ONLINE SHORT TENDER FOR PROCUREMENT OF DR-TB Drugs used under NTEP

Tender No: CMSS/PROC/2023-24/NTEP/029
(National Competitive Bidding)
(FOR CLASS-1 and CLASS-2 LOCAL SUPPLIERS ONLY)

CENTRAL MEDICAL SERVICES SOCIETY
(An Autonomous Society Under Ministry of Health & Family Welfare, Govt. of India)
2nd Floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Marg, Teen Murti Marg,
Chankayapuri, New Delhi-11002, Phone: 011-21410905, 21410906
Website: www.cmss.gov.in, **Email-** dgceocmss@cmss.gov.in,
gmproc1@cmss.gov.in, mgrproc1@cmss.gov.in

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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
Telephones: 011-21410905, 21410906

Telephones: 011-21410906 Fax: 011-23730120
Email: gmproc1@cmss.gov.in
mgrproc1@cmss.gov.in

ONLINE BIDS ARE INVITED IN TWO PACKET BID SYSTEM FOR PROCUREMENT OF ARV DRUGS FOR NACO.

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:

CRITICAL DATE SHEET

Published Date	30.06.2023
Pre bid meeting	05.07.2023 at12:00 AM Venue- Conference Hall, CMSS HQ New Delhi
Last date & time to submit pre-bid queries	05.07.2023 till 05:00 PM
Bid Document Download End Date & time	17.07.2023 till 03:00 PM
Bid Submission End Date and Time	17.07.2023 till 03:00 PM
Last date of submission of original documents	18.07.2023 till 03:00 PM
Bid Opening Date and Time	18.07.2023 at 04:00 PM

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, VishwaYuvak Kendra,
Pandit Uma Shankar Dikshit Road,
Chanakyapuri, New Delhi-110021

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LIST OF ANNEXURES

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Online Tender for Procurement & Supply of DR-TB Drugs used under NTEP

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 2022-23.

The list of items to be quoted and their specifications are given in Annexure- I.

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 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 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/GeM Portal.

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.

4. ELIGIBILITY CRITERIA

a) Only Class-1 and Class-2 local supplier shall be eligible for participation. Bids from supplier (MSE/Non MSE) as defined in Department of Pharmaceuticals under Ministry of Chemicals and Fertilizers order no. F.No 31026/65/2020-MD dated 30.12.2020 shall be accepted. **Bids from firms/vendors other than Class-1 and Class-2 local supplier (MSE/Non MSE) shall be summarily rejected.**

b) The invitation to bid is open to domestic manufacturers (Indian Manufacturers) only.

c) Tenderer shall be a manufacturer of the quoted product and having valid own manufacturing license in the indicate 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. In case of failure to submit the same, the bid shall not be considered any further.

d) For all regulated products, the bidder should have at least two years i.e. 2020-21and 2021-22 OR 2021-22 and 2022-23 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) in less than two years ago. A permission from DCG (I) shall be required for all new regulated products to this effect.

e) (i) Average Annual turnover for Tenderers in the last three years i.e. 2019-20, 2020-21 and 2021-22 OR 2020-21, 2021-22 and 2022-23 shall not be less than the following: -

Sch No.	**Amount (in Rs.) for 100% quantity quoted**	**Amount (in Rs.) for 50% Quantity quoted**
I	90,42,999	45,21,500
II	64,57,416	32,28,708
III	1,20,93,142	60,46,571
IV	96,84,965	48,42,483
V	93,52,512	46,76,256
VI	35,52,072	17,76,036
VII	1,94,95,520	97,47,760
VIII	50,10,784	25,05,392
IX	1,02,23,805	51,11,903
X	15,52,88,052	7,76,44,026

(ii) The turnover benchmark given in (e) above will not apply to Micro and Small Enterprises (MSE).

Note: MSE Traders will not get the benefits of MSE Firm

Note: The applicable turnover has been indicated in above table and is for 100% and 50% quantity of the schedule. If quoted quantity is anywhere between 50% to 100% of the quantity of schedule (as allowed under tender clause no. 4(h)), the applicable Turnover may be calculated by the tenderer proportionately.

f) 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/MOH&FW or any of the procurement agencies/Autonomous Bodies under the organisations stated above or if the Firm/Company is debarred as a whole by these organisations or any of its

procurement agencies/Autonomous Bodies.

g) Department of Expenditure, Ministry of Finance, GOI vide OM No: F.1/20/2018/PPD dtd. 02.11.2021 has issued guidelines on debarment of firms from bidding. The bidders blacklisted by any firm/company/ CMSS /State Govt. /Central Govt./its drug procuring agencies prior to issuance of DOE OM No: F.1/20/2018/PPD dtd. 02.11.2021 are eligible to bid if:- The blacklisting order has been revised post facto with clearly mentioning of category (i) of OM No: F.1/20/2018/PPD dtd. 02.11.2021 and that the debarment is limited to the issuing ministry/department/ organization only. Such vendors should clearly mention the status of blacklisting in the undertaking to be submitted in compliance with clause 6.1 (t) of tender documents and also attach revised blacklisting order.

   For blacklisting orders issued after 02.11.2021, the following shall be applicable: -
   - If the blacklisting order is issued by DoE, the bid of blacklisted bidder shall be out rightly rejected.
   - If the blacklisting order is issued by CPSUs, attached offices/autonomous bodies etc of MoHFW/ Other Ministries/ department and MoHFW/ Other Ministries/ department by written approval has delegated powers under Sr. no. (8) of OM dated 02.11.2021 to such organizations /bodies that the blacklisting is applicable only for the Procurement made by such organization /bodies, the bid of such blacklisted bidders shall be accepted for further evaluation.
   - In absence of such delegation extended by MoHFW/ Other Ministries/ department, the bid of the blacklisted bidder shall be rejected.

h) Tenderer should quote at least for 50% of the tender 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.

i) Tenderer should have supplied 40% of the quoted quantity of same or similar items during the last two 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 at least 40% of the quoted/ similar items.

Similar Items here relate to the following: -

Similar item means quoted/any TB Drug

Supply/Sale/Service order under loan license arrangement shall not be considered.

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. Also the bidder should take utmost care in submitting undertakings/self declaration/certificates along with its bid. If at any stage it is found that the papers/ documents/certificates/declaration/undertaking/ self certification submitted by the bidder are false/incorrect/suppressed/ misrepresented the actual fact or 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 black list 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-XVI to be submitted.

6. TECHNICAL BID – "PACKET 1"

(a) Those indenting 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)."

6.2 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) 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 of firm declares himself as proprietor with specimen signature.

(e) Tenderer should have supplied 40% of the quoted quantity of same or similar items during the last two 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 at least 40% of the quoted/ similar items.

Similar Items here relate to the following: -
Similar item means quoted/any TB Drug
Supply/Sale/Service order under loan license arrangement shall not be considered.

(f) Manufacturing and Market Standing Certificate / Market Standing Certificate issued by the Licensing Authority as a manufacturer for each item quoted for the last 2 years i.e. 2020-21 & 2021-22 OR 2021-22 & 2022-23 for compliance of tender clause no. 4 (d).

(g) Non-Conviction Certificate issued by the FDA/ Drugs Controller of the State certifying that the firm/company (as well as the manufacturer firm in case of non-manufacturer bidders) has not been convicted and the products quoted have not been cancelled during last two years i.e. 2020-21 and 2021-22 OR 2021-22 and 2022-23.

(h) Capacity certificate issued by Licensing authority should be submitted.

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

(j) Performance Statement to establish 2 years market standing as per format given in Annexure-IV.

(k) Annual turnover statement for 3 years i.e. 2019-20, 2020-21 and 2021-22 OR 2020-21, 2021-22 and 2022-23 should be furnished in the format given in Annexure-V duly certified by the Chartered Accountant.

(l) Copies of the audited Annual reports including the Balance Sheet and Profit and Loss Account along with all the annexure for the last three years i.e. 2019-20, 2020-21 and 2021-22 OR 2020-21, 2021-22 and 2022-23 duly certified by a practicing Chartered Accountant.

(m) Certificate of Incorporation along with MOA (Memorandum of Association) & AOA (Articles of Association) in case of Companies or Copy of partnership deed in case of partnership firm or Declaration in case of being a proprietary firm.

(n) Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life and Certificate of Analysis of one batch of the quoted product should be submitted.

(o) List of items quoted (the name and item code of the items quoted) and relevant pharmacopoeia annual production for the last 3 years as per the **Annexure-VI.**

(p) 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.

(q) 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.

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

(s) No Deviation Certificate as per **Annexure-XV**.

(t) Near Relative Certificate as per **Annexure-XVI.**

(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 or practicing chartered accountant (in respect of suppliers other than companies) giving the percentage of local content at the time of submission of bid as per **Annexure-XVII.**

(v) Vendors are requested to fulfil the requirements of Ministry of Finance, Department of Expenditure, Procurement Policy Division Office Memorandum No.- 6/9/2020-PPD dated 24.08.2020.

(w) Tenderer should submit an Undertaking on Letter head to Compliance to Ministry of Finance, DOE order No- 6/18/2019-PPD dated 23.07.2020 and No.F.7/10/2021-PPD (1), dated 2302.2023 as per **Annexure-XVIII.**

(x) Tenderer should submit an undertaking that

"I/ We do hereby declare that our firm has not been blacklisted/ banned/debarred by CMSS/ State Governments/ Central Government/ MOH&FW or any of the procurement agencies/ Autonomous Bodies under the organizations stated above or the Firm/ Company (as whole) has not been debarred as a whole by these organizations or any of its procurement agencies/ Autonomous Bodies"

(y) Para wise compliance of technical specification of the quoted items.

(z) The bidders are requested to submit an undertaking on their letterhead for compliance to the Artwork enclosed for the items quoted by them. No further approval for Artwork would be provided by CMSS to any bidder.

6.3 (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–XX**.

(b) **All original documents in lieu of EMD / Notarised undertaking by MSE companies Annexure-VIII** for exemption of EMD in physical form is to be deposited with the Tender Inviting Authority up to bid submission end date and time as per prescribed in the critical date sheet. If the last date of deposit of original documents in lieu of EMD / Notarised undertaking by MSE companies Annexure-VIII 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 documents in lieu of EMD / Notarised undertaking by MSE companies Annexure-VIII 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 documents in lieu of EMD / Notarised undertaking by MSE companies Annexure-VIII is delivered to the Tender Inviting Authority by the date specified in critical date sheet. Failure to deposit the original documents in lieu of EMD / Notarised undertaking by MSE companies Annexure-VIII by the specified last date shall result in rejection of bid summarily.

