Ministry of Micro Small and Medium Enterprises will be granted exemption from payment of Earnest Money Deposit till 31.03.2021. Registration Certificate has to be produced in support of above.
(i) The MSE Units will be required to furnish a notarized undertaking (as per Annexure-VIII) to the effect that in the event of non-fulfilment or non-observance of any of the conditions stipulated in the contract, the MSE Unit shall pay a penalty, equivalent to the Earnest Money Deposit to offset the loss incurred by the Tender Inviting Authority consequent on such breach of any bid condition.

(ii) The MSEs participating in the tender shall enclose with their tender a copy of their valid registration certificate with District Industries Centers or Khadi and Village Industries Commission or Khadi and Village Industries Board or Coir Board or National Small Industries Corporation or any other body specified by Ministry of Micro Small and Medium Enterprises in support of their being an MSE, failing which their tender will be liable to be ignored/rejected

9.3.(i) Offers of the firms submitted without EMD / for a shorter period/lesser amount as demanded will summarily be rejected.

(i) The Earnest Money Deposit will be refunded to the lowest responsive bidder/s within 30 days from the date of signing the contract agreement and on the deposit of Security Deposit.

(ii) The Earnest Money Deposit (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.
9.4 FORFEITURE OF EMD:

(i) The Earnest Money Deposit (EMD) will be forfeited, if the Tenderer withdraws or amends, impairs or derogates from the tender in any respect within the period of validity of his Tender.

(ii) The Earnest Money Deposit (EMD) will be forfeited, in case of the lowest/ matched bidder, fails to execute the contract agreement and / or deposit the Security Deposit within the stipulated time.

(c) In both the above cases, the bidder will not be eligible to participate in the tender for same item for one year from the date of issue of letter of acceptance cum Purchase Order (LOA cum PO). The bidder will not approach the court against the decision of the CMSS in this regard.

10. OTHER CONDITIONS:

10.1 The details of the annual required quantity of items are shown in Annexure-I.

(i) Central Medical Services Society (CMSS) will have the right to increase or decrease up to 25% of the quantity of goods and/or services specified in the schedule of requirements without any change in the unit price or other terms and conditions at the time of award of contract.

(ii) 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 running tender/contract up to a period of twelve months from the earliest date of acceptance of letter of acceptance (LOA).
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.

10.2 (i) The rates quoted and accepted will be binding on the Tenderer for the full contract period of one years and any increase in the price will not be entertained till the completion of this contract period.

(ii) Any upward/downward revision (only during scheduled delivery period) in statutory taxes, levies will be allowed and benefit will pass on to supplier/purchaser.

(iii) Any increase in taxes and other statutory duties/levies after the expiry of the delivery date shall be to the supplier’s accounts. However, the benefit of any decrease in these taxes/duties shall be passed on to the purchaser by the supplier.

(iv) The delivery of the additional quantity shall be scheduled after the completion of the delivery of the original tendered quantity.

10.3 In accordance to the above notification the participating Micro and Small Enterprises (MSEs) in a tender, quoting price within the band of L 1 + 15% would be allowed to supply a portion of the requirement by bringing down their price to the L 1 price, in a situation where L 1 price is from someone other than an MSE. In exercising of the powers conferred in Section 11 of the Micro, Small and Medium Enterprises Development (MSMED) Act 2009, the Government has notified a new Public Procurement Policy for Micro & Small Enterprises effective from 9th November 2018. The policy mandates that 25% of procurement of annual requirement of goods and services by all Central
Ministries / Public Sector Undertakings will be from the Micro and Small Enterprises. Government has also earmarked a sub target of 4% procurement of goods & services out of 25% from MSEs owned by SC/ST entrepreneurs and 3% to micro and small enterprises owned by women.

10.4 The DIPP has notified a Public Procurement order-2017 (Preference to Make in India) order 2017- Revision vide Order no P-45021/2/2017-PP (BE-II) - dated 4th June 2020. The provision of said order including any subsequent orders issued from time to time will apply in the instant case. Bidders are requested to submit a certificate from the statutory auditor or cost auditor of the company (in the case of companies) or from a practicing cost accountant of practicing chartered accountant (in respect of suppliers other than companies) giving the percentage of local content as per order.

11. ACCEPTANCE OF TENDER

11.1 Technically responsive tenders will be evaluated based only on the “landed price” (all-inclusive price), i.e. Rate per Unit inclusive of all taxes, duties, transportation & other charges as given in Annexure-XIII by the tenderer.

11.2 The evaluation for ranking shall be carried out on the basis of “all inclusive” prices of the goods offered for each schedule separately.

11.3 The purchaser reserves the right to accept or reject any bid, and to annul the bidding process and reject all bids, at any time prior to award of contract without assigning any reason whatsoever and without thereby incurring any liability to the affected bidder or bidders on the grounds of purchaser’s action.

11.4 (i) CMSS or its authorized representative(s) has the
right to inspect the factories of Tenderers, before accepting the rate quoted by them or before releasing any purchase order(s) or at any point of time during the continuance of tender and also has the right to reject the tender or terminate/ cancel the purchase orders issued and/or not to place further order, based on adverse reports brought out during such inspections. In such situation CMSS reserves the right to take other actions against the tenderer including forfeit of security deposit, debarring/blacklisting for appropriate period.

(ii) The Tenderer shall allow inspection of the factory at any time by a team of Experts/ Officials nominated by the Tender Inviting Authority for the purpose. The Tenderer shall extend necessary cooperation to such team in inspection of the manufacturing process, quality control measures adopted etc., in the manufacture of the items quoted. If Company/ Firm does not allow for any such inspection, their tenders will be rejected during the currency of the contract.

11.5 The acceptance of the tenders will be communicated to the lowest / matched tenderers in writing (through email), as per format of the Acceptance Letter given in Annexure- IX.

12. SECURITY DEPOSIT AND AGREEMENT

12.1 Security Deposit: On being intimated about the acceptance of the tender the L1/Matched tenderer shall pay a Security Deposit at the rate of 5% of the total value of goods to be awarded. The Security Deposit amount, is to
be deposited in the form of NEFT/RTGS/Fixed Deposit Receipt/Demand Draft (payable at New Delhi)/Bank Guarantee in favour of Central Medical Service Society. The Security Deposit in any other form like Cash/ Cheque/ Postal-Order will not be accepted. In case of depositing security deposit by Bank Guarantee, the named beneficiary shall be Central Medical Services Society. The Bank Guarantee shall be issued by a bank (Nationalized or Scheduled Bank) in India to make it enforceable and acceptable to the purchaser. The Bank Guarantee shall be in the format as per Annexure- XV provided in the tender document.

12.2 The Security Deposit shall be valid for at least 1625 days from the date of its commencement.

<table>
<thead>
<tr>
<th>LOA Date</th>
<th>15 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate Validity-</td>
<td>365x1</td>
</tr>
<tr>
<td>Delivery Period-</td>
<td>90 days</td>
</tr>
<tr>
<td>Shelf Life-</td>
<td>365x3</td>
</tr>
<tr>
<td>B.G. Extension-</td>
<td>60 days</td>
</tr>
</tbody>
</table>

1625 days

12.3 The proceeds of the performance security shall be payable to the purchaser as compensation for any loss resulting from the supplier’s failure to complete its obligations under the contract.

12.4 The performance security bond will be discharged by the purchaser after completion of the supplier’s performance obligations including any warranty obligations under the contract.

12.5 Failure to deposit the performance security will attract clause 9.4.
13. METHODOLOGY FOR PLACING ORDERS

For placing orders the following procedures will be adopted:

13.1 After the Price Bid opening (Packet 2), the lowest offer will be declared as the L1 tenderer. CMSS reserves right to negotiate prices with L1 bidder in justified cases.

13.2 Generally speaking the draft art work should be given in technical specifications however, in those cases where draft artwork not given in tender specifications, the vendor must need to coordinate with respective programme division of ministry to freeze (get approval) for the art work. No extension would be given on this pretext.

13.3 If two or more than two Tenderers are declared as lowest suppliers for the same item(s)(i.e. emerge L1), such Tenderers shall as specified in the Tender Document on depositing the required amount as Security Deposit 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).

13.4 CMSS will counter offer the lowest rate (L1 rate) to other Tenderers in the order of their ranking i.e. L2, L3 and so on will be asked to match the L1 price.

13.5 (i) In order to maintain uninterrupted supplies, the CMSS will place orders with minimum of three suppliers for tendered product with 50% of the orders given to L1 and the balance 30% to L2 & 20% to the next Matched Lowest Tenderer.
(ii) In case there is no L2 or lower/matched bidder, balance quantity up to extent of quoted quantity or at most for balance 50% quantity can be offered to L1 bidder. Quantity beyond quoted quantity will be ordered on mutual consent.

(iii) 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.

(iv) In case there is no L3/matched bidder at 3rd position (i) above may be followed or balance 50% quantity may be offered to L2/matched bidder in case L1 does not agree to supply 70% of tendered quantity.

(v) In case of requirement of large quantities, CMSS may place orders with 3 suppliers in the ratio of 50:30:20.

13.6 If the lowest supplier has failed to supply the required items within the stipulated time or within the extended time, as the case may be, CMSS may cancel such purchase orders and on cancellation, CMSS may place Purchase Orders with the Matched Lowest Tenderer or to the other tenderers at the risk and cost of the defaulted supplier.

13.7 The supplier shall complete the supply of the items required by CMSS at the consignee destination mentioned in the schedule, within minimum required period as stipulated in LOA from the date of the LOA, which will be sent by email to the successful tenderer.
13.8 The supplier shall supply the items at the specified destination and submit a copy of the LOA, Delivery Challan and other relevant documents at the same destinations.

13.9 After supply of items at the specified destinations, the supplier shall submit Invoice (Original), Certificate of analysis (Batch Wise) and other relevant documents etc., at the Head Office, CMSS for claiming payment.

13.10 Subject to para (h) and para (i) above, CMSS will process the invoices submitted by the supplier and the payments against supply will be made within 60 days from the date of submission of all relevant documents to the CMSS provided the items supplied has been declared of STANDARD QUALITY, by the Empanelled Laboratory of CMSS.

14. SUPPLY / DELIVERY CONDITIONS

14.1 The supplier should acknowledge the receipt of the LOA within 3 days of its receipt.

14.2 The supplies will be made in staggered quantities (if applicable) as detailed in Annexure I

14.3(a) The supplier shall supply the ordered quantity within minimum required period of 90 days from the date of Letter of Acceptance at the destinations mentioned in it. If the above day happened to be a holiday for CMSS, the supply should be completed by 5.00 PM on the next working day. In case of non-execution of the order either partially or fully, CMSS reserves the right to cancel the purchase order or place fresh purchase orders on alternative source at the
risk and cost of the default supplier. In such cases the CMSS, has every right to recover the cost and impose penalty including blacklisting of the supplier and the product.

(b) With the prior approval of CMSS, the supplier may continue to supply the unexecuted quantity after 90th day or after the delivery dates/schedule as mentioned in LOA, with Liquidated Damages as specified in Clause 18 of the tender conditions on the delayed supplies.

(c) Supplies should be made directly by the tenderer and not through any other Agency/Dealer/Distributor.

(d) The Tenderer shall not, at any time, assign, or make over the contract or the benefit there of or any part thereof to any person or persons whatsoever.

14.4 All goods must be of fresh manufacturing and must bear the dates of manufacturing and expiry. The bidder further warrants that all goods supplied will have, at least 5/6th of the minimum shelf life must remain at the time of delivery to the consignee. The supplier will provide manufacturer’s stability test data substantiating the claimed shelf life in the offered package.

14.5 A Certificate of Analysis from manufacturer's own Quality Control Lab covering each batch delivered is to be submitted along with shipping documents. The Certificate of Analysis shall include:

a) Generic name of the product
b) Batch No.
c) Pharmacopoeial Reference and/ or In-house method
d) Batch quantity
e) Date of manufacture

f) Expiry date

g) Date of test

h) Description (clarity, colour etc)
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) Qualified signatures

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

14.6 All the Tenderers are required to supply the product(s) with printed text “Govt. of India Supplies – NOT FOR SALE” in red-colour on the items i.e. kits, 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 CMSS/Consignee. Affixing of rubber stamp shall not be accepted. However, the approved art work will prevail.

14.7 The Tenderer shall take back goods, which are not utilized by the CMSS within the shelf life period, based on mutual agreement.

14.8 If at any time the Tenderer has, in the opinion of the CMSS, delayed the supply of items due to one or more reasons related to Force Majeure events such as riots, mutinies, wars, fire, storm, tempest or other exceptional events at the
manufacturing premises, the time for supplying the items may be extended by the CMSS at its discretion for such period as may be considered reasonable. However, such extension shall be considered only if a specific written request is made by the Tenderer within 10 days from the date of occurrence of such event. The exceptional events do not include scarcity of raw material, increase in the cost of raw material, electricity failure, labour disputes/strikes, insolvency, and closure of the factory/manufacturing unit on any grounds etc.

14.9 The supplier shall not be liable to pay LD/penalty and forfeiture of security deposit for the delay in executing the contract on account of the extension of supply period on the ground of force majeure events.

14.10 Timely supply is the essence of contract/Purchase order. The drugs/medicines/items ordered are meant for key National programmes & delay in supply can have the adverse impact on patients and derail the critical National level Disease Control Programme.

In continuation to provisions of liquidated damages clause no. 18, it may be noted that:

a) Any lot delayed beyond LD period (of 20 weeks) may be short closed by the buyer if delivered qty. is <75% and CMSS reserves the rights/options to procure the undelivered quantity from other approved supplier available in the contract or from open market at the risk & cost of the defaulting supplier.

b) If any lot where delivered qty. is ≥75% and <95% is delayed beyond LD period a final Show Cause Notice will be issued intimating the supplier to deliver the balance qty. within one month time else CMSS reserves the rights/options
to procure the undelivered quantity from other approved supplier available in the contract or from open market at the risk & cost of the defaulting supplier. The same lot shall be short closed after the given time of one month.