(c) Conditional Bids shall be summarily rejected

7. PRICE BID-"Packet 2"

i. "Packet 2" is for the Price Bid of the Tenderer.

ii. Bid should be uploaded online in the form of BOQ.XXXX.xls.

iii. Format of the Schedules of price bid is available in **Annexure-XXI**.

iv. The supplier shall quote as per price schedule given in Annexure-XIII for all the items quoted by him as per schedule of requirement.

v. 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.

vi. The rate quoted in Price Schedule Annexure-XXI 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.

7.1 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.

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.

Breakup of the quoted price indicating the various components like Ex Work, GST, Transportation cost etc. has to be submitted, if desired by the TIA before placing the order

8. OPENING OF "PACKET 1" i.e. 'TECHNICAL BID AND "PACKET 2" i.e. FINANCIAL BID' OF TENDER:

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. Clarification (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 the purchaser.

8.3 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.

8.4 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.

8.5 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.

8.6 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.

8.7 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.

8.8 "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.

8.9 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/Insurance Surety Bonds in the following Bank Account:

Beneficiary Name: Central Medical Services Society
A/C No. : 32719062216
Bank Name: SBI Bank

Branch: Nirman Bhawan, Maulana Azad Road, New Delhi
IFSC Code: SBIN0000583

(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 **Annexure-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 MSME (MICRO & SMALL ENTERPRISES)

(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-fulfillment or non-observance of any of the conditions stipulated in the tender, 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) 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 Ist 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) In accordance with M/o MSME Gazette Notification No S.O. 2119 (E) dt. 26th June 2020, " In case of reverse-graduation of an enterprise, whether as a result of re-classification or due to actual changes in investment in plant and machinery or equipment or turnover or both, and whether the enterprise is registered under the Act or not, the enterprise will continue in its present category till the closure of the financial year and it will be given the benefit of the changed status only with effect from 1st April of the financial year following the year in which such change took place."

c) In accordance with M/o MSME Gazette Notification No S.O. 4926 (E) dt. 18th October 2022, "In case of an upward change in terms of investment in plant and machinery or equipment or turnover or both, and consequent re-classification, an enterprise shall continue to avail of all non - tax benefits of the category (micro or small or medium) it was in before the re-classification, for a period of three years from the date of such upward change."

Note: **Traders will not get benefit of MSE Firms**

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

(ii) 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.

(iii) 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 (if applicable)

(i) The Earnest Money Deposit (EMD) will be forfeited/vendor would be required to deposit the equivalent EMD amount as per Notarised Undertaking by MSE bidder, 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/ vendor would be required to deposit the equivalent EMD amount as per Notarised Undertaking by MSE bidder, in case of the lowest/ matched bidder, fails to execute the contract agreement and / or deposit the Security Deposit within the stipulated time. Additionally, actions as stipulated in clause no. 18.1 will also be taken.

(ii) In both the above cases, the bidder will not be eligible to participate in the tender for same item for two years from the date of issue of letter of acceptance. 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 Long Term agreement (LTA) 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.

(iii) The delivery of the additional quantity (as per ii above) shall be scheduled after the completion of the delivery of the original tendered quantity or on mutual consent between the supplier and CMSS.

10.2 (i) The rates quoted and accepted will be binding on the Tenderer for the full contract period of ONE year 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 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 2006, 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 Department of Pharmaceuticals under Ministry of Chemicals and Fertilizers has issued guidelines for implementation of the provisions of public procurement (Preference to Make in India) order (PPO) 2017 as desired by DPIIT on 16.09.2020 w.r.t public procurement of goods and services in medical devices vide order no **F.No 31026/65/2020-MD dated 30.12.2020**. The relevant provisions of DoP order dt. 16.02.2021 and DPIIT order dt. 16.09.2020 and all subsequent orders from time to time

will apply in the instant case. Bidders are requested to submit a declaration indicating percentage of local content as per **Annexure-XVII**.

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.

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:

In accordance with Department of Expenditure Ministry of Finance notification dated 12.11.2020, the clause may be read as:

On being intimated about the acceptance of the tender the L1/Matched tenderer shall pay a Security Deposit at the rate of 3% 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 favor of Central Medical Service Society.

Beneficiary Name: Central Medical Services Society
A/C No. 32719062216
Bank Name: SBIBank
Branch: Nirman Bhawan, Maulana Azad Road, New Delhi
IFSC Code: SBIN0000583

12.2 The Performance Bank Guarantee shall be valid as per below details from the date of commencement.

For SCH I to V & IX		**For SCH VI to VIII & X**	
LOA Submission	-15 days	LOA Submission	-15 days
Rate Valid	-365 days	Rate Valid	-365 days
Delivery period	-60 days	Delivery period	-60 days
Shelf life	-365 x 2 Years	Shelf life	-365 x 3 Years
B.G. Extension	-60 days	B.G. Extension	-60 days
	1230 days		1595 days

12.3 The lowest/ matched tenderer shall execute an Agreement on a non-judicial stamp paper of value of Rs.100/- (stamp duty to be paid by the Tenderer) within 15 days from the date of the intimation from CMSS informing that his tender has been accepted. The Specimen form of Agreement is available in **Annexure-X.**

12.4 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.

12.5 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.

12.6 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, the lowest offer will be declared as the L1 tenderer. CMSS reserves right to negotiate prices with L1 bidder in justified cases.

13.2 The Tenderer, who has been declared as Lowest Tenderer for certain item(s), shall within the tender issue of LOA (letter of acceptance) execute necessary Agreement for the supply of the allocated quantity of such items as specified in the Tender Document after depositing the required amount as Security Deposit and on execution of the agreement such Tenderer

shall supply goods on receipt of Purchase Orders. The format of LOA, agreement, Purchase Order is attached at **Annexure –IX, X, XI** respectively. 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 execute necessary agreement as specified in the Tender Document on depositing the required amount as Security Deposit and on execution of the agreement such Tenderer 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 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.

i. In order to maintain uninterrupted supplies, the CMSS will place orders with minimum of two suppliers for tendered product with 70% of the orders given to L1 and the balance 30% to the next Matched Lowest Tenderer.

ii. In case there is no L2 /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, L2 bidder/matched bidder refuses to accept the offered quantity, 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 (and including quantity in consideration in Clause No. 10.1 (i)) will be ordered on mutual consent.

iv. 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.

v. 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.

vi. In case of requirement of large quantities, CMSS may place orders with 3 suppliers in the ratio of 50:30:20, which will be indicated in the tender document at **Annexure-I**.

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 order from the date of the orders.

13.8 The supplier shall supply the items at the specified destination and submit a copy of the Purchase Order, 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 (13.6) to para (13.9) 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.

13.11 Provision of Department of Expenditure, Ministry of Finance (No.F.1/4/2021-PPD, dated 18.05.2023) in respect of Concurrent application of Public Procurement Policy for Micro and Small Enterprises Order, 2012 and Public Procurement (Preference to Make in India) Order, 2017 shall be applicable.

14 SUPPLY / DELIVERYCONDITIONS

14.1 The supplier should acknowledge the receipt of the Purchase Order 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 60 days (or as mentioned in LOA/PO) from the date of award at the destinations mentioned. 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 60th day or after the delivery dates/schedule as mentioned in order 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.

14.4All 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 For both items delivered to direct consignees & CMSS warehouses, the supplier should ensure that the items are delivered with the minimum shelf-life as mentioned in the tender document/Purchase Order failing which the consignees/CMSS WHs shall not accept the items. Further, the bidder's attention is invited that if they supply/deliver the items with short shelf-life as per tender/Purchase Order and even if direct consignees receive such items, the invoices shall not be processed by CMSS for payments. It is the sole responsibility of the bidder/vendor to deliver the items with minimum residual shelf-life as mentioned in the tender/Purchase Order.

14.6A Certificate of Analysis/ Performance Evaluation Report 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
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
as applicable
OR/And

The Performance Evaluation Report shall include:
a) Product name
b) Lot/Batch Number
c) Date of manufacture
d) Date of Expiry
e) Manufacturer's name
f) Number of samples tested
g) Testing principle

Information about reference used

h) TESTING PROCEDURE- Sensitivity, Specificity etc
i) Results
j) report number
k) Date of Analysis
l) Designation and signature of analyst
m) Authorized signatory of lab

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

14.7 All the Tenderers are required to supply the product(s) with printed text "NACO SUPPLIES – NOT FOR SALE" in red-colour on the strips, blisters, vials, ampoules & bottles and also on the external packings. The type/thickness of packing materials used in Blister packs may also be specified. Goods received without this print will not be accepted by CMSS/Consignee. Affixing of rubber stamp shall not be accepted. However, the approved art work will prevail.

14.9 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.

14.10 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.

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 develops within 15 days of delivery at specified locations, suppliers at their own cost would lift the entire batch from various locations and supply fresh replaced batches. For LD purposes the date of receipt of replaced batches would count. In addition, the expenses on pest control to be undertaken by CMSS would be borne by the tenderer.

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.
Pre-dispatch inspection for passing the quality of the goods, would be done before direct shipment to the consignees from supplier Warehouses (in India).

(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.

16.5 **Inspection Methodology:**

PDI (Pre-Dispatch Inspection) as mentioned in **Annexure-I** means, the QA inspection/testing shall be completed prior dispatch of supplies direct to consignees/CMSS warehouses. After completion of manufacturing process, the supplier should offer goods for PDI inspection in writing to Quality Assurance department of CMSS at least 10 days before proposed inspection date. The samples of each batch will be collected and sent to designated laboratories (Government/ Private Drugs Testing Laboratories) for testing as decided by the CMSS. Sample quantities will be borne by the supplier. However, handling and testing charges will be borne by CMSS. After the dispatch clearance of Quality Assurance department of CMSS, the supplier will deliver the items to the consignee or CMSS warehouses as per the schedule mentioned in the Purchase Order. If the supplier delivers/dispatches goods without completing the QA inspection, sample testing, dispatch clearance etc., CMSS shall not be processing the payments of such goods and the supplier will be solemnly responsible for the supply of such goods.