Supplier/s will submit proposal/ request for each such case & CMSS reserves the right to decide each case taking all the circumstances & situations into view. CMSS’s decision will be final & binding.

If 2 or more lots are short closed with delivered qty. is <75% in maximum LD period of 20 weeks in same PO, proportionate deductions from the security deposit submitted by the supplier or from running bills/invoices will be forfeited. However, in case where deliveries were to be made in a single lot, the same shall be applicable on single lot.

Note:- In event of Force majeure reasons/ situations as explained herein at clause no. 21, this clause would not be operated.

15. PACKING

15.1 The items shall be supplied in the package specified in the Technical Specifications in Annexure-I.

15.2 The Weight, Volume & Dimensions of shipping cartons & intermediate packaging carton may be mentioned.

15.3 The packing shall be of a sturdy quality to provide adequate protection of the product for carriage to final destination, PAN INDIA including remote locations under adverse climatic and storage conditions and high humidity. Used cartons should never be used.
15.4 Products with specific temperature requirements will be packed and stored and delivered in appropriate conditions.

15.5 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.

15.6 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 develop 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.

16. QUALITY CONTROL

16.1 Quality Control is an essential part of the current procurement and it is the responsibility of the supplier to ensure quality assurance as per specifications/bid document. The products should conform to the standards as specified in Annexure-I of the Tender document.

16.2 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.

16.3 CMSS will embark on stringent quality checks to ensure that tendered goods meet required standards throughout specified shelf life. For this purpose, CMSS reserves the right to carry necessary inspections/tests at any of, or any combination of or/ all of following stages:
(a) At Pre-Dispatch stage.
(b) At Delivery Stage: inspection done once the goods reach at consignee location and before taking over supplied goods in inventory.
(c) Post Delivery Surveillance: The Drugs/goods shall 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. Quality Monitoring Activities may also be organized by CMSS post-delivery.

16.4 CMSS may engage the services of a Quality Control Agent & Quality Control Testing Laboratories for the purpose of Inspection & Quality Control. The sampling quantities shall be borne by the supplier.

16.5 Inspection Methodology: At pre-dispatch and/or delivery stage, samples of supplies in each batch will be chosen for testing. The samples will be collected and sent to designated laboratories (Government/ Private Drugs Testing Laboratories) for testing as decided by the CMSS. Handling and testing charges will be borne by CMSS.
At post-delivery surveillance - The samples will be collected from the warehouse of CMSS/or final consignee in States/UTS and sent to designated Quality Control Labs in respect of supplied goods at any point during specified shelf life as per decision of CMSS.

In case of failure of batches during or at any stage (indicated at 16.3), the testing charges would be claimed for the defaulting vendor.

16.6 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.

16.7 **At any of testing stage**, samples which do not meet quality requirement shall render the relevant batches liable to be rejected. If the sample is declared to be “Not of Standard Quality” or spurious or adulterated or misbranded, such batch/ batches will be deemed to be rejected goods and the cost of entire batch paid will be recovered whether consumed fully/ partially. Besides action may also be initiated for debarring/blacklisting against supplier for suitable period.

16.8 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 testing stages, depending upon the type, nature and seriousness of failure, consequences resulting from such default, availability of alternate sources, the CMSS is at liberty to either:

(i) Ask the supplier to replace entire quantity of the relevant batches, in addition to imposition of penalty @ 25% of batch supply cost or
(ii) to make alternative purchase of the items 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.

(iii) In addition to (i) or (ii) above, action to debar/blacklist the supplier for suitable period, as decided by CMSS may also be initiated. In addition forfeiture of PSD.

(iv) In addition, the FDA/ Drugs Control Authority of concerned State will be informed for initiating necessary action on the Tenderer in their state. Security deposit will also be forfeited without any intimation.

(v) The decision of the CMSS or any officer authorized by CMSS, as to the quality of the supplied drugs, medicines, vaccines etc., shall be final and binding.

16.9 If the product is non-Pharmacopoeial then the supplier must provide the in house test method along with the required reference standards if asked for. The Master Formula of the products shall be provided whenever asked for.

17. PAYMENT PROVISIONS

17.1 No advance payments towards costs of items will be made to the Tenderer.

17.2 The payment towards supply of items to CMSS will be made either by means of Cheque or through RTGS (Real Time Gross Settlement System)/ Core Banking/ NEFT. The Tenderer shall furnish the relevant details in original (Annexure-XII) to make the payment through RTGS/Core Banking/NEFT.
17.3 All bills/ Invoices should be raised in duplicate and the bills should be drawn in the name of Central Medical Services Society, 2nd Floor, Vishwa Yuvak Kendra, Pandit Uma Shankar Dikshit Road, Chanakyapuri, New Delhi-110021 or in the name of any other authority as may be designated. Supplier have to mention e- aushadhi PO No. and tranche/ lot on the invoice.

17.4 Payments for supply will be made only after completion of supply of Items ordered in the individual Purchase Order PROVIDED quality reports are acceptable. 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.

17.5 Part payments for supply will be considered only after supply of 50% of Items ordered in the individual tranche/ lot in the Purchase Order, provided reports of Standard Quality on samples testing are received from approved laboratories of CMSS.

17.6 (i) Variations in prices will be admitted on account of increase or decrease in the Statutory taxes levies, such as customs duty, GST etc., on production of relevant government notification, but during scheduled delivery period only.

(iii) Any increase in taxes and other statutory duties/levies after the expiry of the delivery date shall be to the supplier’s accounts. However, the benefit of any decrease in these taxes/duties shall be passed on to the purchaser by the supplier.

17.7 The supplier shall submit the following documents while claiming payments for supplies:
(a) Delivery challan along with the supplies (POD)  
(b) Packing list  
(c) Certificate of analysis along with the supplies (for each batch supplied).  
(d) Itemized Invoice/ Bill in duplicate to CMSS Head Office.  
(e) Such other documents as required by CMSS.

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

18. LIQUIDATED DAMAGES AND OTHER PENALTIES:  
18.1 DELAYS IN SUPPLIER’S PERFORMANCE:  

(a) Delivery of the goods and performance of services shall be made by the supplier in accordance with the time schedule specified by the purchaser in its purchase order. In case the supply is not completed in the stipulated delivery period, as indicated in the purchase order, purchaser reserves the right either to short-close/cancel this purchase order and/or recover liquidated damage charges. The cancellation/short-closing of the order shall be at the risk and responsibility of the supplier and purchaser reserves the right to purchase balance-unsupplied quantity at the risk and cost of the defaulting vendor.

(b) Repeated/habitual delays by the supplier in the performance of its delivery obligations shall render the supplier liable to any or all of the following sanctions: imposition of
liquidated damages, forfeiture of its performance security, and/or termination of the contract for default and purchaser reserves the right to purchase balance-unsupplied quantity at the risk and cost of the defaulting vendor.

(c) If the suppliers are not completed in the extended delivery period, the purchase order may be short closed without any compensation to supplier and the performance security shall be forfeited.

(d) Quantum of liquidated damages assessed and levied by the purchaser shall be final and not challengeable by the supplier.

(e) Purchaser reserves the right to debar/blacklist the supplier for a suitable period who habitually failed to supply the goods/services in time. The decision of purchaser will be final and binding.

18.2 If the supply reaches the designated consignee places or CMSS Warehouse after the 90th day or after scheduled delivery date mentioned in P.O., a liquidated damages will be levied at 0.5% per week for delayed supply up to a maximum of 10% of P.O. value, irrespective of the fact that whether the CMSS has suffered any damage/ loss or not, on account of delay in effecting supply. If the 60th day happens to be a holiday the supply will be accepted on the next working day without any penalty.

18.3 If the supply is received in damaged condition it shall not be accepted. In case of damage in the packing only, the supply may be accepted subject to purchaser’s decision and after
levying a penalty which may be upto 5% of cost of package received with damaged packing.

19. WARRANTY

19.1 The supplier shall warrant that goods/items to be supplied shall be new and free from all defects and faults in material, workmanship and manufacturing and shall be of the highest grade and consistent with the established and generally accepted standards for materials of the type ordered and shall perform in full conformity with the specifications. Supplier shall warrant that goods supplied will meet and maintain the technical specification throughout specified shelf life. The supplier shall be responsible for any defects that may develop under proper storage/ use, arising because of improper quality of API, Excipients in packaging material etc. manufacturing /packaging details from faulty materials, manufacturing or workmanship or otherwise and shall remedy such defects at his own cost when called upon to do so by the purchaser who shall state in writing in what respect stores is faulty.

19.2 The portion of clause 16.8 (i) to (v) would also apply in case the goods/items supplied doesn’t match to shelf life.

19.3 Replacement under warranty clause shall be made by the Supplier within 60 days period, free of all charges at site including freight, insurance and other incidental charges.

19.4 If any defect is not remedied within a reasonable time the purchaser may proceed to procure such defective quantities at the Supplier’s risk and cost from other tenderer or open market, but without prejudice to may other rights which the purchaser may have against the contract in respect of such defects.
20. DEDUCTION & OTHER PENALTIES ON ACCOUNT OF DELAYS/DEFAULT/TERMINATION/ PART CANCELLATION/SHORT CLOSURE:

20.1 If the samples do not conform to tender specifications, the Tenderer will be liable for relevant action under the existing laws and the entire stock in such batch has to be taken back by the Tenderer within a period of 30 days of the receipt of the letter from the CMSS. Such stock shall be taken back at the expense of the Tenderer. The CMSS has the right to destroy such “NOT OF STANDARD QUALITY ITEMS” if the Tenderer does not take back the goods within the stipulated time. The CMSS will arrange to destroy the “NOT OF STANDARD QUALITY ITEMS” after the expiry of 30 days mentioned above without further notice, and shall also collect demurrage charges calculated at the rate of 0.5% per week on the value of the items rejected till such time stipulated.

20.2 The CMSS will be at liberty to terminate, without assigning any reasons thereof, the contract either wholly or in part or short closed on 30 days notice. The Tenderer will not be entitled for any compensation whatsoever in respect of such termination besides forfeiture of Security Deposit and purchaser reserves the right to purchase balance-unsupplied item at the risk and cost of the defaulting vendor.

20.3 For infringement of the stipulations of the contract, for non-performance/compliance of contractual terms or for other justifiable reasons, the contract may be terminated either wholly, or in part or short closed. by the CMSS and the Tenderer shall be liable to pay for all losses sustained by the CMSS in consequence of the termination which may be recovered personally from the Tenderer or from his properties, as per rules besides forfeiture of Security Deposit.
20.4 In the event of making Alternative Purchase, as specified in Clause 13(f), Clause 14.2(a), Clause 16.8 and other clauses herein, penalty will be imposed on the supplier. The excess expenditure over and above contracted prices incurred by the CMSS, in making such purchases from any other sources or in the open market or from any other Tenderer who has quoted higher rates and other losses sustained in the process, shall be recovered from the Security Deposit or from any other money due and become due to the supplier and in the event of such amount being insufficient, the balance will be recovered personally from the supplier as per rules.

20.5 In all the above conditions, the decision of the CMSS shall be final and binding.

21. FALL CLAUSE

(i) Bidder undertakes and certifies that prices quoted are not higher than currently charged by it to institutional supplies/wholesalers/ any Govt. organisations/Charitable trust organisation for matching purchase terms/conditions. It is distinctly understood by bidder that in case of supply to such bodies (as detailed above) at price lower than the CMSS contracted price (within the contracted period specified) will immediately invite the reduction in the rates of the contract.

(ii) Breach of above, whenever comes to notice of CMSS, will be viewed seriously and action will be taken against the supplier which may include forfeiture of Security Deposit (SD) along with recovery of price differential, termination of the contract and disqualification from participating in future tender for the product.
for a suitable period. Decision of purchaser will be final and binding in this regard.

22. SAVING CLAUSE

No suit, prosecution or any legal proceedings shall lie against the Tender Inviting Authority or any person for anything that is done in good faith or intended to be done in pursuance of the tender.

23. PROHIBITION OF INFLUENCING CMSS BY THE BIDDER:

(i) No bidder shall contact or influence the CMSS or its employees on any matter relating to its bid from the time of bid opening to the time the contract is awarded.

(ii) Any effort by a bidder to influence the CMSS in the bid evaluation, bid comparison or contract award decisions may result in rejection of the bidder’s bid.

(iii) The bidder shall not make any attempt to establish unsolicited and unauthorized contact with the Tender Accepting Authority, Tender Inviting Authority or Tender Evaluation Committee after opening of the bids and prior to the notification of award and any attempt by any bidder to bring to bear extraneous pressures on the Tender Accepting Authority, Inviting Authority or Tender Evaluation Committee, shall be sufficient reason to disqualify the bidder.

(iv) Notwithstanding anything contained in clause (iii) above the Tender Inviting Authority or the Tender Accepting Authority, may seek bonafide clarifications from bidders relating to the bids submitted by them during the evaluation of bids.

24. RESOLUTION OF DISPUTES

(i) The CMSS and the supplier shall make every effort to resolve, amicably by direct informal negotiation any disagreement or
dispute arising between them under or in connection with the contract.

(ii) In case of a dispute or difference arising between the CMSS and a supplier relating to any matter arising out of or connected with this agreement, such dispute or difference shall be settled in accordance with the Arbitration and Conciliation Act, 1996. The venue of arbitration shall be New Delhi.

25. JURISDICTION
In the event of any dispute arising out of the tender such dispute would subject to the jurisdiction of the Civil Court within the city of New Delhi only.
Annexure-I

CENTRAL MEDICAL SERVICES SOCIETY- 110021

TENDER FOR THE SUPPLY OF FIRST LINE ANTI TB DRUGS TO CMSS FOR THE YEAR 2021-22

LIST OF PRODUCT & THEIR TECHNICAL SPECIFICATIONS

<table>
<thead>
<tr>
<th>Sch. No.</th>
<th>Item Code</th>
<th>Drug Name</th>
<th>Unit</th>
<th>Approx. Tender Quantity in Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>DSTB- IP(ADULT)</td>
<td>4FDC (Adult)</td>
<td>Strip of 28 tabs</td>
<td>2,39,98,426</td>
</tr>
<tr>
<td>II</td>
<td>DSTB- CP(ADULT)</td>
<td>3FDC (Adult)</td>
<td>Strip of 28 tabs</td>
<td>3,96,21,379</td>
</tr>
<tr>
<td>III</td>
<td>DSTB- IP(Pediatric)</td>
<td>3 FDC (PEDIATRIC)</td>
<td>Strip of 28 tabs</td>
<td>10,96,214</td>
</tr>
<tr>
<td>IV</td>
<td>DSTB- CP(Pediatric)</td>
<td>2 FDC (PEDIATRIC)</td>
<td>Strip of 28 tabs</td>
<td>15,82,294</td>
</tr>
<tr>
<td>V</td>
<td>PC-48</td>
<td>Ethambutol 100mg</td>
<td>Strip of 10 tabs</td>
<td>84,10,128</td>
</tr>
</tbody>
</table>

Delivery Terms:

(a) The delivery shall be on DDP (Destination basis) as shown at Annexure-I B.
(b) The delivery (In lot wise manner) shall be within 90 days from the date of LOA for Tranche I, 120-210 days (for tranche II) from the date of LOA.

Annexure 1A – Technical Specification (Refer page No 95)
Annexure 1B – CMSS warehouses (Consignee Location) (Refer page No 160)
Annexure II

TENDER FORWARDING LETTER

Date:

To,
DG&CEO,
Central Medical Services Society
2nd Floor, Vishwa Yuvak Kendra,
Pandit Uma Shaker Dixit Marg,
Chankyaapuri, New Delhi- 110021

Sub: Acceptance of Terms & Conditions of Tender.
Tender No: CMSS/PROC/2020-21/NTEP/010
Name of Tender: - Online tender for Procurement of First Line Anti TB Drugs for NTEP.

Dear Sir,

1. I/ We have downloaded / obtained the tender document(s) for the above mentioned ‘Tender/Work’ from the web site(s) namely:

as per your advertisement, given in the above mentioned website(s).
2. I / We hereby certify that I / we have read the entire terms and conditions of the tender documents (Including all document like annexure(s), schedule(s), etc . ), which form part of the contract agreement and I / we shall abide hereby by the terms / conditions / clauses contained therein.
3. The corrigendum(s) issued from time to time by your department/ organization too has also been taken into consideration, while submitting this acceptance letter.
4. I / We hereby unconditionally and unequivocally accept the tender conditions of above mentioned tender document(s) / corrigendum(s) in its totality / entirety.
5. I / We do hereby declare that our Firm has not been blacklisted/ debarred by any Govt. Department/Public sector undertaking for the quoted product from any procurement agency or as a whole.
6. I/We hereby declare that bid will remain valid for a period of 150 days after opening of Tender bid/packet1
7. I / We certify that all information furnished by our Firm is true & correct and in the event that the information is found to be incorrect/untrue or found violated, then your department/ organization shall without giving any notice or reason therefore or summarily reject the bid or...
terminate the contract, without prejudice to any other rights or remedy including the forfeiture of the full said earnest money deposit absolutely.

Yours Faithfully,

(Signature of the Tenderer, with Official Seal)
This page is intentionally left blank
DETAILS OF E.M.D. SUBMITTED

We herewith submit the E.M.D. of Rs.____________________ in the form of DD/FDR/RTGS/NEFT/Bank Guarantee vide document Ref. No.________________ Dated: ________________ Bank: ________________________________ in favour of Central Medical Services Society for the following items of FIRST LINE ANTI TB DRUGS:

<table>
<thead>
<tr>
<th>Sch. No.</th>
<th>Product Code</th>
<th>Name of the product</th>
<th>UOM</th>
<th>Quantity in Bid</th>
<th>Amount of EMD Payable (in INR) for 100% quantity</th>
<th>Amount of EMD Payable (in INR) for 50% quantity</th>
<th>Quantity Quoted</th>
<th>% of the Bid</th>
<th>Amount of EMD</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>DSTB-IP(ADULT)</td>
<td>4FDC (Adult)</td>
<td>Strip of 28 tabs</td>
<td>2,39,98,426</td>
<td>38951846</td>
<td>19475923</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>DSTB-CP(ADULT)</td>
<td>3FDC (Adult)</td>
<td>Strip of 28 tabs</td>
<td>3,96,21,379</td>
<td>50505372</td>
<td>25252686</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>DSTB-IP(Pediatric)</td>
<td>3 FDC (PEDIATRIC)</td>
<td>Strip of 28 tabs</td>
<td>10,96,214</td>
<td>2011114</td>
<td>1005557</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IV</td>
<td>DSTB-CP(Pediatric)</td>
<td>2 FDC (PEDIATRIC)</td>
<td>Strip of 28 tabs</td>
<td>15,82,294</td>
<td>2417112</td>
<td>1208556</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IV</td>
<td>PC- 48</td>
<td>Ethambutol 100mg</td>
<td>Strip of 10 tabs</td>
<td>84,10,128</td>
<td>1271612</td>
<td>635806</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total</td>
<td></td>
<td>95157056</td>
<td>47578528</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total: 95157056 INR
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PROFORMA FOR PERFORMANCE STATEMENT

(FOR A PERIOD OF LAST 3 YEARS)

Name of firm ________________________________
Sr. No. of the Product _______________
Name of the Product ________________

<table>
<thead>
<tr>
<th>Sch. No</th>
<th>Name of Product</th>
<th>Year 2016-17</th>
<th>Year 2017-18</th>
<th>Year 2017-18</th>
<th>Quantity manufactured and marketed</th>
<th>UOM</th>
<th>Name and full address of the Purchaser</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>4FDC (Adult)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>3FDC (Adult)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>3 FDC (PEDIATRIC)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IV</td>
<td>2 FDC (PEDIATRIC)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>V</td>
<td>Ethambutol 100mg</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note:

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

Signature of Tenderer
Name in Capitals
Date:
Seal:

Signature of Auditor/ Chartered Accountant
Name in Capitals
Date:
Seal
**ANNUAL TURN OVER STATEMENT**

The Annual Turnover (Sales) of M/s.____________________________ for the past two years are given below and certified that the statement is true and correct.

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Financial Year</th>
<th>Turnover in Lakhs(Rs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>2017-2018</td>
<td>-</td>
</tr>
<tr>
<td>2.</td>
<td>2018-2019</td>
<td>-</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>Rs. ___________</strong></td>
</tr>
</tbody>
</table>

Average Turnover Per Annum in the last two years mentioned above - Rs.___________ Lakhs.

Date: ________________________________

Signature of Auditor/ Chartered Accountant
Seal: ________________________________
(Name in Capital)
**LIST OF ITEMS QUOTED & THEIR PRODUCTION CAPACITY**

1. Name of the firm : 

2. Address of the firm as given in Drug license : 

3. Details of Endorsement for all products quoted :

<table>
<thead>
<tr>
<th>Sch No</th>
<th>Item Code</th>
<th>Drug Name</th>
<th>UOM</th>
<th>Quantity Tendered</th>
<th>Quantity quoted</th>
<th>Manufacturing Capacity</th>
<th>Quantity Manufactured</th>
<th>Average Quantity Manufactured</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8A</td>
<td>8B</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**TOTAL**

Date:  

Authorized Signatory:
## CHECK LIST

### Packet 1

<table>
<thead>
<tr>
<th>No.</th>
<th>Description</th>
<th>Attached</th>
<th>Pg. No. in bid</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Checklist – Annex-VII (Clause 6 n)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>EMD in the form of DD/ BG as per Annex-III / MSME certificate for exemption (Clause 6 a)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Certificate by MSME/ SSI units in support of being a MSE/ SSI unit. (Clause 6 a)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Duly attested photocopy of Manufacturing License (valid on the date of tender opening) for the product duly approved by the Licensing Authority for each and every product quoted. (Clause 6 c)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Authorization letter nominating a responsible person of the tenderer to transact the business with the Tender inviting Authority. (Clause 6 p)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Market Standing Certificate issued by the Licensing Authority(Clause 6 e)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Non Conviction Certificate issued by the Drugs Controller (Clause 6 h)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>WHO-GMP Certificate (valid on the date of tender opening) (Clause 6 i)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>Annual Turnover Statement for 2 Years i.e. 2017-18 and 2018-19(Clause 6 j) (Annex-V)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>Copies of Balance Sheet &amp; Profit &amp; Loss Account for last two years i.e. 2017-18 and 2018-19(Clause 6 k)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11.</td>
<td>Proforma for Performance Statement (Annex-IV)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12.</td>
<td>List of items quoted and their production capacity – Annex-VI (Clause 6 l)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13.</td>
<td>Mandate Form for RTGS Annex-XII.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>-----</td>
<td>----</td>
</tr>
<tr>
<td>14. The Tender document signed by the tenderer in all pages with office seal. (Clause 6 o)</td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>15. Long Term Stability Data of the quoted products (at least for 3 batches) to support specified shelf life. (Clause 6 m)</td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>16. Capacity and Quality Certificate issued by the Licensing Authority (Clause 6 f)</td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>17. Undertaking that Firm is not blacklisted or debarred from any Govt. Agency (Clause 4 d)</td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>18. Notarized Undertaking by MSE (Annex – VIII) (Clause 6 a)</td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>19. No Deviation Certificate (Clause 6 q)</td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>20. CoPP (Certificate of Pharmaceutical Product) - Valid on the date of tender opening (Clause 6 i)</td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>21. Tender forwarding letter (Annexure-II) (Clause 6 b)</td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>22. Near Relative Certificate (Annexure-XVIII) (Clause 6 r)</td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>23. Supplied Quantity (PO Copies) (minimum 50% of the quoted quantity) (Clause 6 g)</td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>24. Draft Artwork</td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>25. Certificate i.r.o Class I Local Bidder</td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

**NOTE:**
Bidders are requested to submit all documents with the bid as shown as checklist (Annexure VII). NO CLARIFICATIONS may be sought from bidders and incomplete bid may be summarily rejected at sole responsibility of bidder(s). CMSS decision in this regard will be final and binding.

*M/s _________________________________*  
*For Self and Firm / Company Ltd.*  

*Signature and Seal*
NOTARISED UNDERTAKING BY MSE COMPANIES

(In 20- Rupees stamp paper)

I ____________, S/o ____________, Proprietor / Partner / Managing Director of ____________________________ (Proprietary Concern / Firm / Company Ltd.) execute this Undertaking for myself and on behalf of ________________________ (Proprietary Concern / Firm / Company Ltd.).

2. Whereas, CMSS (Tender Inviting Authority) has invited Tender for supply of Drugs and medicines for the year 2021 and in pursuant to the conditions in the tender documents. M/s ____________________________ (Proprietary Concern / Firm / Company Ltd.), having its Office at ___________________________________________________________________________________________ is exempted from payment of Earnest Money Deposit as indicated in the Annexure-III of tender document.

3. And whereas, in pursuant to the conditions in Clause Nos. 9.2, 9.3 & 9.4 of the tender, the Earnest Money Deposit can be forfeited by the Tender Inviting Authority in case of violation of any of the conditions and for non-performance of the obligation under tender document.

4. In consideration of exempting M/s.__________________________ (Proprietary Concern / Firm / Company Ltd.) from payment of Earnest Money Deposit as indicated in the Annexure-III of tender document, I undertake to pay the said sum without any demur on receipt of demand issued by the tender inviting authority.

M/s ____________________________
For Self and Firm / Company Ltd.

Signature and Seal

Witness:-
(1)

(2)
LETTER OF ACCEPTANCE

No: CMSS/PROC/2020-21/NTEP/010 Date _________

To,

M/s ______________________________
Address: ________________________
Attn: _____________________________
Phone: __________________________
Email ____________________________

(Kind Attn: _________________(Name), _____________ Designation)

Sub: Acceptance of Tender for supply of First Line Anti TB Drugs to CMSS

Ref: 1) CMSS Tender No. CMSS/PROC/2020-21/NTEP/010 opened on ___________
    2) Your Ref. No. _____ dated _________ in response to above mentioned tender.

Dear Sir,

1. I am pleased to inform you that your offer in response to above mentioned tender for supply of ITEMS FOR NTEP has been accepted for following items:

<table>
<thead>
<tr>
<th>Sch No.</th>
<th>Items Description</th>
<th>Quantity</th>
<th>Unit</th>
<th>Ex- Works per Unit (Rs.)</th>
<th>GST (%)</th>
<th>GST (Rs)</th>
<th>Transport &amp; any other charges (Rs.)</th>
<th>Total unit price (all incl) (Rs.)</th>
<th>Grand Total (Rs.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. You are requested to deposit Security Deposit @ 5% 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 Annex-X of the Tender document, within 15 days from the date of receipt of this letter. The Security Deposit shall be valid for 1625 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/2020-21/NTEP/010 and subsequent amendments to it.
5. Delivery Period: As specified in Annexure I of Tender Document.

6. Manufacturing license as per Annexure A and Consignee List as per Annexure B.

7. Payment Terms: Within 75 days of supplies in respect of items requiring sterility tests and within 60 days of supplies for other items.

Encl: - **Annexure A**: List of manufacturing license and site address.  
**Annexure B**: List of consignee.

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 to LOA No:
Supplier: M/s ________________

Annexure - A

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Item Code</th>
<th>Item Description</th>
<th>Manufacturing Site Address</th>
<th>Manufacturing License No.</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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LONG TERM AGREEMENT (LTA) NO.: CMSS/PROC/2020-21/NTEP/010/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 First Line Anti TB Drugs in the Tender Reference No. CMSS/PROC/2020-21/NTEP/010, 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 First Line Anti TB Drugs, 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/2020-21/NTEP/010 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 Annexes, however with due consideration of the order of precedence among the LTA and individual Annexes.

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:
(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, Annex 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.

2. PURPOSE OF LTA:

1.1 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.