Non-PDI (Post Delivery Inspection) as mentioned in **Annexure-I** means, the supplier will deliver/dispatch the manufactured items (as per the technical specifications) directly to CMSS warehouses. The samples will be collected from the warehouse of CMSS and sent to designate Quality Control Labs in respect of supplied goods at any point during specified shelf life as per decision of CMSS. Sample quantities will be borne by Purchaser. Also, handling and testing charges will be borne by CMSS

In case of failure of batches during or at any stage (indicated at 16.5), 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 Inspection/testing stage,** samples which do not meet quality requirement/specifications 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 (as mentioned in clause no. 16.3), 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 the entire quantity of relevant batches, in addition to imposition of penalty @ 25% of batch supply cost or

(ii) To make alternative purchase of the items of Drugs from other approved suppliers or in the open market or from any other Tenderer who might have quoted higher rates, at the risk and the cost of the supplier.

(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 to forfeiture of Performance Security Deposit.

(iv) In addition, the FDA/ Drugs Control Authority of concerned State will be informed for initiating necessary action on the Tenderer in their state. 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 In case of supply of "NOT OF STANDARD QUALITY" goods to CMSS, the supplier shall make replace the rejected quantity by replacement within 2 months. If replaced batch is also found "NOT OF STANDARD QUALITY", the supplier shall be blacklisted for the product and no further supplies shall be accepted for the particular product category. In addition, the licensing authority will be informed for initiating necessary action on the supplier in their state. The security deposit will also be forfeited without any intimation. The warranty shall apply to replacement batches also. The decision of CMSS, as to the quality of the supplied goods shall be final and binding.

16.10 If the product is non-Pharmacopoeia, 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. The payment will be in INR only.

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-110021or in the name of any other authority as may be designated. Supplier have to mention e- aushadhi PO No. and tranche/ lot on the invoice.

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 Lot/Tranche/PO vise Part payments for supply will be considered only after completion of supply of at least 50% quantity ordered in the individual Purchase Order/Lot/Tranche PROVIDED original consignee receipts (or on GeM by consignee for the receipt, with original CRC to be submitted before next payment is released) are produced and the quality pass 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.

(ii) 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.
(f) Bidders are requested to submit their Original Invoice along with copies of Lorry Receipt/ Delivery challans and original Consignee Receipt Certificate (CRC) or such CRC to be uploaded on GeM by the consignee (if applicable) (with originals to be submitted before next payment is processed) as per format given in the tender document Annexure duly signed & stamped with other necessary documents for smooth processing of payment

17.8 Supplier will integrate with e- aushdhi system of CMSS and Supplier Interface Module in which selected bidders shall be required to enter/upload batch no, qty, mfg & expiry date, tranche no, invoice/challan copy etc. against PO no. Bidders are requested to submit their Original Invoice along with copies of Lorry Receipt/ Deliver challans 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 LOA/purchase order. In case the supply is not completed in the stipulated delivery period, as indicated in the LOA/purchase order or in case of non-submission of Security Deposit within the stipulated time, purchaser reserves the right either to short-close/cancel this LOA/purchase order and/or recover liquidated damage charges. The cancellation/short-closing of the

LOA/Purchase 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. This purchase at the risk and cost of the defaulting vendor can be at the same L1 cost of the tender or at higher cost and can be met through other vendors available in the present tender/contract or through any vendor from the open market. Any additional cost towards this risk purchase will be entirely borne/adjusted from running bills/demanded from 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 scheduled delivery date mentioned in LOA/P.O, liquidated damages will be levied @ 2.5% per week to be applied proportionately on per day basis up to a maximum of 10% of P.O. Cost, irrespective of the fact that whether the CMSS has suffered any damage/ loss or not, on account of delay in effecting supply. If the last scheduled delivery 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 up to 5% of cost of package received with damaged packing.

18.4 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 can derail the critical National level Disease Control Programme.

For each lot/tranche, the delivery schedule (dates) are mentioned in the LOA/PO. The vendors are to make every effort to complete the delivery of each Lot/Tranche as per delivery schedule mentioned in the LoA/PO.

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

If the vendor is not able to supply the total qty. of each lot/tranche within the scheduled delivery dates, the following may be noted:

a. The supplier will not dispatch/supply stocks/goods after the last date of scheduled delivery of the Lot/Tranche without PO amendment issued by procurement wing.
b. CMSS Warehouses/Direct consignees would not accept any stock/goods of any Lot/tranche beyond scheduled delivery period in absence of delivery extension PO amendment. E-Aushadhi software functionality has been made that CMSS WHs would not be able to receive the goods (GRN creation barred). These consignees will accept the stocks beyond scheduled delivery date only if Procurement wing has issued PO Amendment for delivery extension.

c. No extension of the delivery date would be granted suo motu unless the supplier specifically asks for it. However, in a few cases, it may be necessary to grant an extension of the delivery period suo motu in the interest of the administration. In such cases, the supplier should mandatorily submit clear acceptance of the extension letter.

d. If at any time during the currency of the contract, the supplier encounters conditions hindering delivery of goods, he shall promptly inform the concerned officer in writing. The supplier/vendor should raise request for delivery time extension well in advance i.e. at least 15 days before scheduled delivery date, should mention the likely duration within which it intends to complete the supplies and request for extension of delivery schedule accordingly. On receiving the supplier's communication, CMSS shall examine the proposal and on approval from the CA, may consider issuing delivery extension with/without LD provided: -

    i. That there are sufficient grounds for acceptance of such requests.
    ii. That there is no falling trend in prices for this item as evidenced from the fact that, in the intervening period, neither orders have been placed at rates lower than this contract nor any tender been opened where such rates have been received even though the tender is not yet decided.

e. In such cases, for delivery extension, PO amendment would be issued and the supplier should mandatorily supply the goods in extended time period.

f. Vendors are strictly advised not to deliver/transport any consignment reaching beyond scheduled delivery date without proper PO amendment issued by Procurement wing of CMSS, as it would not be received by consignees. CMSS shall not process any bills of such supplies if made beyond LOA/PO delivery schedule and without any PO amendment. For such actions, vendor would be solely responsible.

g. If the supplier again fails to deliver the balance quantity within extended time, CMSS reserves the rights/options to procure the undelivered quantity from other approved supplier available in the contract at the same rates (with no financial implication and without regular tender to save time) or from open market at the risk & cost of the defaulting supplier (which may be with financial implication) or grant further extension if deemed fit.

Note- Vendors may note that it may not be necessary that each request for extension in delivery dates is accepted and scheduled delivery date is extended by CMSS.

h. After completion of complete LD period, if the supplier/vendor still fails to deliver goods (or a part of it) within extended timelines, actions against the supplier/vendor may be initiated for default in supplies as per terms & conditions stipulated in the tender including:-

i. CMSS reserves the rights/options to short close the delayed lot/tranche undelivered without going for purchase of balance quantity or

ii. Short close the delayed lot/tranche and go for procurement of the undelivered quantity from other approved supplier available in the contract at the same rates (with no financial implication) or from open market at the risk & cost of the defaulting supplier (which may be with financial implication).

For repeated defaults in delivery in same or various POs, to debar such habitual defaulting vendor for suitable period.

Note: - In event of Force majeure reasons/ situations as explained herein at clause no. 18, this clause would not be operated.

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 DRUGS" if the Tenderer does not take back the goods within the stipulated time. The CMSS will arrange to destroy the "NOT OF STANDARD QUALITY DRUGS" 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 drugs 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 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. 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.

22. 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) Not withstanding 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.

23. 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.

24. 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
NEW DELHI- 110021

Online Tender of Procurement of ARV Drugs for NACO

LIST OF PRODUCT & THEIR TECHNICAL SPECIFICATIONS

Sch. No.	Item Name	Total Tentative Quantity	Unit	Detailed Technical Specifications of the Goods/Drugs	Order Distribution Criteria	Inspection Methodology (PDI/Non-PDI)	Consignee Location
I	Isoniazid - 300mg	61,51,700	Tablet	Annexure-IA	70:30 as per clause no. 13	Non-PDI (Inspection at Delivery Stages)	CMSS Warehouses
II	Levofloxacin - 250mg	65,89,200	Tablet	Annexure-IA			
III	Levofloxacin - 500mg	67,93,900	Tablet	Annexure-IA			
IV	Pyrazinamide - 500mg	1,01,94,700	Tablet	Annexure-IA			
V	Pyrazinamide- 750mg	64,94,800	Tablet	Annexure-IA			
VI	Rifampicin - 150mg	25,19,200	Capsule	Annexure-IA			
VII	Rifampicin - 300mg	25,65,200	Capsule	Annexure-IA			
VIII	Rifampicin - 450mg	8,29,600	Capsule	Annexure-IA			
IX	Clofazimine- 50mg	1,65,300	Tablet	Annexure-IA			
X	Clofazimine- 100mg	49,72,400	Capsule/ Tablet	Annexure-IA			

(Please refer Technical specifications attached in Annexure-IA)

Delivery Terms:

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

(b) Delivery Schedule

For SCH. I to VII

TRANCHE I- 35% to be delivered within 60days from the date of issue of LOA.
TRANCHE II- 35% to be delivered within 120-150 days from the date of issue of LOA.
TRANCHE III- 35% to be delivered within 210-240 days from the date of issue of LOA.

For SCH. VIII to IX

TRANCHE I- 70% to be delivered within 60 days from the date of issue of LOA.
TRANCHE II- 30% to be delivered within 120 days from the date of issue of LOA.

For SCH. X

TRANCHE I- 100% to be delivered within 120 days from the date of issue of LOA.

Annexure 1A – Technical Specification & Artwork
Annexure 1B – Consignee Location
Annexure 1C- CMSS Warehouses

Product Code 11 : Isoniazid-300mg

A. Specific requirements

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

Description:

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

Isoniazid Tablet contain Isoniazid.

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

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

Protocols and Testing:

For manufacturer outside India:

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

For Indian manufacturer:

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

Package Integrity Test:

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

Microbial Count:

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

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

B. Labelling:

General requirements of the labels:

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

Labelling on Strip of Blisters:

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

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

Labelling on Millboard/Greyboard Box:

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

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

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

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

Each Blister Strip contains 10 Tablets of Isoniazid-300 mg

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

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

"NTEP Central Government Supply NOT FOR SALE"

Manufacturer's Name
Manufacturing Lic. No.