1.2 Brief particulars of the Products or goods which shall be supplied / provided by the Supplier are as under.

<table>
<thead>
<tr>
<th>Sch No.</th>
<th>Items Description</th>
<th>Quantity</th>
<th>Unit</th>
<th>Ex-Works per Unit (Rs.)</th>
<th>GST (%)</th>
<th>GST (Rs)</th>
<th>Transport &amp; any other charges (Rs.)</th>
<th>Total unit price (all incl) (Rs.)</th>
<th>Grand Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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</tbody>
</table>

1.3 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 Address:

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

Supplier: M/s

**LIST OF MANUFACTURING LICENSES & SITE ADDRESSES**

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Item Code</th>
<th>Item Description</th>
<th>Manufacturing Site Address</th>
<th>Manufacturing License No.</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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</tbody>
</table>
CENTRAL MEDICAL SERVICES SOCIETY  
Ministry of Health & Family Welfare  
(Government of India)  
2nd Floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Marg,  
Opposite Police Station Chankaya Puri, New Delhi-110021, India  

PURCHASE ORDER  
PO No: CMSS/PROC/ 2020-2021/ NTEP/010/PO/....... Dated: _____________ 

To,  
M/s ______________________________  
Address: ________________________  
Attn: _____________________________  
Phone: __________________________  
Email ____________________________  

Subject: Purchase Order for supply of First Line Anti TB Drugs.  
Ref : Long Term Agreement No: CMSS/PROC/ 2020-21/ NTEP/010/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:  

<table>
<thead>
<tr>
<th>Sr.No</th>
<th>Item Code</th>
<th>Item Description</th>
<th>Quantity Accepted by the Purchaser</th>
<th>Unit</th>
<th>Ex Works Price per Unit (Rs)</th>
<th>GST (%)</th>
<th>GST (Rs)</th>
<th>Transportation Charges (Rs)</th>
<th>Rate Per Unit (Landed Price)(Rs)</th>
<th>Total Value (Rs)</th>
<th>Destination</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>As per Annex 1</td>
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<td>As per Annex 1</td>
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<td>3</td>
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<td>As per Annex 1</td>
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</tbody>
</table>

1. All the Terms & Conditions of the Agreement signed by you on acceptance of your tender are applicable.  

2. Delivery Period: 90 Days from the date of LOA.  

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

Supplier: M/s

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Item Description</th>
<th>Consignee Location</th>
<th>Consignee Address</th>
<th>Quantity</th>
<th>UOM</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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<td>3</td>
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</tr>
</tbody>
</table>
Annexure B to PO No:
Supplier: M/s

### LIST OF MANUFACTURING LICENSES & SITE ADDRESSES

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Item Code</th>
<th>Item Description</th>
<th>Manufacturing Site Address</th>
<th>Manufacturing License No.</th>
<th>Remarks</th>
</tr>
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<tbody>
<tr>
<td>1</td>
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</tbody>
</table>
# MANDATE FORM

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>01</td>
<td>Company Name</td>
</tr>
<tr>
<td>02</td>
<td>Postal Address of the company with Telephone No., Fax No. and Mail ID.</td>
</tr>
<tr>
<td>03</td>
<td>Name of the Managing Director / Director / Manager Mobile No. / Phone No. E-mail ID.</td>
</tr>
<tr>
<td>04</td>
<td>Name and Designation of the authorized company official Mobile No. E-mail ID</td>
</tr>
</tbody>
</table>

Date: [Blank]  
Place: [Blank]  
Company Seal & Signature  
(Name of the person signing & designation)
Mandate Form contd..

<table>
<thead>
<tr>
<th>No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Name of the Bank. Branch Name&amp; address. Branch Code No. Branch Manager Mobile No. Branch Telephone no. Branch E-mail ID</td>
</tr>
<tr>
<td>02</td>
<td>9 digit MICR code number of the bank and branch appearing on the MICR cheque issued by the bank</td>
</tr>
<tr>
<td>03</td>
<td>IFSC code of the Branch</td>
</tr>
<tr>
<td>04</td>
<td>Type of Account (Current / Savings)</td>
</tr>
<tr>
<td>05</td>
<td>Account Number (as appear in Cheque book)</td>
</tr>
</tbody>
</table>

(in lieu of the bank certificate to be obtained, please attach the original cancelled cheque issued by your bank for verification of the above particulars).

I /We hereby declare that the particulars given above are correct and complete. If the transaction is delayed or not effected at all for reasons of incomplete or incorrect information, I would not hold M/s. Central Medical Services Society (CMSS) responsible. I have read the conditions of the tender/agreement entered and agree to discharge the responsibility expected of me / from the company as a tenderer /successful tenderer.

Date:                             Company Seal    Signature
Place:                             (Name of the person signing& designation)

CERTIFIED THAT THE PARTICULARS FURNISHED ABOVE BY THE COMPANY ARE CORRECT AS PER OUR RECORDS.

Bank Seal with address.    Signature of the authorized official of the bank.

----------------------------------------------------------------------------------------------------------------
### TENDER FOR PROCUREMENT OF FIRST LINE ANTI TB DRUGS FOR YEAR 2021

Schedule of price bid in the form of BOQ_XXXX.xls uploaded online.

(Below sheet is only for reference)

<table>
<thead>
<tr>
<th>Sl No.</th>
<th>Name of the Item</th>
<th>Location</th>
<th>Quantity in Tents</th>
<th>Tender Offered</th>
<th>Total Price per Unit in Rs.</th>
<th>CST (in Rs.)</th>
<th>Transport &amp; Other Charges in Rs. (Till Container Loaders DEP basis. All inclusive &amp; firm &amp; fixed)</th>
<th>Total Unit Price (Col 7 + Col 8)</th>
</tr>
</thead>
<tbody>
<tr>
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<td>10000</td>
</tr>
</tbody>
</table>

**Note:**

1. List of CMSS warehouses as per Annex-I B.
2. Details of weight, volume and dimensions of shipping cartons and intermediate cartons may be provided as an additional annex to this form.
Bank Guarantee for EMD (Format)

[The Bank shall fill in this Bank Guarantee Form in accordance with the instructions indicated.]

[insert Bank’s Name, and Address of Issuing Branch or Office]
Beneficiary:  [insert Name and Address of Purchaser]
Date:  ________________
BIDGUARANTEE No.:  __________________

We have been informed  that [insert name of the Tenderer ] (hereinafter called “the Tenderer “) has submitted to you its bid dated (hereinafter called “the Bid“) for the execution of [insert name of contract] under Tender No…………………………

Further more, we understand that, according to your conditions, bids must be supported by an EMD.

At the request of the Tenderer ,we [insert name of Bank] hereby irrevocably undertake 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)]
Security Bank Guarantee (Format)

____________________ [insert: Bank’s Name, and Address of Issuing Branch or Office]

Beneficiary: ______________ [insert: Name and Address of Purchaser]
Date: ______________

PERFORMANCE GUARANTEE No.: ____________

We have been informed that [insert: name of Supplier] (hereinafter called “the Supplier”) has received a Letter of Acceptance No. [insert: reference number of the Letter of Acceptance] dated __________ for entering into a Rate Agreement with you, for the supply of [insert: description of goods]

Furthermore, we understand that, according to the conditions of the Tender, a performance guarantee is required post acceptance of letter of Acceptance.

At the request of the Supplier, we [insert: name of Bank] hereby irrevocably undertake 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 Supplier is in breach of its obligation(s) under the Tender, without your needing to prove or to show grounds for your demand or the sum specified therein.

This guarantee shall expire no later than the ___ day of __________, 2________, and any demand for payment under it must be received by us at this office on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No. 758, except that subparagraph (ii) of Sub-article 20(a) is hereby excluded.

____________________
[signature(s)]

The Guarantor shall insert an amount representing the percentage of the Price specified in the letter of Acceptance and denominated in the currency of the Contract.

Established in accordance with tender conditions taking into account any warranty obligations of the Supplier as per tender conditions. The Purchaser should note that in the event of an extension of the time to perform the Contract, the Purchaser would need to request an extension of this guarantee from the Guarantor. Such request must be in writing and must be made prior to the expiration date established in the guarantee. In preparing this guarantee, the Purchaser might consider adding the following text to the form, at the end of the penultimate paragraph: “The Guarantor agrees to a one-time extension of this guarantee for a period not to exceed [six months] [one year], in response to the Purchaser’s written request for such extension, such request to be presented to the Guarantor before the expiry of the guarantee.”
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Instructions for Online Bid Submission

The tenderers are required to submit soft copies of their bids electronically on the CPP Portal, using valid Digital Signature Certificates. The instructions given below are meant to assist the tenderers in registering on the CPP Portal, prepare their bids in accordance with the requirements and submitting their bids online on the CPP portal.

More information useful for submitting online bids on the CPP Portal may be obtained at:

REGISTRATION

1) Tenderers are required to enroll on the e-Procurement module of the Central Public Procurement Portal (URL: https://eprocure.gov.in/eprocure/app) by clicking on the link “Online tenderer Enrolment” on the CPP Portal which is free of charge.

2) As part of the enrolment process, the tenderers will be required to choose a unique user name and assign a password for their accounts.

3) Tenderers are advised to register their valid email address and mobile numbers as part of the registration process. These would be used for any communication from the CPP Portal.

4) Upon enrolment, the tenderers will be required to register their valid Digital Signature Certificate (Class II or Class III Certificates with signing key usage) issued by any Certifying Authority recognized by CCA India (e.g. Sify/ n- Code/e-Mudhra etc.), with their profile.

5) Only one valid DSC should be registered by a tenderer. Please note that the tenderers are responsible to ensure that they do not lend their DSC’s to others which may lead to misuse.

6) Tenderer then logs into the site through the secured log-in by entering their user ID /password and the password of the DSC /e-Token.

SEARCHING FOR TENDER DOCUMENTS

1) There are various search options built in the CPP Portal, to facilitate tenderers to search active tenders by several parameters. These parameters could include Tender ID, Organization Name, Location, Date, Value, etc. There is also an option of advanced search for tenders, wherein the tenderers may combine a number of search parameters such as Organization Name, Form of Contract, Location, Date, Other keywords etc. to search for a tender published on the CPP Portal.

2) Once the tenderers have selected the tenders they are interested in, they may download the required documents/tender schedules. These tenders can be moved to the respective ‘My Tenders’ folder. This would enable the CPP Portal to intimate the tenderers through SMS /e-mail in case there is any corrigendum issued to the tender document.

3) The tenderer should make a note of the unique Tender ID assigned to each tender, in case they want to obtain any clarification/help from the Helpdesk.
PREPARATION OF BIDS

1) Tenderer should take into account any corrigendum published on the tender document before submitting their bids.

2) Please go through the tender advertisement and the tender document carefully to understand the documents required to be submitted as part of the bid. Please note the number of covers in which the bid documents have to be submitted, the number of documents—including the names and content of each of the document that need to be submitted. Any deviations from these may lead to rejection of the bid.

3) Tenderer, in advance, should get ready the bid documents to be submitted as indicated in the tender document/schedule and generally, they can be in PDF/XLS/RAR/DWF/JPG formats. Bid documents may be scanned with 100dpi with black and white option which helps in reducing size of the scanned document.

4) To avoid the time and effort required in uploading the same set of standard documents which are required to be submitted as a part of every bid, a provision of uploading such standard documents (e.g. PAN card copy, annual reports, auditor certificates etc.) has been provided to the tenderers. Tenderer scan use “My Space” or “Other Important Documents” area available to them to upload such documents. These documents may be directly submitted from the “My Space” area while submitting a bid, and need not be uploaded again and again. This will lead to a reduction in the time required for bid submission process.

SUBMISSION OF BIDS

1) Tenderer should log into the site well in advance for bid submission so that they can upload the bid in time i.e. on or before the bid submission time. Tenderer will be responsible for any delay due to other issues.

2) The tenderer has to digitally sign and upload the required bid documents one by one as indicated in the tender document.

3) Tenderer has to select the payment option as “offline” to pay the tender fee/ EMD as applicable and enter details of the instrument.

4) Tenderer should prepare the EMD as per the instructions specified in the tender document. The original should be posted/couriered/given in person to the concerned official, latest by the last date of bid submission or as specified in the tender documents. The details of the DD/any other accepted instrument, physically sent, should tally with the details available in the scanned copy and the data entered during bid submission time. Otherwise the uploaded bid will be rejected.
5) Tenderers are requested to note that they should necessarily submit their financial bids in the format provided and no other format is acceptable. If the price bid has been given as a standard BoQ format with the tender document, then the same is to be downloaded and to be filled by all the tenderers. Tenderers are required to download the BoQ file, open it and complete the white coloured (unprotected) cells with their respective financial quotes and other details (such as name of the tenderer). No other cells should be changed. Once the details have been completed, the tenderer should save it and submit it online, without changing the file name. If the BoQ file is found to be modified by the tenderer, the bid will be rejected.

6) The server time (which is displayed on the tenderers' dashboard) will be considered as the standard time for referencing the deadlines for submission of the bids by the tenderers, opening of bids etc. The tenderers should follow this time during bid submission.

7) All the documents being submitted by the tenderers would be encrypted using PKI encryption techniques to ensure the secrecy of the data. The data entered cannot be viewed by unauthorized persons until the time of bid opening. The confidentiality of the bids is maintained using the secured Socket Layer128 bit encryption technology. Data storage encryption of sensitive fields is done. Any bid document that is uploaded to the server is subjected to symmetric encryption using a system generated symmetric key. Further this key is subjected to a symmetric encryption using buyers/bid openers' public keys. Overall, the uploaded tender documents become readable only after the tender opening by the authorized bid openers.

8) The uploaded tender documents become readable only after the tender opening by the authorized bid openers.

9) Upon the successful and timely submission of bids (i.e. after Clicking “Freeze Bid Submission” in the portal), the portal will give a successful bid submission message & a bid summary will be displayed with the bid no. and the date & time of submission of the bid with all other relevant details.