Labelling on 5-Ply Shipper:

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

Labelling for 5 – Ply Shipper packaging:

5 – Ply Shipper

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

20 Millboard/Greyboard Boxes

Batch No:
Mfg. Date:
Exp. Date:

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

"NTEP Central Government Supply NOT FOR SALE"

Manufacturer's Name
Manufacturing Lic. No.

Numbering of shipper packaging:

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

C. Quality Assurance:

Compliance:

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

Evidence:

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

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

Inspection:

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

Testing:

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

D. Storage:

As per applicable Pharmacopoeia.

E. Shelf Life:

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

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

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

F. Qualification of the Manufacturer:

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

G. Recalls:

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

H. Colour Coding:

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

I. Bar Coding

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

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

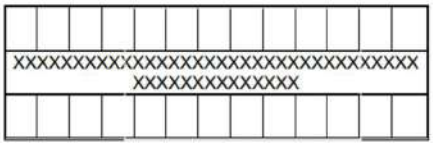
1) Product Name/content
2) Product Strength
3) Batch Number
4) Date of Manufacturing
5) Date of Expiry
6) Manufacturer Address
7) Manufacturer License number
8) Storage conditions requirement
9) Number of Tablets in a Blister Strip/ Millboard/Greyboard Boxes and 5 Ply Shipper

J. Packaging

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

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

Complex Constructions with PVC Films



TECHNICAL DATA FOR THE STANDARD COMPLEXES

Complex:

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

Water Vapour Transmission Rate (W V T R):

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

Shrinkage longitudinally

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

Millboard/ Grey board Box:

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

5-Ply Shipper Package:

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

K. Markings

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

Millboard/Greyboard Box:

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

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

5 – Ply Shipper:

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

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

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

L. Documentation

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

M. Dimensions of the logos

MILLBOARD/GREYBOARD BOX

3.5x3cm	3.5x3cm
	

11

5 – Ply Shipper

5.5x4.7 cm	5.5x4.7 cm
	

12

Product Code 28 (Tab Levofloxacin 250 mg)

A. Specific requirements

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

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

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

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

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

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

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

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

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

B. Labelling:

General requirements of the labels:

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

Labelling on Strip of Blisters:

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

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

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

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

MILLBOARD/GREYBOARD BOX

National Tuberculosis Elimination Programme (NTEP)
MDR-TB TREATMENT DRUG CONTAINS PRODUCT CODE 28
LEVOFLOXACIN TABLETS 250 mg (10 x 10 Tablets)

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

Batch No:

Mfg. Date:

Exp. Date:

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

"NTEP – Central Government Supply – Not for Sale"

Manufacturer's Name

Manufacturing Lic. No.

Labelling on 5-Ply Shipper:

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

3

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

5 – PLY SHIPPER

National Tuberculosis Elimination Programme (NTEP)
MDR-TB TREATMENT DRUG CONTAINS PRODUCT CODE 28
LEVOFLOXACIN TABLETS 250 mg
20 Millboard/Greyboard Boxes

Batch No. :

Mfg. Date:

Exp. Date:

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

"NTEP - Central Government Supply – Not for Sale"

Manufacturer's Name

Manufacturing Lic. No.

Numbering of shipper packaging:

4

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

C. Quality Assurance:

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

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

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

Testing:

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

D. Storage:

As per applicable Pharmacopoeia.

E. Shelf Life:

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

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

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

F. Qualification of the Manufacturer:

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

G. Recalls:

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

H. Colour Coding:

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

I. Bar Coding

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

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

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

J. Packing

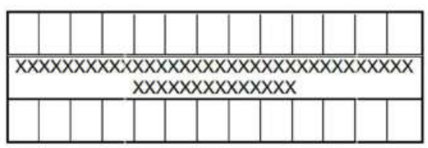
The drug is initially packed in a Blister Strip each containing 10 tablets. 10 such strips would be further packed in white coloured Millboard/Grey board boxes and 20 such Boxes are ultimately packed in 5-Ply Shipper.

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

Aluminium-PVC Blister:

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

Complex Constructions with PVC Films



TECHNICAL DATA FOR THE STANDARD COMPLEXES

Complex:

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

Water Vapour Transmission Rate (W V T R):

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

Shrinkage longitudinally

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

Millboard/ Grey board Box:

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

5-Ply Shipper Package:

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

K. Markings

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

Millboard/Greyboard Box:

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

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

5 – Ply Shipper:

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

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

L. Documentation

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

M. Dimensions of the logos

MILLBOARD/GREYBOARD BOX

3.5x3cm	3.5x3cm
	

11

5 – Ply Shipper

5.5x4.7 cm	5.5x4.7 cm
	

12

Product Code 29 (Tab Levofloxacin 500 mg)

A. Specific requirements

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

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

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

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

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

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

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

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

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

B. Labelling:

General requirements of the labels:

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

Labelling on Strip of Blisters:

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

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

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

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

MILLBOARD/GREYBOARD BOX

National Tuberculosis Elimination Programme (NTEP)
MDR-TB TREATMENT DRUG CONTAINS PRODUCT CODE 29
LEVOFLOXACIN TABLETS 500 mg (10 x 10 Tablets)

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

Batch No:

Mfg. Date:

Exp. Date:

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

"NTEP – Central Government Supply – Not for Sale"

Manufacturer's Name
Manufacturing Lic. No.

Labelling on 5-Ply Shipper:
The labels on shipper package must be attached to at least two sides. The label should include the name of the product, the number of Millboard/Greyboard Boxes, the number of strips, the name of the manufacturer, batch number, Mfg. date & Expiry date of the drug. The label shall also include storage handling instructions. The label shall include Bar Code and be tear proof, to be pasted on smooth surface to enable it to be read by Bar Code reader / Hand held device (Tablet computer / Smartphone). The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

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5 – PLY SHIPPER

National Tuberculosis Elimination Programme (NTEP)
MDR-TB TREATMENT DRUG CONTAINS PRODUCT CODE 29
LEVOFLOXACIN TABLETS 500 mg

20 Millboard/Greyboard Boxes

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

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

"NTEP - Central Government Supply – Not for Sale"

Manufacturer's Name

Manufacturing Lic. No.

Numbering of shipper packaging:

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

4

C. Quality Assurance:

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

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

Inspection:

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

Testing:

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

D. Storage:

As per applicable Pharmacopoeia.

E. Shelf Life:

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

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

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

F. Qualification of the Manufacturer:

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

G. Recalls:

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

H. Colour Coding:

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

I. Bar Coding

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

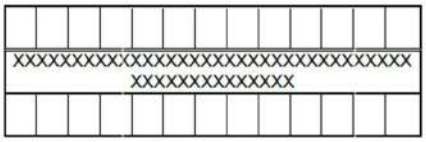
The important information which shall be incorporated in bar code is:

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

J. Packing

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

Complex Constructions with PVC Films



TECHNICAL DATA FOR THE STANDARD COMPLEXES

Complex:

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

Water Vapour Transmission Rate (W V T R):

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

Shrinkage longitudinally

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

Millboard/ Grey board Box:

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

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

K. Markings

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

Millboard/Greyboard Box:

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

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

5 – Ply Shipper:

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

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

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

L. Documentation

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

M. Dimensions of the logos

MILLBOARD/GREYBOARD BOX

3.5x3cm	3.5x3cm
	

11

5 – Ply Shipper

5.5x4.7 cm	5.5x4.7 cm
	

12

Product Code 08 : Pyrazinamide-500mg

A. Specific requirements

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

Description:

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

Pyrazinamide Tablets contain Pyrazinamide.

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

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

Protocols and Testing:

For manufacturer outside India:

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

For Indian manufacturer:

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

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

Package Integrity Test:

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

Microbial Count:

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

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

B. Labelling:

General requirements of the labels:

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

Labelling on Strip of Blisters:

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

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

Labelling on Millboard/Greyboard Box:

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

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

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

National Tuberculosis Elimination Program (NTEP)
TB TREATMENT DRUG CONTAINS PRODUCT CODE 08
PYRAZINAMIDE 500 mg (10 x10 TABLET)

Each Blister Strip contains 10 Tablets of Pyrazinamide-500mg

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

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

"NTEP Central Government Supply
NOT FOR SALE"

Manufacturer's Name
Manufacturing Lic. No.

3

Labelling on 5-Ply Shipper:

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

Labelling for 5 – Ply Shipper packaging:

5 – Ply Shipper

National Tuberculosis Elimination Program (NTEP)
TB TREATMENT DRUG CONTAINS PRODUCT CODE 08
PYRAZINAMIDE TABLETS 500 mg

20 Millboard/Greyboard Boxes

Batch No:
Mfg. Date:
Exp. Date:

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

"NTEP Central Government Supply
NOT FOR SALE"

Manufacturer's Name
Manufacturing Lic. No.

4

Numbering of shipper packaging:

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

C. Quality Assurance:

Compliance:

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

Evidence:

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

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

Inspection:

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

Testing:

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

D. Storage:

As per applicable Pharmacopoeia.

E. Shelf Life:

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

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

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

F. Qualification of the Manufacturer:

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

G. Recalls:

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

H. Colour Coding:

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

I. Bar Coding

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

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

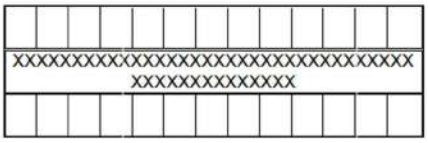
1) Product Name/content
2) Product Strength
3) Batch Number
4) Date of Manufacturing
5) Date of Expiry
6) Manufacturer Address
7) Manufacturer License number
8) Storage conditions requirement
9) Number of Tablets in a Blister Strip/ Millboard/Greyboard Boxes and 5 Ply Shipper

J. Packaging

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

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

Complex Constructions with PVC Films



TECHNICAL DATA FOR THE STANDARD COMPLEXES

Complex:

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

Water Vapour Transmission Rate (W V T R):

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

Shrinkage longitudinally

T = 140°C, t = 20 min. (%) 5 – 6
Application temperature ($^{\circ}$C) 68 – 74

Millboard/ Grey board Box:

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

5-Ply Shipper Package:

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

K. Markings

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

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

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

5 – Ply Shipper:

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

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

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

L. Documentation

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

M. Dimensions of the logos

MILLBOARD/GREYBOARD BOX

3.5x3cm	3.5x3cm
	

11

5 – Ply Shipper

5.5x4.7 cm	5.5x4.7 cm
	

12

Product Code 23: Pyrazinamide-750mg

A. Specific requirements

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

Description:

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

Pyrazinamide Tablets contain Pyrazinamide.