10) The bid summary has to be printed and kept as an acknowledgement of the submission of the bid. This acknowledgement may be used as an entry pass for any bid opening meetings.

ASSISTANCE TO TENDERERS

1) Any queries relating to the tender document and the terms and conditions contained therein should be addressed to the Tender Inviting Authority for a tender or the relevant contact person indicated in the tender.

2) Any queries relating to the process of online bid submission or queries relating to CPP Portal in general may be directed to the 24x7 CPP Portal Helpdesk Ph.:0120-4200462, 0120-4001002. Mobile: 91 8826246593

.......................................................................................................................
........................................................................
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Annexure- XVII

No Deviation Certificate

This is to certify that the product(s) quoted by our firm, M/s. is as per the given technical specifications in the tender document & there is no deviation in relation to any conditions/requirements specified in the tender document.

Authorized Signatory
Near Relative Certificate

(In case of Proprietorship firm certificate will be given by the proprietor. For partnership firm certificate will be given by all the partners and in case of limited company by all the Directors of the company excluding Govt. of India/Financial Institutions nominees and independent non-official part time directors appointed by Govt. of India or the Governor of the state. Authorised signatory of bid may also sign this bid on behalf of the entire directors/partners/proprietor).

This is to certify that none of my/our Company Directors’ near relative as defined below currently works in CMSS where I am/we are going to apply for the tender. I/We also agree to the condition that due to any breach of conditions by the company or firm or any other related person the bid submitted on behalf of the company or firm will be cancelled and bid security will be forfeited at any stage whenever it is noticed and CMSS will not pay any damage to the company or firm or the concerned person. The company or firm will also be debarred for further participation for the quoted item in CMSS for a period of one year.

The near relatives for this purpose are defined as:

(a) Members of a Hindu undivided family.

(b) They are husband and wife.

(c) The one is related to the other in the manner as father, mother, son(s) & son’s wife (Daughter in law), daughter(s) and daughter’s husband (son in law), brothers(s) and brother’s wife, sister(s) and sister’s husband (brother in law).

Signature/Signatures (with Stamp)
Annexure 1A- Technical Specification
Product Code DSTB- IP (Adult Patients)

A. Specific requirements

Item:

Product Code DSTB-IP(A) (Drug Sensitive Anti Tuberculosis Drugs for Intensive Phase-Adult Patients) consists of 24 blister packs of Schedule 13 for Intensive Phase. The drugs 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 drugs contained in the product shall also have valid registration in India and shall meet all the requirements of the licensing authority in India.

<table>
<thead>
<tr>
<th>Serial no.</th>
<th>Item : Schedule 13</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td></td>
<td>Schedule 13 is a blister pack of 28 tablets, each tablet consisting of Isoniazid, Rifampicin, Pyrazinamide and Ethambutol in fixed dose combination (HRZE–Fixed Dose Combination). The FDCs in blister pack shall conform to the general requirements of Tablets and the requirements under individual monograph given in IP or any other International Pharmacopoeia of equivalent accuracy. Each FDC tablet shall contain - Isoniazid *Selected Pharmacopeia (IP/ BP/USP/Other International pharmacopeia 75 mg  Rifampicin *Selected Pharmacopeia (IP/ BP/USP/Other International pharmacopeia 150 mg  Pyrazinamide *Selected Pharmacopeia (IP/ BP/USP/Other International pharmacopeia 400 mg  Ethambutol Hydrochloride *Selected Pharmacopeia (IP/ BP/USP/Other International pharmacopeia 275 mg  The quality of Isoniazid, Rifampicin, Ethambutol Hydrochloride and Pyrazinamide shall conform to the requirements of the individual monograph given in IP or any other International Pharmacopoeia of equivalent accuracy.</td>
</tr>
</tbody>
</table>

*Only one of the selected pharmacopeia to be indicated.
<table>
<thead>
<tr>
<th>02</th>
<th>Protocol and Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>For manufacturer outside India: Complete test protocols along with the samples of all the batches should be sent to the Head of a Testing laboratory identified and specified by the purchaser.</td>
<td></td>
</tr>
<tr>
<td>For Indian manufacturer: Complete Test Protocol and samples are taken and sent to the laboratory (identified by the purchaser) by the Inspecting Officer duly sealed and signed by him or his authorized representative. Protocols of tests should include the requirements given for Capsules or Tablets as the case may be and those included under individual monograph given in I IP or any other International Pharmacopoeia, besides the following tests</td>
<td></td>
</tr>
<tr>
<td><strong>Package Integrity Test:</strong> Check 10 strips (com bipacks). Bundle up the strips and submerge them under water in a vacuum desiccator or equivalent device. Draw a vacuum of about 18k Pa and hold for a minute. Examine for the air leakage indicated by a fine stream of bubbles. Reestablish normal pressure and open strips to examine for water penetration</td>
<td></td>
</tr>
<tr>
<td><strong>Microbial Count:</strong> When the test is conducted as per IP</td>
<td></td>
</tr>
<tr>
<td>-Total viable aerobic count- Not more than $10^3$ bacteria and not more than $10^2$ fungi per gram</td>
<td></td>
</tr>
<tr>
<td>-Absence of Escherichia coli</td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>
Design & alignment of the tablets should be strictly as per figure given below.

The label shall indicate the content of Isoniazid identified as ‘H’; content of Rifampicin identified as ‘R’; content of Ethambutol Hydrochloride identified as ‘E’; and content of Pyrazinamide identified as ‘Z’ in each tablet.

All labeling 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 drugs, Schedule H1 drug warning and storage requirements.

Information pertaining to date of manufacturing, date of expiry & batch no. of a blister should be imprinted on atleast 2 edges of the blister. Remaining requisite information i.e. manufacturing license no., Schedule H1 drug warning and storage requirements etc. may be printed once on reverse side of the blister. All the requisite information printed on blisters should be displayed clearly & prominently.

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

Each blister strip will contain 28 tablets of HRZE –Fixed Dosed Combination, in the packaging designed and aligned as given above.
| 05 | 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. |
| 06 | Quality Assurance - Evidence | The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned. The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for shipment. The Supplier shall provide a copy of Validation records with regards to process validation demonstrating batch to batch consistency. The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment. The Supplier shall provide to the Purchaser a copy of the approval of each source material, constituent material and component for each lot intended for shipment. The Supplier shall provide evidence of basis for expiration dating and other stability data concerning the commercial final package at the time of bid submission. 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 Millboard/grayboard 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. |
| 07 | 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. |
| 08 | 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. |
| 09 | Primary Packaging (Blister): | A blister consisting of 28 tablets of the drugs duly identified should be packed in an Aluminium-PVC blister pack. The blister should be tropicalized with regard to moisture barrier properties for drug stability under field conditions. Quality Assurance shall be according to ISO 9001 for all 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 **Red coloured**, Thickness: 0.025mm. |
Strip size: Schedule – 13 Approx. 187 mm X 106 mm +/– 5mm

Blister Strips should have perforations and spacing between tablets enough to allow removal by patients with finger deformities and easier separation of individual tablets from the strips.

**Complex Constructions with PVC Films**

!![](image)

**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):**

<table>
<thead>
<tr>
<th>Temperature (°C)</th>
<th>Relative Humidity (% RH)</th>
<th>Vapour Transmission rate (gsm/24h)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thermoformed</td>
<td>Not thermoformed</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>85</td>
<td>0.15</td>
</tr>
<tr>
<td>38</td>
<td>90</td>
<td>0.7</td>
</tr>
</tbody>
</table>

**Shrinkage longitudinally**

T = 140°C, t = 20 min. (%) 5 – 6

Application temperature (°C) 68 – 74
A. Storage & Shelf-life

**Storage:** Store protected from light and moisture at room temperature.

**Shelf-life:** 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 test data substantiating the claimed shelf life in the proposed package (blister pack). 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:

<table>
<thead>
<tr>
<th>Study</th>
<th>Storage condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long Term Stability</td>
<td>25 °C ± 2 °C/60% RH ± 5% RH or</td>
</tr>
<tr>
<td></td>
<td>30 °C ± 2 °C/65% RH ± 5% RH</td>
</tr>
</tbody>
</table>

**Shelf life would be as follows:**

- **Rifampicin:** shelf life should not be less than Minimum 24 months from the date of manufacture.
- **Isoniazid:** shelf life should not be less than Minimum 24 months from the date of manufacture.
- **Ethambutol hydrochloride:** shelf life should not be less than Minimum 24 months from the date of manufacture.
- **Pyrazinamide:** shelf life should not be less than Minimum 24 months from the date of manufacture.
- **Shelf-life** of the drugs in Fixed Dose Combination should not be less than Minimum 24 months from the date of manufacturing.

B. Labelling:

**Requirements applicable to all Labels:**

- Shall meet WHO GMP standards.
- All the labels should be peel proof.
- NTEP Central Government Supply – NOT FOR SALE to be imprinted on the blister strips, Mill board / Grey Board and 5-Ply Shipper.
- NTEP TB logo to be imprinted on the Millboard/Greyboard Box and 5-Ply Shipper.
The labels on the Millboard/Greyboard and 5 – Ply Shipper should be readable from a distance. The label of 5 – Ply Shipper should be of at least A-4 paper size with date of manufacture, date of expiry, batch no., to be mentioned in bold Arial font size 18 so as to be readable from a distance. It should be seen clearly by naked eyes.

**Labeling for Millboard/ Grey board Box:**

<table>
<thead>
<tr>
<th>National Tuberculosis Elimination Programme (NTEP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANTI-TB DRUG REGIMEN CATEGORY DSTB- IP (A)</td>
</tr>
<tr>
<td>DAILY TREATMENT REGIMEN CONTAINS DRUGS FOR INTENSIVE PHASE (Adult Patients)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>24 Blister packs for Intensive Phase (Schedule 13)</th>
</tr>
</thead>
<tbody>
<tr>
<td>H E R Z</td>
</tr>
</tbody>
</table>

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.

“NTEP Central Government Supply NOT FOR SALE”
Manufacturer’s Name
Manufacturing Lic. No.
The labels on Millboard/Grey board Box must be attached to at least two sides and shall be red in colour. The label should include the name of the product, name of the manufacturer, batch number/Mfg. date/Expiry date of the drug. The label shall also include storage instruction. 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).

Labeling for 5 – Ply Shipper packaging:

5 – PLY SHIPPER

National Tuberculosis Elimination Programme (NTEP)
ANTI-TB DRUG REGIMEN CATEGORY DSTB- IP (A)

DAILY TREATMENT REGIMEN CONTAINS DRUGS FOR
INTENSIVE PHASE (Adult Patients)
20 Millboard/Greyboard Boxes

H E R Z

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.

“NTEP Central Government Supply
NOT FOR SALE”

Manufacturer's Name
Manufacturing Lic. No.
The labels on shipper package must be attached to at least two sides and shall be Red in colour. The label should include the name of the product, the number of Millboard/Greyboard Boxes, the name of the manufacturer, batch number/Mfg. date/Expiry date of the drug within the schedule. The label shall also include storage/handling instructions as well as the Batch No. of the Box along with Date of Expiry of Box. 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).

**Numbering of shipper packaging:**
All 5 Ply Shippers boxes should be numbered consecutively. Shipping documents should be included in the Shipper numbered first (consignee wise).

**C. 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.

**D. 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.

**E. Colour Coding:**

The labels on Millboard/Greyboard Box and 5 Ply Shipper shall be identified as indicated below:-

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Blister</th>
<th>Millboard (Label)</th>
<th>5 – PLY SHIPPER (Label)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PC- DSTB- IPA)</td>
<td>Red</td>
<td>Red</td>
<td>Red</td>
</tr>
</tbody>
</table>

**B. Bar Coding**

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

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

**F. Packing**

The drug is initially packed in a Blister Strip each containing 28 Tablets. 24 such strips would be further packed in white coloured Millboard/Grey board boxes and 20 such Boxes are ultimately packed in 5-Ply Shipper.

**G. Mill board/ Grey board Box:**

Each box shall contain 24 strips. The boxes shall be labelled and fabricated from 3 mm corrugated cardboard surrounded on inside and outside by tightly affixed millboard of at least 400 gsm. The style of the box shall be top and bottom tuck-in-flap type. The standardized box size of Millboard / Greyboard is to be confirmed by the supplier with programme at the time of approval of art work. Self-adhesive patient label should also be present on the Millboard Box.

**H. 5 – Ply Shipper Package:**

Each shipper shall contain 20 millboard.greyboard boxes labeled in RED. 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. Each shipping carton when packed should weigh not more than 50 kg.

**I. Markings**

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

**Millboard/Grey board 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.
• Date of manufacture (month and year) of drugs.
• Expiration date (month and year) of drugs.
• Instructions for storage and handling.
• Logo of DOTS.
• Place of manufacture (Made in_______)

**5 – Ply Shipper:**

The following information shall be stenciled or labeled on the 5 – Ply Shipper 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.
• Date of manufacture of the drugs (month and year).
• Expiration date of the drugs (month and year).
• Manufacturer’s name and registered address.
• Manufacturer’s national registration number.
• Logo of DOTS.
• Destination country license or registration number.
• Consignee’s address and emergency phone number including mobile number.
• Destination airport (if any).
• Contract number.
• Number of boxes contained in the carton (5 Ply Shipper).
• Gross weight of each carton (in kg).
• Instructions for storage and handling.
• Place of manufacture (Made in____).

**J. Documentation**

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

MILLBOARD/GREYBOARD BOX

3.5x3 cm

- M = 20
  - Y = 100
- M = 100
  - Y = 100
- M = 60
  - Y = 100
- K = 100
5 – Ply Shipper

5.5x4.7 cm

M = 20
Y = 100

M = 100
Y = 100

M = 60
Y = 100

K = 100
A. Specific requirements

Product Code **DSTB-CP** (Drug Sensitive Anti Tuberculosis Drugs for Continuous Phase-Adult Patients) consists of 24 blister packs of Schedule 14 for Continuous Phase. The drugs 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 drugs contained in the product shall also have valid registration in India and shall meet all the requirements of the licensing authority in India.

<table>
<thead>
<tr>
<th>Serial no.</th>
<th>Description</th>
</tr>
</thead>
</table>
| 01 | Schedule 14 is a blister pack of 28 tablets, each tablet consisting of Isoniazid, Rifampicin and Ethambutol in fixed dose combination (HRE–Fixed Dose Combination).  

The FDCs in blister pack shall conform to the general requirements of Tablets and the requirements under individual monograph given in IP or any other International Pharmacopoeia of equivalent accuracy.  

Each FDC tablet shall contain -  
Isoniazid *Selected Pharmacopeia (IP/ BP/USP/Other International pharmacopeia* 75 mg  
Rifampicin *Selected Pharmacopeia (IP/ BP/USP/Other International pharmacopeia* 150 mg  
Ethambutol Hydrochloride *Selected Pharmacopeia (IP/ BP/USP/Other International pharmacopeia* 275 mg  

The quality of Isoniazid, Rifampicin & Ethambutol Hydrochloride shall conform to the requirements of the individual monograph given in IP or any other International Pharmacopoeia of equivalent accuracy. |

*Only one of the selected pharmacopeia to be indicated.*
| 02 | Protocol and Testing | For manufacturer outside India:  
Complete test protocols along with the samples of all the batches should be sent to the Head of a Testing laboratory identified and specified by the purchaser.  

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

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

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

The drug should be dispatched to the consignee only on clearance from the Testing Laboratory. The drug shall be released on the basis of Protocol scrutiny by the authorized representative of the Purchaser and testing of the drugs by authorized laboratory.  

Each batch should be accompanied with a certificate from the manufacturer that the drugs meet the specified requirements. |
Design & alignment of the tablets should be strictly as per figure given below.

The label shall indicate the content of Isoniazid identified as ‘H’; content of Rifampicin identified as ‘R’; & content of Ethambutol Hydrochloride identified as ‘E’ in each tablet.
All labeling 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 drugs, Schedule H1 drug warning and storage requirements.

Information pertaining to date of manufacturing, date of expiry & batch no. of a blister should be imprinted on atleast 2 edges of the blister. Remaining requisite information i.e. manufacturing license no., Schedule H1 drug warning and storage requirements etc. may be printed once on reverse side of the blister. All the requisite information printed on blisters should be displayed clearly & prominently.

The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.
Each blister strip will contain 28 tablets of HRE –Fixed Dosed Combination, in the packaging designed and aligned as given above.
| 05 | 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. |
| 06 | Quality Assurance - Evidence | The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned. The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for shipment. The Supplier shall provide a copy of Validation records with regards to process validation demonstrating batch to batch consistency. The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment. The Supplier shall provide to the Purchaser a copy of the approval of each source material, constituent material and component for each lot intended for shipment. The Supplier shall provide evidence of basis for expiration dating and other stability data concerning the commercial final package at the time of bid submission. 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 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. |
| 07 | 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. |
| 08 | 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. |
| 09 | Primary Packaging (Blister): | A blister consisting of 28 tablets of the drugs duly identified should be packed in an Aluminium-PVC blister pack. The blister should be tropicalized with regard to moisture barrier properties for drug stability under field conditions. Quality Assurance shall be according to ISO 9001 for all 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 **Green coloured**, Thickness: 0.025mm. |
Strip size: Schedule – 14 Approx. 168 X 97 mm +/- 5mm

Blister Strips should have perforations and spacing between tablets enough to allow removal by patients with finger deformities and easier separation of individual tablets from the strips.

Complex Constructions with PVC Films

|                                | XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX | XXXXXXXXXXXXXXX
|                                | XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX   |

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):**

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Relative Humidity</th>
<th>gsm/24h</th>
<th>Vapour Transmission rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>(°C)</td>
<td>% RH</td>
<td>gsm/24 h</td>
<td>Thermoformed</td>
</tr>
<tr>
<td>20</td>
<td>85</td>
<td>gsm/24 h</td>
<td>0.15</td>
</tr>
<tr>
<td>38</td>
<td>90</td>
<td>gsm/24 h</td>
<td>0.7</td>
</tr>
</tbody>
</table>

**Shrinkage Longitudinally**

- T = 140°C, t = 20 min. (%) 5 – 6
- Application temperature (°C) 68 – 74
A. Storage & Shelf-life

**Storage:** Store protected from light and moisture

**Shelf-life:** 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 (blister pack). 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:

<table>
<thead>
<tr>
<th>Study</th>
<th>Storage condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long Term Stability</td>
<td>25 °C ± 2 °C/60% RH ± 5% RH or</td>
</tr>
<tr>
<td></td>
<td>30 °C ± 2 °C/65% RH ± 5% RH</td>
</tr>
</tbody>
</table>

**Shelf life would be as follows:**

- **Rifampicin:** shelf life should not be less than Minimum 24 months from the date of manufacture.
- **Isoniazid:** shelf life should not be less than Minimum 24 months from the date of manufacture.
- **Ethambutol hydrochloride:** shelf life should not be less than Minimum 24 months from the date of manufacture.
- **Shelf-life of the drugs in Fixed Dose Combination** should not be less than Minimum 24 months from the date of manufacturing.

B. Labelling:

**Requirements applicable to all Labels:**

- Shall meet WHO GMP standards.
- All the labels should be peel proof.
- NTEP Central Government Supply – NOT FOR SALE to be imprinted on the blister strips, Mill board / Grey Board and 5-Ply Shipper.
- NTEP TB logo to be imprinted on the Millboard/Greyboard Box and 5-Ply Shipper
The labels on the Millboard/Greyboard and 5 – Ply Shipper should be readable from a distance. The label of 5 – Ply Shipper should be of at least A-4 paper size with date of manufacture, date of expiry, batch no., to be mentioned in bold Arial font size 18 so as to be readable from a distance. It should be seen clearly by naked eyes.

**Labeling for Millboard/ Grey board Box:**

<table>
<thead>
<tr>
<th>National Tuberculosis Elimination Programme (NTEP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANTI-TB DRUG REGIMEN  CATEGORY DSTB - CP (A)</td>
</tr>
<tr>
<td>DAILY TREATMENT REGIMEN CONTAINS DRUGS FOR CONTINUOUS PHASE (Adult Patients)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>24 Blister packs for Continuous Phase (Schedule 14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>H R E</td>
</tr>
</tbody>
</table>

Batch No:
Mfg. Date:
Exp. Date:

<table>
<thead>
<tr>
<th>SCHEDULE H1 PRESCRIPTION DRUG – CAUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>It is dangerous to take this preparation except in accordance with the medical advice.</td>
</tr>
<tr>
<td>Not to be sold by retail without the prescription of a Registered Medical Practitioner.</td>
</tr>
</tbody>
</table>

“NTEP Central Government Supply NOT FOR SALE”

Manufacturer’s Name
Manufacturing Lic. No.

The labels on Millboard/Grey board Box must be attached to at least two sides and shall be green in colour. The label should include the name of the product, name of the manufacturer, batch number/Mfg. date/Expiry date of the drug. The
label shall also include storage instruction. 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).

Labeling for 5 – Ply Shipper packaging:

5 – PLY SHIPPER

National Tuberculosis Elimination Programme (NTEP)

ANTI-TB DRUG REGIMEN CATEGORY DSTB- CP (A)

DAILY TREATMENT REGIMEN CONTAINS DRUGS FOR CONTINOUS PHASE (Adult Patients)

20 Millboard/Greyboard Boxes

H R E

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.

“NTEP Central Government Supply NOT FOR SALE”

Manufacturer’s Name
Manufacturing Lic. No.
The labels on shipper package must be attached to at least two sides and shall be **Green** in colour. The label should include the name of the product, the number of Millboard/Greyboard Boxes, the name of the manufacturer, batch number/Mfg. date/Expiry date of the drug within the schedule. The label shall also include storage/handling instructions as well as Batch No. of the Box along with Date of Expiry of Box. 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).

**Numbering of shipper packaging:**
All 5 Ply Shippers boxes should be numbered consecutively. Shipping documents should be included in the Shipper numbered first (consignee wise).

**B. 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.

**C. 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.

**D. Colour Coding:**

The label on Millboard/Greyboard Box and 5 Ply Shipper shall be identified as indicated below:-

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Blister</th>
<th>Millboard (Label)</th>
<th>5 – PLY SHIPPER (Label)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PC- DSTB- CP (A)</td>
<td><strong>Green</strong></td>
<td><strong>Green</strong></td>
<td><strong>Green</strong></td>
</tr>
</tbody>
</table>

**E. Bar Coding**

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

The important information which shall be incorporated in bar code is:
1) Product Name/content  
2) Product Strength  
3) Batch Number  
4) Date of Manufacturing  
5) Date of Expiry  
6) Manufacturer Address  
7) Manufacturer License number  
8) Storage conditions requirement  
9) Number of Tablets in a Blister Strip/ Millboard/Greyboard Boxes and 5 Ply Shipper

F. Packaging

The drug is initially packed in a Blister Strip each containing 28 Tablets. 24 such strips would be further packed in white coloured Millboard/Grey board boxes and 20 such Boxes are ultimately packed in 5-Ply Shipper.

Mill board/ Grey board Box:

Each box shall contain 24 strips. The boxes shall be labeled and fabricated from 3 mm corrugated cardboard surrounded on inside and outside by tightly affixed millboard of at least 400 gsm. The style of the box shall be top and bottom tuck-in-flap type. The standardized box size of Millboard / Greyboard is to be confirmed by the supplier with programme at the time of approval of art work. Self-adhesive patient label should also be present on the Millboard Box.

5 – Ply Shipper Package:

Each shipper shall contain 20 millboard/greyboard boxes labeled in GREEN. 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. Each shipping carton when packed should weigh not more than 50 kg.

G. Markings

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

Millboard/Grey board 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.
• Date of manufacture (month and year) of drugs.
• Expiration date (month and year) of drugs.
• Instructions for storage and handling.
• Logo of DOTS.
• Place of manufacture (Made in_________

5 – Ply Shipper:

The following information shall be stenciled or labeled on the 5 – Ply Shipper 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.
• Date of manufacture of the drugs (month and year).
• Expiration date of the drugs (month and year).
• Manufacturer’s name and registered address.
• Manufacturer’s national registration number.
• Logo of DOTS.
• Destination country license or registration number.
• Consignee’s address and emergency phone number including mobile number.
• Destination airport (if any).
• Contract number.
• Number of boxes contained in the carton (5 Ply Shipper).
• Gross weight of each carton (in kg).
• Instructions for storage and handling.
• Place of manufacture (Made in_____).

H. Documentation

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

MILLBOARD/GREYBOARD BOX

3.5x3 cm

- M = 20
  Y = 100

- M = 100
  Y = 100

- M = 60
  Y = 100

- K = 100
5 – Ply Shipper

5.5x4.7 cm

- M = 20
- Y = 100
- M = 100
- Y = 100
- M = 60
- Y = 100
- K = 100
### A. Specific requirements

**Item:**
Product Code DSTB-IP(P) consist of Drug Sensitive Anti Tuberculosis Drugs for the Pediatric patients and used for Intensive Phase regimen. The Product Code DSTB-IP(P) consists of drugs as per the Schedule 15. The drugs 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 drugs contained in the product shall also have valid registration in India and shall meet all the requirements of the licensing authority in India.

<table>
<thead>
<tr>
<th>S no.</th>
<th>Description</th>
<th>Schedule 15</th>
</tr>
</thead>
</table>
| 01    | Schedule 15 is a blister/strip pack having 28 dispersible tablets of Fixed Dose combination of Isoniazid, Rifampicin and Pyrazinamide. The drugs in the blister/strip pack shall conform to the general requirements of Tablets and the requirements under individual monograph given in IP or any other International Pharmacopoeia of equivalent accuracy. Each blister pack shall contain the below mentioned drugs in Fixed Dose combination and in the Dispersible form:  

Tab Isoniazid *Selected Pharmacopeia (IP/ BP/USP/Other International pharmacopeia 50 mg  
Tab Rifampicin *Selected Pharmacopeia (IP/ BP/USP/Other International pharmacopeia 75 mg  
Tab Pyrazinamide *Selected Pharmacopeia (IP/ BP/USP/Other International pharmacopeia 150 mg  

The quality of Isoniazid, Rifampicin and Pyrazinamide shall conform to the requirements of the individual monograph given in IP or any other International Pharmacopoeia of equivalent accuracy. Each blister pack should have enough spacing between tablets to allow easier removal by patients with finger deformities and easier separation of individual tablets within the strips. |

*Only one of the selected pharmacopeia to be indicated*
<table>
<thead>
<tr>
<th>02</th>
<th>Blister pack design and Labelling (blisters)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Design &amp; alignment of the tablets should be strictly as per figure given below.</td>
</tr>
<tr>
<td></td>
<td>The label shall indicate the content of Isoniazid identified as ‘H’; content of Rifampicin identified as ‘R’ and content of Pyrazinamide identified as ‘Z’ in each tablet. Each aluminum foil strip shall have 28 dispersible tablets of HRZ–Fixed Dosed Combination in the packaging designed and aligned as given below:</td>
</tr>
<tr>
<td></td>
<td><img src="image" alt="Diagram of blister pack design" /></td>
</tr>
<tr>
<td></td>
<td>All labeling 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 drugs, Schedule H1 drug warning and storage requirements.</td>
</tr>
<tr>
<td></td>
<td>Information pertaining to date of manufacturing, date of expiry &amp; batch no. of a blister should be imprinted on atleast 2 edges of the blister. Remaining requisite information i.e. manufacturing license no., Schedule H1 drug warning and storage requirements etc. may be printed once on reverse side of the blister. All the requisite information printed on blisters should be displayed clearly &amp; prominently.</td>
</tr>
<tr>
<td></td>
<td>The label shall conform to the requirements of Drugs &amp; Cosmetics Act 1940 and Rules made there under and as amended from time to time.</td>
</tr>
</tbody>
</table>
| 03 | Protocol and Testing          | For manufacturer outside India:  
Complete test protocols along with the samples of all the batches should be sent to the Head of a Testing laboratory identified and specified by the purchaser.  