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

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

Protocols and Testing:

For manufacturer outside India:

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

For Indian manufacturer:

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

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

Package Integrity Test:

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

Microbial Count:

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

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

B. Labelling:

General requirements of the labels:

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

Labelling on Strip of Blisters:

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

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

Labelling on Millboard/Greyboard Box:

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

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

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

National Tuberculosis Elimination Program (NTEP)
TB TREATMENT DRUG CONTAINS PRODUCT CODE 23
PYRAZINAMIDE 750 mg (10 x10 TABLET)

Each Blister Strip contains 10 Tablets of Pyrazinamide-750mg

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.

3

Labelling on 5-Ply Shipper:

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

Labelling for 5 – Ply Shipper packaging:

5 – Ply Shipper

National Tuberculosis Elimination Program (NTEP)
TB TREATMENT DRUG CONTAINS PRODUCT CODE 23
PYRAZINAMIDE TABLETS 750 mg

20 Millboard/Greyboard Boxes

Batch No:
Mfg. Date:
Exp. Date:

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

"NTEP Central Government Supply NOT FOR SALE"

Manufacturer's Name
Manufacturing Lic. No.

4

Numbering of shipper packaging:

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

C. Quality Assurance:

Compliance:

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

Evidence:

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

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

Inspection:

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

Testing:

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

D. Storage:

As per applicable Pharmacopoeia.

E. Shelf Life:

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

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

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

F. Qualification of the Manufacturer:

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

G. Recalls:

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

H. Colour Coding:

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

I. Bar Coding

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

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

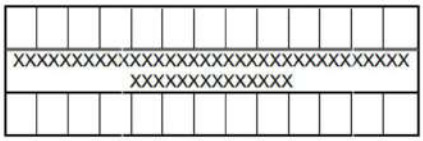
1) Product Name/content
2) Product Strength
3) Batch Number
4) Date of Manufacturing
5) Date of Expiry
6) Manufacturer Address
7) Manufacturer License number
8) Storage conditions requirement
9) Number of Tablets in a Blister Strip/ Millboard/Greyboard Boxes and 5 Ply Shipper

J. Packaging

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

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

Complex Constructions with PVC Films



TECHNICAL DATA FOR THE STANDARD COMPLEXES

Complex:

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

Water Vapour Transmission Rate (W V T R):

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

Shrinkage longitudinally

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

Millboard/ Grey board Box:

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

5-Ply Shipper Package:

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

K. Markings

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

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

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

5 – Ply Shipper:

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

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

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

L. Documentation

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

M. Dimensions of the logos

MILLBOARD/GREYBOARD BOX

3.5x3cm	3.5x3cm
	

11

5 – Ply Shipper

5.5x4.7 cm	5.5x4.7 cm
	

12

Product Code 06 (Cap Rifampicin-150mg)

A. Specific requirements

Item:
Product Code 06 (PC 06) consists of strips and each strip contains ten blisters of Rifampicin Capsules. 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:

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

Rifampicin Capsules contain Rifampicin.
Each capsule shall contain - Rifampicin IP 150 mg, Pharmacopeia* (IP/ BP/USP/Other International Pharmacopeia)

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

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

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

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

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

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

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

B. Labelling:

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

Labelling on Strip of Blisters:
The label shall indicate the content of Rifampicin in each capsule.
All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact.
The label shall incorporate manufacturing license no., batch no., date of mfg., date of expiry of the individual drug and storage requirements.
The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

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

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

MILLBOARD/GREYBOARD BOX

National Tuberculosis Elimination Programme (NTEP)
TB TREATMENT DRUG CONTAINS PRODUCT CODE 06
Cap RIFAMPICIN 150 mg (10 x 10 Caps)

Each Blister Strip Contains 10 Capsules of Rifampicin(150 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).

3

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

5 – PLY SHIPPER

National Tuberculosis Elimination Programme (NTEP)
TB TREATMENT DRUG CONTAINS PRODUCT CODE 06
CAPSULE RIFAMPICIN 150 mg
20 Millboard/Greyboard Boxes

Batch No. :

Mfg. Date:

Exp. Date:

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

"NTEP - Central Government Supply – Not for Sale"
Manufacturer's Name
Manufacturing Lic. No.

Numbering of shipper packaging:

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

4

C. Quality Assurance:

Compliance:

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

Evidence:

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

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

Inspection:

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

Testing:

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

D. Storage:

As per applicable Pharmacopoeia.

E. Shelf Life:

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

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

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

F. Qualification of the Manufacturer:

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

G. Recalls:

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

H. Colour Coding:

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

I. Bar Coding

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

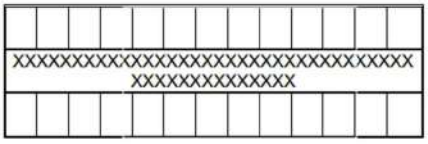
The important information which shall be incorporated in bar code is:

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

J. Packing

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

Complex Constructions with PVC Films



TECHNICAL DATA FOR THE STANDARD COMPLEXES

Complex:

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

Water Vapour Transmission Rate (W V T R):

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

Shrinkage longitudinally

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

Millboard/ Grey board Box:

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

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

K. Markings

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

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

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

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

- Generic name of the product
- Batch number of the drug
- Date of manufacture of the drug (month and year)
- Expiration date of the drug (month and year)
- Manufacturer's name and registered address
- Manufacturer's national registration number
- Destination country license or registration number

Consignee's address and emergency phone number including mobile number

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

L. Documentation

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

M. Dimensions of the logos

MILLBOARD/GREYBOARD BOX

3.5x3cm	3.5x3cm
	

5 – Ply Shipper

5.5x4.7 cm	5.5x4.7 cm
	

11

Product Code 47 (Cap Rifampicin-300mg)

A. Specific requirements

Item:
Product Code 47 (PC 47) consists of strips and each strip contains ten blisters of Rifampicin Capsules. 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:

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

Rifampicin Capsules contain Rifampicin.
Each capsule shall contain - Rifampicin IP 300 mg, Pharmacopeia* (IP/ BP/USP/Other International Pharmacopeia)

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

Protocols and Testing:

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

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

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

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

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

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

B. Labelling:

General requirements of the labels:

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

Labelling on Strip of Blisters:
The label shall indicate the content of Rifampicin in each capsule.
All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact.
The label shall incorporate manufacturing license no., batch no., date of mfg., date of expiry of the individual drug and storage requirements.
The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

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

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

MILLBOARD/GREYBOARD BOX

National Tuberculosis Elimination Programme (NTEP)
TB TREATMENT DRUG CONTAINS PRODUCT CODE 47
Cap RIFAMPICIN 300 mg (10 x 10 Caps)

Each Blister Strip Contains 10 Capsules of Rifampicin(300 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.

5 – PLY SHIPPER

National Tuberculosis Elimination Programme (NTEP)
TB TREATMENT DRUG CONTAINS PRODUCT CODE 47

CAPSULE RIFAMPICIN 300mg

20 Millboard/Greyboard Boxes

Batch No. :

Mfg. Date:

Exp. Date:

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

"NTEP - Central Government Supply – Not for Sale"

Manufacturer's Name

Manufacturing Lic. No.

Numbering of shipper packaging:

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

C. Quality Assurance:

Compliance:

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

Evidence:

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

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

Inspection:

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

Testing:

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

D. Storage:

As per applicable Pharmacopoeia.

E. Shelf Life:

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

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

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

F. Qualification of the Manufacturer:

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

G. Recalls:

If products must be recalled because of problems with product quality or adverse reactions to the drug, the Supplier will be obliged to notify the purchaser providing full details about the reason leading to the recall and shall take steps to

replace the product in question at its own cost with a fresh batch of acceptable quality, or withdraw and give a full refund if the product has been taken off the market due to safety problems.

H. Colour Coding:

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

I. Bar Coding

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

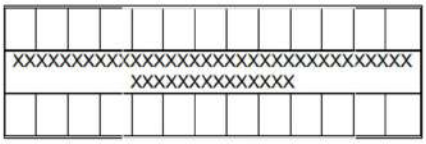
The important information which shall be incorporated in bar code is:

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

J. Packing

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

Complex Constructions with PVC Films



TECHNICAL DATA FOR THE STANDARD COMPLEXES

Complex:

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

Water Vapour Transmission Rate (W V T R):

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

Shrinkage longitudinally

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

Millboard/ Grey board Box:

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

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

K. Markings

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

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

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

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

- Generic name of the product
- Batch number of the drug
- Date of manufacture of the drug (month and year)
- Expiration date of the drug (month and year)
- Manufacturer's name and registered address

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

L. Documentation

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

M. Dimensions of the logos

MILLBOARD/GREYBOARD BOX

3.5x3cm	3.5x3cm
	

5 – Ply Shipper

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

Product Code 12 (Cap Rifampicin-450mg)

A. Specific requirements

Item:
Product Code 12 (PC 12) consists of strips and each strip contains ten blisters of Rifampicin Capsules. 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:

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

Rifampicin Capsules contain Rifampicin.
Each capsule shall contain - Rifampicin IP 450 mg, Pharmacopeia* (IP/ BP/USP/Other International Pharmacopeia)

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

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

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

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

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

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

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

B. Labelling:

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

Labelling on Strip of Blisters:
The label shall indicate the content of Rifampicin in each capsule.
All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact.
The label shall incorporate manufacturing license no., batch no., date of mfg., date of expiry of the individual drug and storage requirements.
The label shall conform to the requirements of Drugs & Cosmetics Act 1940 and Rules made thereunder and as amended from time to time.

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

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

MILLBOARD/GREYBOARD BOX

National Tuberculosis Elimination Programme (NTEP)
TB TREATMENT DRUG CONTAINS PRODUCT CODE 12
Cap RIFAMPICIN 450 mg (10 x 10 Caps)

Each Blister Strip Contains 10 Capsules of Rifampicin(450 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).

3

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

5 – PLY SHIPPER

National Tuberculosis Elimination Programme (NTEP)
TB TREATMENT DRUG CONTAINS PRODUCT CODE 12
CAPSULE RIFAMPICIN 450 mg
20 Millboard/Greyboard Boxes

Batch No. :

Mfg. Date:

Exp. Date:

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

"NTEP - Central Government Supply – Not for Sale"
Manufacturer's Name
Manufacturing Lic. No.