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

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

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

The drug should be dispatched to the consignee only on clearance from the Testing Laboratory. The drug shall be released on the basis of Protocol scrutiny by the authorized representative of the Purchaser and testing of the drugs by authorized laboratory. Each batch should be accompanied with a certificate from the manufacturer that the drugs meet the specified requirements. |
| 04 | 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.  

The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned. The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for |
<table>
<thead>
<tr>
<th>05</th>
<th>Quality Assurance Evidence</th>
</tr>
</thead>
</table>
| The Supplier shall provide a copy of Validation records with regards to process validation demonstrating batch to batch consistency.  
The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment.  
The Supplier shall provide to the Purchaser a copy of the approval of each source material, constituent material and component for each lot intended for shipment.  
The Supplier shall provide evidence of basis for expiration dating and other stability data concerning the commercial final package at the time of bid submission.  
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 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. |

<table>
<thead>
<tr>
<th>06</th>
<th>Inspection</th>
</tr>
</thead>
</table>
| 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. |

<table>
<thead>
<tr>
<th>08</th>
<th>Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>09</th>
<th>Primary Packaging</th>
</tr>
</thead>
</table>
| A blister consisting of 28 dispersible tablets of HRZ duly identified should be packed in an Aluminium-PVC blister pack / Alu Alu strip pack. The blister / strip should be tropicalized with regard to moisture barrier properties for drug stability under field conditions. Quality Assurance shall be according to ISO 9001 for all 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 Orange coloured. Thickness: 0.025mm.  

Strip size: Approx. 187 mm X 55 mm +/- 5%  

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):**

<table>
<thead>
<tr>
<th>Temperature (°C)</th>
<th>Relative Humidity (% RH)</th>
<th>Vapour Transmission rate (gsm/24h)</th>
<th>Thermoformed</th>
<th>Not</th>
</tr>
</thead>
<tbody>
<tr>
<td>thermoformed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>85</td>
<td>gsm/24 h</td>
<td>0.15</td>
<td>0.06</td>
</tr>
<tr>
<td>38</td>
<td>90</td>
<td>gsm/24 h</td>
<td>0.7</td>
<td>0.4</td>
</tr>
</tbody>
</table>

**Shrinkage longitudinally**

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

**A Storage:**

Store protected from light and moisture.
B. Shelf life:

- **RIFAMPICN**: shelf life should be minimum 24 months from the date of manufacture.
- **ISONIAZID**: shelf life should be minimum 24 months from the date of manufacture.
- **PYRAZINAMIDE**: shelf life should be minimum 24 months from the date of manufacture.
- Shelf-life of the drugs in Fixed Dose Combination should not be less than Minimum 24 months from the date of manufacturing.

Stipulated Shelf-life upon arrival at Consignee warehouse:

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:

<table>
<thead>
<tr>
<th>Study</th>
<th>Storage condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long Term Stability</td>
<td>25 °C ± 2 °C/60% RH ± 5% RH</td>
</tr>
<tr>
<td></td>
<td>or</td>
</tr>
<tr>
<td></td>
<td>30 °C ± 2 °C/65% RH ± 5% RH</td>
</tr>
</tbody>
</table>

C. Labelling:

Requirements applicable to all Labels:

- Shall meet WHO GMP standards.
- All the labels should be peel proof.
- NTEP Central Government Supply – NOT FOR SALE to be imprinted on the blister strips, Mill board / Grey Board and 5-Ply Shipper.
- NTEP TB logo to be imprinted on the Millboard/Greyboard Box and 5-Ply Shipper.
- The labels on the Millboard/Greyboard and 5 – Ply Shipper should be readable from a distance. The label of 5 – Ply Shipper should be of at least A-4 paper size with date of manufacture, date of Expiry, batch no. etc; of the individual component as well as Master Batch no. and Date of Expiry of the Boxes to be mentioned in bold Arial font size 18 so as to be readable from a distance.
- “Schedule H1 Drug” to be imprinted on label of strips, Millboard/Greyboard Boxes & 5 Ply Shippers.
D. Packaging

a) Packaging of Schedule 15 / Millboard/Grey board Box

The drug is initially packed in a Blister / Strip each containing 28 Tablets. Three such strips would be further re-packed in white coloured Millboard/Grey board boxes and 20 such Boxes are ultimately packed in 5-Ply Shipper. The labels on Schedule 15 must be attached to atleast two sides. Further, Schedule 15 should be labeled in Orange colour.

The label on each box of Schedule 15 should include the name of the product, storage instructions, flavour used in dispersible formulations, name of the manufacturer, batch number, Mfg. date, Expiry date. 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).

Labeling for Millboard/Grey board Box

<table>
<thead>
<tr>
<th>National Tuberculosis Elimination Programme (NTEP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANTI-TB DRUG REGIMEN CATEGORY DSTB- IP (P) / 3FDC (P)</td>
</tr>
<tr>
<td>DAILY TREATMENT REGIMEN CONTAINS DRUGS FOR INTENSIVE PHASE</td>
</tr>
<tr>
<td>(PEDIATRIC PATIENTS)</td>
</tr>
<tr>
<td>3 x 28 Blister Packs each of Schedule 15 for Intensive Phase</td>
</tr>
<tr>
<td>H R Z</td>
</tr>
<tr>
<td>Batch Nos:</td>
</tr>
<tr>
<td>Mfg. Date:</td>
</tr>
<tr>
<td>Exp. Date:</td>
</tr>
</tbody>
</table>
b) 5 – Ply Shipper Package:

Each shipper shall contain 20 millboard/greyboard boxes labeled in Orange. 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. Each shipping carton when packed should weigh not more than 50 kg.

The labels on shipper package must be attached to at least two sides and **Orange** in colour. The label should include the name of the product, number of Millboard/Greyboard Boxes, name of the manufacturer, flavour used in dispersible formulations, storage instruction, batch number, Mfg. date, Expiry date. 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).
Labelling for 5 – Ply Shipper packaging:

5 – PLY SHIPPER

National Tuberculosis Elimination Programme (NTEP)  
ANTI-TB DRUG REGIMEN CATEGORY DSTB- IP (P) / 3 FDC(P)  
DAILY TREATMENT REGIMEN CONTAINS DRUGS FOR INTENSIVE PHASE  
(PEDIATRIC PATIENTS)  
20 Millboard/Greyboard Boxes each of Schedule 15 for  
H R Z  
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.  
“NTEP Central Government Supply  
NOT FOR SALE”  
Manufacturer’s Name  
Manufacturing Lic. No.

c) Markings

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

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

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

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

**Millboard/Grey board 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 individual drugs.
- Master Batch number and Date of Expiry of Box.
- Number of Co-blister packs contained in the box.
- Date of manufacture (month and year) of individual drugs.
- Flavour used in dispersible formulations
- Expiration date (month and year) of individual drugs.
- Instructions for storage and handling.
- Logo of DOTS.
- Place of manufacture (Made in_________)

**5 – Ply Shipper:**
The following information shall be stenciled or labeled on the 5 – Ply Shipper 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 individual drugs.
- Master Batch number and Date of Expiry of Box
- Date of manufacture of the individual drugs (month and year).
- Flavour used in dispersible formulations
- Expiration date of the individual drugs as well as that of the product (month and year).
- Manufacturer’s name and registered address.
- Manufacturer’s national registration number.
- Logo of DOTS.
- Destination country license or registration number.
- Consignee’s address and emergency phone number including mobile number.
- Destination airport (if any).
- Contract number.
- Number of boxes contained in the carton (5 Ply Shipper).
- Gross weight of each carton (in kg).
- Instructions for storage and handling.
- Place of manufacture (Made in____).

d) Documentation

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

Dimensions of the logos

MILLBOARD/GREYBOARD BOX
5 – Ply Shipper
5.5x4.7 cm

- M = 20
  Y = 100

- M = 100
  Y = 100

- M = 60
  Y = 100

- K = 100
DSTB-CP (Pediatric Patients) / 2 FDC (P)

A. Specific requirements

Item:

Product Code DSTB-CP(P) or 2 FDC(P) consist of Drug Sensitive Anti Tuberculosis Drugs for the Pediatric patients and used for Continuous Phase regimen. The Product Code DSTB-CP(P) consists of drugs as per the Schedule 17. The drugs 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 drugs contained in the product shall also have valid registration in India and shall meet all the requirements of the licensing authority in India.

<table>
<thead>
<tr>
<th>S no.</th>
<th>Schedule 17</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Schedule 17 is a blister/strip pack having 28 dispersible tablets of Fixed Dose combination of Isoniazid and Rifampicin.</td>
</tr>
<tr>
<td></td>
<td>The drugs in the blister/strip pack shall conform to the general requirements of Tablets and the requirements under individual monograph given in IP or any other International Pharmacopoeia of equivalent accuracy.</td>
</tr>
<tr>
<td></td>
<td>Each blister pack shall contain the below mentioned drugs in Fixed Dose combination and in the Dispersible form:</td>
</tr>
<tr>
<td></td>
<td>Tab Isoniazid *Selected Pharmacopeia (IP/ BP/USP/Other International pharmacopeia 50 mg</td>
</tr>
<tr>
<td></td>
<td>Tab Rifampicin *Selected Pharmacopeia (IP/ BP/USP/Other International pharmacopeia 75 mg</td>
</tr>
<tr>
<td></td>
<td>The quality of Isoniazid, Rifampicin and Pyrazinamide shall conform to the requirements of the individual monograph given in IP or any other International Pharmacopoeia of equivalent accuracy.</td>
</tr>
<tr>
<td></td>
<td>Each blister pack should have enough spacing between tablets to allow easier removal by patients with finger deformities and easier separation of individual tablets within the strips.</td>
</tr>
</tbody>
</table>

*Only one of the selected pharmacopeia to be indicated
| 02 | Blister pack design and Labelling (blisters) | Design & alignment of the tablets should be strictly as per figure given below. The label shall indicate the content of Isoniazid identified as ‘H’; and content of Rifampicin identified as ‘R’. Each aluminum foil strip shall have 28 dispersible tablets of HR–Fixed Dosed Combination in the packaging designed and aligned as given below:

![Diagram of blister pack design](image)

All labeling 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 drugs, Schedule H1 drug warning and storage requirements.

Information pertaining to date of manufacturing, date of expiry & batch no. of a blister should be imprinted on atleast 2 edges of the blister. Remaining requisite information i.e. manufacturing license no., Schedule H1 drug warning and storage requirements etc. may be printed once on reverse side of the blister. All the requisite information printed on blisters should be displayed clearly & prominently.

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

| 03 | Protocol | For manufacturer outside India: |
and Testing

<table>
<thead>
<tr>
<th>and Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

For Indian manufacturer:

Complete Test Protocol and samples are taken and sent to the laboratory (identified by the purchaser) by the Inspecting Officer duly sealed and signed by him or his authorized representative.

Protocols of tests should include the requirements given for Capsules or Tablets as the case may be and those included under individual monograph given in IP or any other International Pharmacopoeia, besides the following tests

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

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

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

<table>
<thead>
<tr>
<th>Quality Assurance Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quality Assurance Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned. The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for shipment. The Supplier shall provide a copy of Validation records with regards to process validation demonstrating batch to batch consistency.</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td><strong>05</strong></td>
</tr>
<tr>
<td><strong>06</strong> Inspection</td>
</tr>
<tr>
<td><strong>08</strong> Testing</td>
</tr>
</tbody>
</table>
| **09** Primary Packaging | A blister consisting of 28 dispersible tablets of HRZ duly identified should be packed in an Aluminium-PVC blister pack / Alu Alu strip pack. The blister / strip should be tropicalized with regard to moisture barrier properties for drug stability under field conditions. Quality Assurance shall be according to ISO 9001 for all 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 **Green coloured**, Thickness: 0.025mm.

**Strip size:** Approx. 187 mm X 55 mm +/− 5% 

**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):**

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Relative Humidity</th>
<th>gsm/24h</th>
<th>Vapour Transmission rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>thermoformed</td>
<td>Not thermoformed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(°C)</td>
<td>% RH</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>85</td>
<td>gsm/24 h</td>
<td>0.15</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.06</td>
</tr>
<tr>
<td>38</td>
<td>90</td>
<td>gsm/24 h</td>
<td>0.7</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.4</td>
</tr>
</tbody>
</table>

**Shrinkage longitudinally**
- $T = 140^\circ C$, $t = 20$ min. (%): 5 – 6
- Application temperature (°C): 68 – 74

**A Storage:**

Store protected from light and moisture.
B. Shelf life:

- **RIFAMPICN**: shelf life should be minimum 24 months from the date of manufacture.
- **ISONIAZID**: shelf life should be minimum 24 months from the date of manufacture.
- Shelf-life of the drugs in Fixed Dose Combination should not be less than Minimum 24 months from the date of manufacturing.

Stipulated Shelf-life upon arrival at Consignee warehouse:

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:

<table>
<thead>
<tr>
<th>Study</th>
<th>Storage condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long Term Stability</td>
<td>25 °C ± 2 °C/60% RH ± 5% RH or</td>
</tr>
<tr>
<td></td>
<td>30 °C ± 2 °C/65% RH ± 5% RH</td>
</tr>
</tbody>
</table>

C. Labelling:

Requirements applicable to all Labels:

- Shall meet WHO GMP standards.
- All the labels should be peel proof.
- NTEP Central Government Supply – NOT FOR SALE to be imprinted on the blister strips, Mill board / Grey Board and 5-Ply Shipper.
- NTEP TB logo to be imprinted on the Millboard/Greyboard Box and 5-Ply Shipper
- The labels on the Millboard/Greyboard and 5 – Ply Shipper should be readable from a distance. The label of 5 – Ply Shipper should be of at least A-4 paper size with date of manufacture, date of Expiry, batch no. etc; of the individual component as well as Master Batch no. and Date of Expiry of the Boxes to be mentioned in bold Arial font size 18 so as to be readable from a distance.
- “Schedule H1 Drug” to be imprinted on label of strips, Millboard/Greyboard Boxes & 5 Ply Shippers.
D. Packaging

a) Packaging of Schedule 17 / Millboard/Grey board Box

The drug is initially packed in a Blister / Strip each containing 28 Tablets. Three such strips would be further packed in white coloured Millboard/Grey board boxes and 20 such Boxes are ultimately packed in 5-Ply Shipper. The labels on Schedule 17 must be attached to at least two sides. Further, Schedule 17 should be labeled in Green colour.

The label on each box of Schedule 17 should include the name of the product, storage instructions, flavour used in dispersible formulations, name of the manufacturer, batch number, Mfg. date, Expire date. 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).

Labeling for Millboard/Grey board Box

<table>
<thead>
<tr>
<th>National Tuberculosis Elimination Programme (NTEP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANTI-TB DRUG REGIMEN CATEGORY DSTB- CP (P) / 2FDC (P)</td>
</tr>
<tr>
<td>DAILY TREATMENT REGIMEN CONTAINS DRUGS FOR CONTINOUS PHASE (PEDIATRIC PATIENTS)</td>
</tr>
<tr>
<td>3 x 28 Blister Packs each of Schedule 17 for Continuous Phase</td>
</tr>
</tbody>
</table>

Batch Nos: 
Mfg. Date: 
Exp. Date: 

H R
b) 5 – Ply Shipper Package:

Each shipper shall contain 20 millboard/greyboard boxes labeled in Green. 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. Each shipping carton when packed should weigh not more than 50 kg.

The labels on shipper package must be attached to at least two sides and **Green** in colour. The label should include the name of the product, number of Millboard/Greyboard Boxes, name of the manufacturer, flavour used in dispersible formulations, storage instruction, batch number, Mfg. date, Expiry date. 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).
Labelling for 5 – Ply Shipper packaging:

5 – PLY SHIPPER

National Tuberculosis Elimination Programme (NTEP)
ANTI-TB DRUG REGIMEN CATEGORY DSTB- IP (P) / 2 FDC(P)

DAILY TREATMENT REGIMEN CONTAINS DRUGS FOR CONTINUOUS PHASE (PEDIATRIC PATIENTS)

20 Millboard/Greyboard Boxes (Schedule 17)

H R

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.

“NTEP Central Government Supply NOT FOR SALE”

Manufacturer’s Name
Manufacturing Lic. No.
c) **Markings**

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

### E. Bar Coding

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

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

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

**Millboard/Grey board 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 individual drugs.
- Master Batch number and Date of Expiry of Box.
- Number of Co-blisters packs contained in the box.
- Date of manufacture (month and year) of individual drugs.
- Flavour used in dispersible formulations
- Expiration date (month and year) of individual drugs.
- Instructions for storage and handling.
- Logo of DOTS.
• Place of manufacture (Made in__________)

5 – Ply Shipper:

The following information shall be stenciled or labeled on the 5 – Ply Shipper 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 individual drugs.
• Master Batch number and Date of Expiry of Box
• Date of manufacture of the individual drugs (month and year).
• Flavour used in dispersible formulations
• Expiration date of the individual drugs as well as that of the product (month and year).
• Manufacturer’s name and registered address.
• Manufacturer’s national registration number.
• Logo of DOTS.
• Destination country license or registration number.
• Consignee’s address and emergency phone number including mobile number.

• Destination airport (if any).
• Contract number.
• Number of boxes contained in the carton (5 Ply Shipper).
• Gross weight of each carton (in kg).
• Instructions for storage and handling.
• Place of manufacture (Made in______).

d) Documentation

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

e) Dimensions of the logos

MILLBOARD/GREYBOARD BOX
5 – Ply Shipper
Product Code 48 (Tab Ethambutol-100mg)

A. Specific requirements

Item:

Product Code 48 (PC-48) consists of Ethambutol (100mg) tablets. The drug contained in the product shall have valid registration in the country of manufacture and shall meet all requirements of the licensing authority of the country of manufacture. The drug contained in the product shall also have valid registration in India and shall meet all the requirements of the licensing authority in India.

Description:

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

Ethambutol Tablets contain Ethambutol Hydrochloride. Each tablet shall contain - Ethambutol Hydrochloride *Selected Pharmacopeia (IP/ BP/USP/Other International pharmacopeia) 100 mg

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

* Only one of the selected pharmacopeia to be indicated

Protocols and Testing:

For manufacturer outside India:

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

For Indian manufacturer:

Complete Test Protocol and samples are taken and sent to the laboratory (identified by the purchaser) by the Inspecting Officer duly sealed and signed by him or his authorized representative. Protocols of tests should include the requirements given for Tablets and those included under individual monograph given in IP or any other International Pharmacopoeia, besides the following tests.
Package Integrity Test:
Check 10 strips. Bundle up the strips and submerge them under water in a vacuum desiccator or equivalent device. Draw a vacuum of about 18k Pa and hold for a minute. Examine for the air leakage indicated by a fine stream of bubbles. Reestablish normal pressure and open strips to examine for water penetration.

Microbial Count:

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

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

B. Labelling:

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

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

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

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

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

**MILLBOARD/GREYBOARD BOX**

<table>
<thead>
<tr>
<th>National Tuberculosis Elimination Programme (NTEP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TB TREATMENT DRUG CONTAINS PRODUCT CODE 48</td>
</tr>
<tr>
<td>ETHAMBUTOL TABLETS 100 mg (10 x 10 Tablets)</td>
</tr>
</tbody>
</table>

Each Blister Strip Contains 10 Tablets of Ethambutol (100 mg)

**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.

“NTEP – Central Government Supply
– Not for Sale”

Manufacturer’s Name

Manufacturing Lic. No.

Labelling on 5-Ply Shipper:

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

TB TREATMENT DRUG CONTAINS PRODUCT CODE 48

ETHAMBUTOL TABLETS 100mg

20 Millboard/Greyboard Boxes

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

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

“NTEP - Central Government Supply – Not for Sale”
Manufacturer’s Name
Manufacturing Lic. No.
Numbering of shipper packaging:

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

C. Quality Assurance:

Compliance:

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

Evidence:

The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned.
The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for shipment.
The Supplier shall provide a copy of Validation records with regards to process validation demonstrating batch to batch consistency.
The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment.
The Supplier shall provide to the Purchaser a copy of the approval of each source material, constituent material and component for each lot intended for shipment.
The Supplier shall provide evidence of basis for expiration dating and stability data concerning the commercial final package upon request.

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

Inspection:

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

**Testing:**

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

**D. Storage:**

As per applicable Pharmacopoeia.

**E. Shelf Life:**

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

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

<table>
<thead>
<tr>
<th>Study</th>
<th>Storage condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long Term Stability</td>
<td>25 °C ± 2 °C/60% RH ± 5% RH or 30 °C ± 2 °C/65% RH ± 5% RH</td>
</tr>
</tbody>
</table>

**F. Qualification of the Manufacturer:**

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

**G. Recalls:**

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

H. Colour Coding:

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

I. Bar Coding

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

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

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

J. Packaging

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

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

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

### Complex:

<table>
<thead>
<tr>
<th>Rigid PVC film gauge (microns)</th>
<th>200</th>
</tr>
</thead>
<tbody>
<tr>
<td>PE coating (microns)</td>
<td>25</td>
</tr>
<tr>
<td>PVdC coating (gsm)</td>
<td>60</td>
</tr>
<tr>
<td>Total weight (gsm)</td>
<td>356</td>
</tr>
<tr>
<td>Complex gauge (mm)</td>
<td>0.280</td>
</tr>
</tbody>
</table>

### Water Vapour Transmission Rate (W V T R):

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Relative Humidity</th>
<th>Vapour Transmission rate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Thermoformed</td>
</tr>
<tr>
<td>(°C)</td>
<td>% RH</td>
<td>gsm/24h</td>
</tr>
<tr>
<td>20</td>
<td>85</td>
<td>gsm/24 h</td>
</tr>
<tr>
<td>38</td>
<td>90</td>
<td>gsm/24 h</td>
</tr>
</tbody>
</table>

### Shrinkage Longitudinally

\[ T = 140^\circ C, t = 20 \text{ min. (\%)} 5 – 6 \]

Application temperature (°C) 68 – 74
**Millboard/ Grey board Box:**
Each box shall contain 10 strips. The boxes shall be labelled and fabricated from 3 mm corrugated cardboard surrounded on inside and outside by tightly affixed millboard of at least 400 gsm. The style of top and bottom shall be tuck-in-flap.

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

**K. Markings**

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

**Millboard/Greyboard Box:**
The Boxes shall be marked with the following information in a clearly legible manner which is acceptable to the Purchaser:
- Manufacturer’s name and registered address
- Manufacturer’s License number
- Batch number of the drug
- Number of Tablets/strips contained in the box
- Date of manufacture (month and year) of the drug
- Expiration date (month and year) of the drug
- Instructions for storage and handling
- Logo of DOTS
- Place of manufacture (Made in________)

**5 – Ply Shipper:**
The following information shall be stenciled or labeled on 5 – Ply Shippers on all four sides in bold letters of at least Arial font size 18 with waterproof indelible ink in a clearly legible manner which is acceptable to the Purchaser:
- Generic name of the product
- Batch number of the drug
- Date of manufacture of the drug (month and year)
- Expiration date of the drug (month and year)
- Manufacturer’s name and registered address
- Manufacturer’s national registration number
L. Documentation

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

M. Dimensions of the logos

MILLBOARD/GREYBOARD BOX

3.5x3 cm

M = 20
Y = 100

M = 100
Y = 100

M = 60
Y = 100

K = 100
5 – Ply Shipper

5.5x4.7 cm

- M = 20
- Y = 100
- M = 100
- Y = 100
- M = 60
- Y = 100
- K = 100
Annexure 1B – CMSS Warehouse (Consignee Location)
The details of CMSS warehouses are given below:

### Annexure 1B

<table>
<thead>
<tr>
<th>Sr No</th>
<th>Warehouse Location</th>
<th>States/UT’s covered by the Warehouse</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Agartala</td>
<td>Tripura</td>
<td>Near ONGC Complex, PO-Hapania, Agartala-799014</td>
</tr>
<tr>
<td>2</td>
<td>Ahmedabad</td>
<td>Gujarat</td>
<td>Opp. P&amp;T Colony, Shahalam, Ahmedabad-380028</td>
</tr>
<tr>
<td>3</td>
<td>Bangalore</td>
<td>Karnataka</td>
<td>APMC Yard, Yeswanthpur, Bangalore - 560022</td>
</tr>
<tr>
<td>4</td>
<td>Bhopal</td>
<td>Madhya Pradesh</td>
<td>Chhola Road, Near Nishatpura Cabin, Bhopal, M.P.</td>
</tr>
<tr>
<td>5</td>
<td>Chandigarh</td>
<td>Chandigarh</td>
<td>Plot no 5, Industrial Area, Phase -II, Chandigarh-160002</td>
</tr>
<tr>
<td>6</td>
<td>Chennai</td>
<td>Tamil Nadu</td>
<td>Chitalapakkam(P.O), Chennai - 600064, T.N.</td>
</tr>
<tr>
<td>7</td>
<td>Jaipur</td>
<td>Odisha</td>
<td>Dhawalgiri, Post-Jaipur Road, Dist-Jaipur, Odisha</td>
</tr>
<tr>
<td>8</td>
<td>Delhi</td>
<td>Delhi</td>
<td>WareHousing Scheme Block No 2, Kirti Nagar, New Delhi-110015</td>
</tr>
<tr>
<td>9</td>
<td>Guwahati</td>
<td>Assam</td>
<td>EPIP Complex, Amingaon, Guwahati-781031</td>
</tr>
<tr>
<td>10</td>
<td>Hyderabad</td>
<td>Andhra Pradesh</td>
<td>Behind Gandhibhavan, Nampally, Hyderabad-500001</td>
</tr>
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<td>14</td>
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<td>15</td>
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<td>Jammu &amp; Kashmir</td>
<td>Base Depot, Chakki Bank, Prem Nagar, Pathankot</td>
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<td>16</td>
<td>Patna</td>
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<td>17</td>
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<td>18</td>
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<td>Jharkhand</td>
<td>Po-Hehal, Ratu Road, Dist-Ranchi-834005</td>
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<tr>
<td>19</td>
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<td>Near Anchal Dairy, Pauri Road, Srinagar-246174 (Garhwai)</td>
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<tr>
<td>20</td>
<td>Trivandrum</td>
<td>Kerala</td>
<td>Kinfra Apparel Park, Thumba, Palliphura(P.O), Trivandrum-695586</td>
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CMSS reserve to right the change the consignee at any time if required.
## Consignee List - 1st Tranche

<table>
<thead>
<tr>
<th>CMSS Stores</th>
<th>4-FDC-A</th>
<th>3-FDC -A</th>
<th>3-FDC -P</th>
<th>2-FDC -P</th>
<th>Ethambutol 100mg</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Strips of 28Tabs</td>
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<td>Strips of 10Tabs</td>
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<td>213,310</td>
</tr>
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<td>Hyderabad</td>
<td>951,020</td>
<td>1,570,130</td>
<td>43,450</td>
<td>62,710</td>
<td>333,280</td>
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<tr>
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<td>353,210</td>
<td>583,140</td>
<td>16,140</td>
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<td>123,780</td>
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<tr>
<td>Patna</td>
<td>554,320</td>
<td>915,180</td>
<td>25,330</td>
<td>36,550</td>
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<tr>
<td>Chandigarh</td>
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<td>1,275,290</td>
<td>35,290</td>
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<td>Raipur</td>
<td>236,900</td>
<td>391,110</td>
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<tr>
<td>Ahemdbad</td>
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<td>1,301,290</td>
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<td>356,790</td>
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<td>595,370</td>
<td>16,480</td>
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</tr>
<tr>
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