Numbering of shipper packaging:

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

4

C. Quality Assurance:

Compliance:

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

Evidence:

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

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

Inspection:

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

Testing:

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

D. Storage:

As per applicable Pharmacopoeia.

E. Shelf Life:

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

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

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

F. Qualification of the Manufacturer:

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

G. Recalls:

If products must be recalled because of problems with product quality or adverse reactions to the drug, the Supplier will be obliged to notify the purchaser providing full details about the reason leading to the recall and shall take steps to

replace the product in question at its own cost with a fresh batch of acceptable quality, or withdraw and give a full refund if the product has been taken off the market due to safety problems.

H. Colour Coding:

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

I. Bar Coding

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

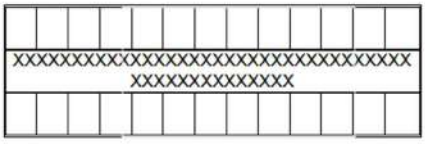
The important information which shall be incorporated in bar code is:

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

J. Packing

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

Complex Constructions with PVC Films



TECHNICAL DATA FOR THE STANDARD COMPLEXES

Complex:

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

Water Vapour Transmission Rate (W V T R):

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

Shrinkage longitudinally

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

Millboard/ Grey board Box:

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

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

K. Markings

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

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

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

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

- Generic name of the product
- Batch number of the drug
- Date of manufacture of the drug (month and year)
- Expiration date of the drug (month and year)
- Manufacturer's name and registered address

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

L. Documentation

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

M. Dimensions of the logos

MILLBOARD/GREYBOARD BOX

3.5x3cm	3.5x3cm
	

5 – Ply Shipper

11

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

12

Product Code 51 : Clofazimine-50mg (Scored and Uncoated Tablet)

A. Specific requirements

Product Code 51 (PC-51) is for Scored and Uncoated Tablet of Clofazimine-50mg. 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:

Scored and Uncoated Tablets of Clofazimine 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.

Clofazimine Scored and Uncoated Tablet contain Clofazimine.

Each scored and uncoated tablet shall contain - Clofazimine-50mg, Pharmacopeia* (IP/ BP/USP/Other International Pharmacopeia)

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

Protocols and Testing:

For manufacturer outside India:

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

For Indian manufacturer:

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

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

Package Integrity Test:

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

Microbial Count:

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

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

B. Labelling:

General requirements of the labels:

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

Labelling on Strip of Blisters:

The label shall indicate the content of Clofazimine in each scored and uncoated 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 Clofazimine in each scored and uncoated tablet.

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

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

Millboard/Greyboard Box

National Tuberculosis Elimination Program (NTEP)
TB TREATMENT DRUG CONTAINS PRODUCT CODE - 51
CLOFAZIMINE -50MG (SCORED & UNCOATED TABLET) 10 x 10 Tablets

Each Blister Strip contains 10 Tablets of Clofazimine-50 mg (Scored & Uncoated)

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.

3

Labelling on 5-Ply Shipper:

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

Labelling for 5 – Ply Shipper packaging:

5 – Ply Shipper

National Tuberculosis Elimination Program (NTEP)
TB TREATMENT DRUG CONTAINS PRODUCT CODE - 51
CLOFAZIMINE -50MG (SCORED & UNCOATED TABLET)

20 Millboard/Greyboard Boxes

Batch No:
Mfg. Date:
Exp. Date:

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

"NTEP Central Government Supply NOT FOR SALE"

Manufacturer's Name
Manufacturing Lic. No.

4

Numbering of shipper packaging:

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

C. Quality Assurance:

Compliance:

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

Evidence:

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

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

Inspection:

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

Testing:

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

D. Storage:

As per applicable Pharmacopoeia.

E. Shelf Life:

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

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

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

F. Qualification of the Manufacturer:

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

G. Recalls:

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

H. Colour Coding:

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

I. Bar Coding

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

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

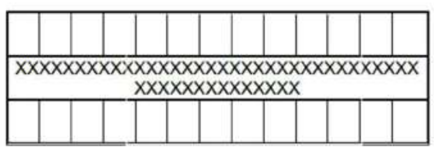
1) Product Name/content
2) Product Strength
3) Batch Number
4) Date of Manufacturing
5) Date of Expiry
6) Manufacturer Address
7) Manufacturer License number
8) Storage conditions requirement
9) Number of Tablets in a Blister Strip/ Millboard/Greyboard Boxes and 5 Ply Shipper

J. Packaging

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

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

Complex Constructions with PVC Films



TECHNICAL DATA FOR THE STANDARD COMPLEXES

Complex:

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

Water Vapour Transmission Rate (W V T R):

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

Shrinkage longitudinally

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

Millboard/ Grey board Box:

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

5-Ply Shipper Package:

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

K. Markings

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

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

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

5 – Ply Shipper:

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

- Generic name of the product
- Batch number of the drug
- Date of manufacture of the drug (month and year)
- Expiration date of the drug (month and year)
- Manufacturer's name and registered address

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

L. Documentation

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

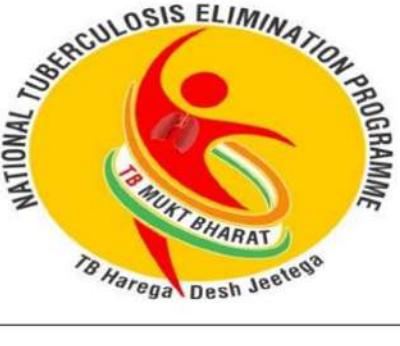
M. Dimensions of the logos

MILLBOARD/GREYBOARD BOX

3.5x3cm	3.5x3cm
	

11

5 – Ply Shipper

5.5x4.7 cm	5.5x4.7 cm
	

12

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

A. Specific requirements

Item:

Product Code 40 (PC 40) consists of blister strips of Clofazimine Capsules or 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:

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

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

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

Protocols and Testing:

For manufacturers outside India:

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

For Indian manufacturers:

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

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

Package Integrity Test:

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

Microbial Count:

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

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

B. Labelling:

General requirements of the labels:

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

Labelling on Strip of Blisters:

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

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

MILLBOARD/GREYBOARD BOX

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

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

Batch Nos:

Mfg. Date:

Exp. Date:

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

"NTEP – Central Government Supply – Not for Sale"

Manufacturer's Name

Manufacturing Lic. No.

3

Labelling on 5-Ply Shipper:

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

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

5 – PLY SHIPPER

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

Batch No. :

Mfg. Date:

Exp. Date:

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

"NTEP - Central Government Supply – Not for Sale"

Manufacturer's Name

Manufacturing Lic. No.

4

Numbering of shipper packaging:

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

C. Quality Assurance:

Compliance:

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

Evidence:

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

Inspection:

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

Testing:

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

D. Storage:

As per applicable Pharmacopoeia.

E. Shelf Life:

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

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

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

F. Qualification of the Manufacturer:

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

G. Recalls:

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

H. Colour Coding:

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

I. Bar Coding

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

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

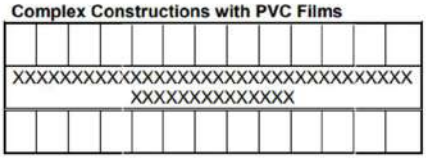
1) Product Name/content
2) Product Strength
3) Batch Number
4) Date of Manufacturing
5) Date of Expiry
6) Manufacturer Address
7) Manufacturer License number
8) Storage conditions requirement
9) Number of Capsules /Tablets in a Blister Strip/ Millboard/Greyboard Boxes and 5 Ply Shipper

J. Packing

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

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

Complex Constructions with PVC Films



TECHNICAL DATA FOR THE STANDARD COMPLEXES

Complex:

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

Water Vapour Transmission Rate (W V T R):

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

Shrinkage longitudinally

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

Millboard/ Grey board Box:

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

5-Ply Shipper Package:

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

K. Markings

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

Millboard/Greyboard Box:

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

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

5 – Ply Shipper:

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

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

L. Documentation

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

M. Dimensions of the logos

MILLBOARD/GREYBOARD BOX

MILLBOARD/GREYBOARD BOX

3.5x3cm	3.5x3cm
	

11

5 – Ply Shipper

5.5x4.7 cm	5.5x4.7 cm
	

12

Annexure-1B

CONSIGNEE LIST

S. No.	State Name	Clofazimine 50mg	Clofazimine 100mg		Isoniazid 300mg		
		Tab	Cap / Tab		Tab		
		Single Tranche (CMSS Consignees)	1st Tranche (70%) (State stores)	2nd Tranche (30%) (CMSS Stores)	1st Tranche (35%) (State stores)	2nd Tranche (35%) (State stores)	3rd Tranche (30%) (CMSS stores)
1	Andaman and Nicobar Islands	200	4,900	2,100	400	400	300
2	Andhra Pradesh	4,000	76,600	32,900	20,300	20,300	17,400
3	Arunachal Pradesh	-	6,600	2,900	1,100	1,100	1,000
4	Assam	1,000	18,400	7,900	1,75,200	1,75,200	1,50,100
5	Patna - Bihar	2,000	1,47,600	63,300	21,800	21,800	18,700
6	Darbhanga - Bihar	1,300	98,400	42,200	14,500	14,500	12,500
7	Chandigarh	200	7,000	3,000	8,100	8,100	6,900
8	Chhattisgarh	2,200	39,300	16,900	4,600	4,600	3,900
9	Delhi	8,100	1,83,700	78,700	4,800	4,800	4,100
10	Goa	100	6,100	2,700	6,200	6,200	5,400
11	Gujarat	8,200	1,82,400	78,200	2,14,100	2,14,100	1,83,500
12	Haryana	1,400	99,300	42,600	37,000	37,000	31,800
13	Himachal Pradesh	2,400	14,000	6,000	600	600	600
14	Jammu	1,400	10,200	4,400	7,500	7,500	6,400
15	Jharkhand	900	46,200	19,800	84,600	84,600	72,600
16	Kashmir	100	2,200	1,000	1,500	1,500	1,300
17	Bangalore - Karnataka	1,600	41,800	17,900	37,400	37,400	32,100
18	Dharwad - Karnataka	1,100	27,900	12,000	25,000	25,000	21,400
19	Kerala	500	20,100	8,700	18,400	18,400	15,800
20	Madhya Pradesh	4,500	1,63,000	69,900	2,38,100	2,38,100	2,04,100
21	Mumbai - Maharashtra	18,700	2,86,500	1,22,800	80,700	80,700	69,100
22	Pune - Maharashtra	21,400	3,27,400	1,40,300	92,200	92,200	79,000
23	Nagpur - Maharashtra	13,400	2,04,600	87,700	57,600	57,600	49,400
24	Manipur	-	4,700	2,000	33,200	33,200	28,500
25	Meghalaya	1,200	15,500	6,700	13,200	13,200	11,300
26	Mizoram	-	6,200	2,700	12,900	12,900	11,100
27	Nagaland	300	6,600	2,800	21,200	21,200	18,100
28	Odisha	1,700	29,500	12,700	35,600	35,600	30,500
29	Puducherry	100	1,400	600	2,800	2,800	2,400
30	Punjab	1,500	24,300	10,400	82,100	82,100	70,400
31	Rajasthan	3,700	1,58,400	67,900	98,300	98,300	84,200
32	Sikkim	800	18,300	7,900	3,200	3,200	2,700
33	Tamil Nadu	14,000	71,000	30,400	7,400	7,400	6,400
34	Telangana	3,300	72,100	30,900	2,000	2,000	1,800
35	Tripura	-	2,200	1,000	1,300	1,300	1,100
36	Bareilly - Uttar Pradesh	8,300	1,90,900	81,800	48,000	48,000	41,200
37	Agra - Uttar Pradesh	9,000	2,07,500	88,900	52,200	52,200	44,700
38	Lucknow-Uttar Pradesh	9,700	2,24,100	96,100	56,400	56,400	48,300
39	Varanasi - Uttar Pradesh	9,000	2,07,500	88,900	52,200	52,200	44,700
40	Uttarakhand	400	53,500	22,900	32,700	32,700	28,000
41	West Bengal	8,100	1,75,300	70,700	4,48,900	4,48,900	3,78,300
	Total	**1,65,800**	**34,83,200**	**14,89,200**	**21,55,300**	**21,55,300**	**18,41,100**
	G. Total	**1,65,300**	**49,72,400**		**61,51,700**		

S. No.	State Name	Levofloxacin 250mg			Levofloxacin 500mg		
		Tab			Tab		
		1st Tranche (35%) (State stores)	2nd Tranche (35%) (State stores)	3rd Tranche (30%) (CMSS stores)	1st Tranche (35%) (State stores)	2nd Tranche (35%) (State stores)	3rd Tranche (30%) (CMSS stores)
1	Andaman and Nicobar Islands	2,900	2,900	2,500	3,600	3,600	3,100
2	Andhra Pradesh	99,200	99,200	85,000	1,04,100	1,04,100	89,200
3	Arunachal Pradesh	8,700	8,700	7,500	5,000	5,000	4,300
4	Assam	15,500	15,500	13,300	12,600	12,600	10,800
5	Patna - Bihar	56,900	56,900	48,700	54,200	54,200	46,500
6	Darbhanga - Bihar	37,900	37,900	32,500	36,200	36,200	31,000
7	Chandigarh	5,800	5,800	5,000	9,500	9,500	8,100
8	Chhattisgarh	18,900	18,900	16,200	38,800	38,800	33,300
9	Delhi	1,15,600	1,15,600	99,100	1,57,600	1,57,600	1,35,100
10	Goa	8,300	8,300	7,100	5,500	5,500	4,700
11	Gujarat	1,07,200	1,07,200	91,800	1,14,800	1,14,800	98,400
12	Haryana	62,200	62,200	53,300	62,700	62,700	53,700
13	Himachal Pradesh	4,000	4,000	3,400	53,700	53,700	46,000
14	Jammu	7,900	7,900	6,700	12,400	12,400	10,600
15	Jharkhand	25,000	25,000	21,400	19,700	19,700	16,900
16	Kashmir	4,100	4,100	3,600	3,600	3,600	3,100
17	Bangalore - Karnataka	27,300	27,300	23,400	33,900	33,900	29,000
18	Dharwad - Karnataka	18,200	18,200	15,600	22,600	22,600	19,400
19	Kerala	25,900	25,900	22,200	51,500	51,500	44,100
20	Madhya Pradesh	1,45,900	1,45,900	1,25,100	1,05,600	1,05,600	90,500
21	Mumbai - Maharashtra	1,42,500	1,42,500	1,22,200	1,61,500	1,61,500	1,38,400
22	Pune - Maharashtra	1,62,800	1,62,800	1,39,600	1,84,600	1,84,600	1,58,200
23	Nagpur - Maharashtra	1,01,800	1,01,800	87,300	1,15,400	1,15,400	98,900
24	Manipur	3,800	3,800	3,200	4,800	4,800	4,200
25	Meghalaya	19,100	19,100	16,400	15,400	15,400	13,200
26	Mizoram	2,600	2,600	2,300	4,000	4,000	3,400
27	Nagaland	7,300	7,300	6,300	6,400	6,400	5,500
28	Odisha	26,100	26,100	22,400	24,400	24,400	20,900
29	Puducherry	3,300	3,300	2,800	2,700	2,700	2,400
30	Punjab	23,500	23,500	20,100	35,400	35,400	30,300
31	Rajasthan	1,24,000	1,24,000	1,06,300	1,21,000	1,21,000	1,03,800
32	Sikkim	8,700	8,700	7,500	15,000	15,000	12,900
33	Tamil Nadu	1,37,200	1,37,200	1,17,600	86,700	86,700	74,400
34	Telangana	67,900	67,900	58,200	62,800	62,800	53,900
35	Tripura	4,600	4,600	4,000	4,700	4,700	4,000
36	Bareilly - Uttar Pradesh	1,02,500	1,02,500	86,600	1,00,700	1,00,700	85,200
37	Agra - Uttar Pradesh	1,11,400	1,11,400	94,100	1,09,500	1,09,500	92,600
38	Lucknow-Uttar Pradesh	1,20,300	1,20,300	1,01,700	1,18,200	1,18,200	1,00,000
39	Varanasi - Uttar Pradesh	1,11,400	1,11,400	94,100	1,09,500	1,09,500	92,600
40	Uttarakhand	47,900	47,900	41,000	27,000	27,000	23,100
41	West Bengal	1,82,500	1,82,500	1,54,900	1,62,900	1,62,900	1,37,800
	Total	**23,08,600**	**23,08,600**	**19,72,000**	**23,80,200**	**23,80,200**	**20,33,500**
	G. Total	**65,89,200**			**67,93,900**		

S. No.	State Name	Rifampicin 150mg			Rifampicin 300mg			Rifampicin 450mg	
		Cap			Cap			Cap	
		1st Tranche (35%) (State stores)	2nd Tranche (35%) (State stores)	3rd Tranche (30%) (CMSS stores)	1st Tranche (35%) (State stores)	2nd Tranche (35%) (State stores)	3rd Tranche (30%) (CMSS stores)	1st Tranche (70%) (State stores)	2nd Tranche (30%) (CMSS Stores)
1	Andaman and Nicobar Islands	2,100	2,100	1,800	2,600	2,600	2,200	-	-
2	Andhra Pradesh	46,700	46,700	40,100	68,900	68,900	59,100	38,500	16,500
3	Arunachal Pradesh	1,300	1,300	1,100	1,400	1,400	1,200	3,600	1,600
4	Assam	17,600	17,600	15,100	14,100	14,100	12,100	31,600	13,600
5	Patna - Bihar	4,700	4,700	4,000	2,200	2,200	1,900	-	-
6	Darbhanga - Bihar	3,100	3,100	2,700	1,500	1,500	1,300	-	-
7	Chandigarh	7,700	7,700	6,600	4,100	4,100	3,500	14,000	6,000
8	Chhattisgarh	1,500	1,500	1,300	1,500	1,500	1,300	37,100	15,900
9	Delhi	97,100	97,100	83,300	88,200	88,200	75,600	-	-
10	Goa	18,500	18,500	15,800	3,200	3,200	2,700	100	100
11	Gujarat	38,800	38,800	33,200	49,300	49,300	42,300	12,700	5,400
12	Haryana	13,300	13,300	11,400	14,600	14,600	12,500	-	-
13	Himachal Pradesh	6,500	6,500	5,600	14,100	14,100	12,100	14,700	6,300
14	Jammu	1,600	1,600	1,400	1,300	1,300	1,100	500	300
15	Jharkhand	5,200	5,200	4,500	6,900	6,900	5,900	2,900	1,300
16	Kashmir	2,900	2,900	2,500	1,200	1,200	1,000	3,600	1,600
17	Bangalore - Karnataka	37,900	37,900	32,500	33,700	33,700	28,900	-	-
18	Dharwad - Karnataka	25,300	25,300	21,700	22,500	22,500	19,300	-	-
19	Kerala	75,200	75,200	64,400	81,100	81,100	69,500	71,200	30,500
20	Madhya Pradesh	26,100	26,100	22,300	41,000	41,000	35,200	-	-
21	Mumbai - Maharashtra	44,900	44,900	38,500	50,500	50,500	43,300	65,200	28,000
22	Pune - Maharashtra	51,300	51,300	44,000	57,700	57,700	49,500	74,500	32,000
23	Nagpur - Maharashtra	32,100	32,100	27,500	36,100	36,100	30,900	46,600	20,000
24	Manipur	1,800	1,800	1,500	1,000	1,000	900	-	-
25	Meghalaya	29,700	29,700	25,500	3,700	3,700	3,200	15,900	6,900
26	Mizoram	1,800	1,800	1,500	3,000	3,000	2,600	1,500	700
27	Nagaland	2,700	2,700	2,300	1,400	1,400	1,200	1,900	800
28	Odisha	6,000	6,000	5,200	22,700	22,700	19,400	-	-
29	Puducherry	6,100	6,100	5,200	7,000	7,000	6,000	-	-
30	Punjab	20,000	20,000	17,100	22,800	22,800	19,600	-	-
31	Rajasthan	26,300	26,300	22,500	31,900	31,900	27,400	10,700	4,600
32	Sikkim	4,200	4,200	3,600	5,000	5,000	4,300	-	-
33	Tamil Nadu	88,900	88,900	76,200	90,500	90,500	77,600	81,600	35,000
34	Telangana	5,200	5,200	4,400	5,600	5,600	4,800	-	-
35	Tripura	8,300	8,300	7,100	4,500	4,500	3,800	4,200	1,800
36	Bareilly - Uttar Pradesh	5,500	5,500	4,700	15,000	15,000	11,700	800	400
37	Agra - Uttar Pradesh	5,900	5,900	5,100	16,200	16,200	12,700	900	400
38	Lucknow-Uttar Pradesh	6,400	6,400	5,500	17,500	17,500	13,700	1,000	500
39	Varanasi - Uttar Pradesh	5,900	5,900	5,100	16,200	16,200	12,700	900	400
40	Uttarakhand	6,300	6,300	5,400	3,500	3,500	3,000	5,400	2,400
41	West Bengal	91,700	91,700	71,800	34,700	34,700	28,400	40,500	14,500
	Total	8,84,100	8,84,100	7,51,000	8,99,900	8,99,900	7,65,400	5,82,100	2,47,500
	G. Total	25,19,200			25,65,200			8,29,600	

S. No.	State Name	Pyrazinamide 500mg			Pyrazinamide 750mg		
		Tab			Tab		
		1st Tranche (35%) (State stores)	2nd Tranche (35%) (State stores)	3rd Tranche (30%) (CMSS stores)	1st Tranche (35%) (State stores)	2nd Tranche (35%) (State stores)	3rd Tranche (30%) (CMSS stores)
1	Andaman and Nicobar Islands	1,900	1,900	1,600	2,400	2,400	2,100
2	Andhra Pradesh	88,500	88,500	75,900	1,18,800	1,18,800	1,01,800
3	Arunachal Pradesh	2,600	2,600	2,300	5,400	5,400	4,700
4	Assam	14,200	14,200	12,200	35,100	35,100	30,100
5	Patna - Bihar	1,07,700	1,07,700	92,300	56,000	56,000	48,000
6	Darbhanga - Bihar	71,800	71,800	61,500	37,400	37,400	32,000
7	Chandigarh	4,700	4,700	4,100	9,800	9,800	8,400
8	Chhattisgarh	11,500	11,500	9,900	12,700	12,700	10,900
9	Delhi	44,800	44,800	38,400	1,67,900	1,67,900	1,43,900
10	Goa	6,500	6,500	5,600	15,700	15,700	13,500
11	Gujarat	92,000	92,000	78,800	1,21,500	1,21,500	1,04,100
12	Haryana	67,600	67,600	57,900	57,500	57,500	49,300
13	Himachal Pradesh	6,600	6,600	5,700	81,800	81,800	70,200
14	Jammu	3,700	3,700	3,100	12,200	12,200	10,400
15	Jharkhand	26,200	26,200	22,400	21,700	21,700	18,600
16	Kashmir	4,000	4,000	3,400	3,200	3,200	2,700
17	Bangalore - Karnataka	24,300	24,300	20,900	31,100	31,100	26,700
18	Dharwad - Karnataka	16,200	16,200	13,900	20,800	20,800	17,800
19	Kerala	30,900	30,900	26,500	43,900	43,900	37,600
20	Madhya Pradesh	78,300	78,300	67,200	1,28,300	1,28,300	1,10,000
21	Mumbai - Maharashtra	6,58,100	6,58,100	5,64,100	1,21,000	1,21,000	1,03,700
22	Pune - Maharashtra	7,52,100	7,52,100	6,44,600	1,38,300	1,38,300	1,18,500
23	Nagpur - Maharashtra	4,70,100	4,70,100	4,02,900	86,400	86,400	74,100
24	Manipur	1,800	1,800	1,500	3,900	3,900	3,300
25	Meghalaya	29,900	29,900	25,600	47,800	47,800	41,000
26	Mizoram	3,800	3,800	3,200	15,000	15,000	12,800
27	Nagaland	6,500	6,500	5,500	9,100	9,100	7,800
28	Odisha	27,500	27,500	23,600	23,300	23,300	20,000
29	Puducherry	2,100	2,100	1,800	4,800	4,800	4,100
30	Punjab	24,700	24,700	21,200	27,900	27,900	23,900
31	Rajasthan	1,18,300	1,18,300	1,01,400	1,13,100	1,13,100	96,900
32	Sikkim	8,800	8,800	7,500	16,900	16,900	14,500
33	Tamil Nadu	73,000	73,000	62,500	1,05,500	1,05,500	90,400
34	Telangana	57,100	57,100	48,900	36,000	36,000	30,900
35	Tripura	2,700	2,700	2,300	4,000	4,000	3,400
36	Bareilly - Uttar Pradesh	1,15,300	1,15,300	97,500	86,900	86,900	73,100
37	Agra - Uttar Pradesh	1,25,300	1,25,300	1,06,000	94,400	94,400	79,500
38	Lucknow-Uttar Pradesh	1,35,300	1,35,300	1,14,500	1,02,000	1,02,000	85,900
39	Varanasi - Uttar Pradesh	1,25,300	1,25,300	1,06,000	94,400	94,400	79,500
40	Uttarakhand	18,400	18,400	15,800	37,000	37,000	31,800
41	West Bengal	1,10,500	1,10,500	93,500	1,24,700	1,24,700	1,05,700
	Total	35,70,600	35,70,600	30,53,500	22,75,600	22,75,600	19,43,600
	G. Total	1,01,94,700			64,94,800		

Annexure-1C

The details of CMSS warehouses are given below:-

CMSS Warehouse & Mapped States			
Sr No	**Warehouse Location**	**States/UT's covered by the Warehouse**	**Address**
1	Agartala	Tripura	Near ONGC Complex, PO-Hapania , Agartala-799014
2	Ahmadabad	Gujarat	Opp. P&T Colony, Shahalam, Ahmedabad-380028
3	Bangalore	Karnataka	APMC Yard, Yeswanthpur, Bangalore - 560022
4	Bhopal	Madhya Pradesh	Chhola Road, Near Nishatpura Cabin, Bhopal, M.P.
5	Chandigarh	Chandigarh Punjab Haryana Himanchal Pradesh Jammu & Kashmir, Leh Ladakh Uttarakhand	Central Medical Services Society Godown no. B014/3433, Near Vivekanand School, Godown area, Village Bhabat, Thana-Zirakpur, Dist: SAS Nagar-140603(Punjab)
6	Chennai	Tamil Nadu Pondicherry Andaman & Nicobar Islands	Chitalapakkam(P.O), Chennai - 600064, T.N.
7	Jajpur	Odisha	Dhawalgiri, Post-Jajpur Road, Dist-Jajpur, Odisha
8	Delhi	Delhi	Ware Housing Scheme Block No 2.,Kirti Nagar, New Delhi-110015.
9	Guwahati	Assam Arunachal Pradesh Meghalaya Nagaland Sikkim Manipur Mizoram	EPIP Complex, Amingaon, Guwahati-781031
10	Hyderabad	Telangana Andhra Pradesh	Behind Gandhibhavan, Nampally, Hyderabad-500001
11	Jaipur	Rajasthan	Plot no SPL-1296, EPIP Sitapura, Ind Area, Jaipur-302002
12	Kolkata	West Bengal	Rehabilitation Industries Corporation Estate, Bonhooghly, Kolkatta - 700 108
13	Lucknow	Uttar Pradesh	New Mandi Complex, Sitapur Road Lucknow-226020
14	Navi Mumbai	Maharastra Goa Dadra and Nagar Haveli Daman and Diu	Sector-20 Near APMC Fruit Market , VashiNavi Mumbai-400613
15	Patna	Bihar	Bazar Sammittee , Katra Bazar, Patna city-800008
16	Raipur	Chattisgarh	Rawabhata , Raipur -493221
17	Ranchi	Jharkhand	Po-Hehal , Ratu Road , Dist-Ranchi-834005
18	Trivandrum	Kerala Lakshadweep	Kinfra Apparel Park, Thumba, Palliphura(PO), Trivandrum-695586

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

Annexure-II

TENDER FORWARDING LETTER

Date:

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

Sub: Acceptance of Terms & Conditions of Tender.

Tender No: CMSS/PROC/2023-24/NTEP/029
Name of Tender: - ONLINE SHORT TENDER FOR PROCUREMENT OF DR-TB Drugs used under NTEP.

Dear Sir,

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)

Annexure-III

DETAILS OF E.M.D. SUBMITTED

We herewith submit the EMD (**Annexure-XIV**) in favour of Central Medical Services Society for the following items.

Sch. No.	Item Name	UOM	Quantity in Bid	Quantity Quoted	% of the Bid Quantity	Amount of EMD Payable (in INR) for 100% quantity	Amount of EMD Payable (in INR) for 50% quantity	Amount of Bid Security
I	Isoniazid - 300mg	Tab	61,51,700			1,80,860	90,430	
II	Levofloxacin - 250mg	Tab	65,89,200			1,29,148	64,574	
III	Levofloxacin - 500mg	Tab	67,93,900			2,41,863	1,20,931	
IV	Pyrazinamide -500mg	Tab	1,01,94,700			1,93,699	96,850	
V	Pyrazinamide-750mg	Tab	64,94,800			1,87,050	93,525	
VI	Rifampicin - 150mg	Cap	25,19,200			71,041	35,521	
VII	Rifampicin - 300mg	Cap	25,65,200			3,89,910	1,94,955	
VIII	Rifampicin - 450mg	Cap	8,29,600			1,00,216	50,108	
IX	Clofazimine-50mg	Tab	1,65,300			2,04,476	1,02,238	
X	Clofazimine-100mg	Cap/Tab	49,72,400			31,05,761	15,52,881	

Annexure-IV

PROFORMA FOR PERFORMANCE STATEMENT

(FOR A PERIOD OF LAST 2 YEARS)

Name of Bidder with Address_____
Manufacturer with Address_____
Tender No _____
Sr. No. of the Product _____
Name of the Product _____

Sl.	Name of Product	Year 2020-21	Year 2021-22	Quantity manufactured and marketed	UOM	Name and full address of the Purchaser
1	2	3	4	5	6	7
1.						
2.						
3.						

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 Statutory Auditor
Name in Capitals
Date
Seal

Annexure-V

ANNUAL TURN OVER STATEMENT

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

Sl. No.	Financial Year	Turnover in Lakhs (Rs)
1.	2019-2020	-
2.	2020-2021	-
3.	2021-2022	-

Total - Rs. _____ Lakhs.

Average Turnover Per Annum in the last three years mentioned above - Rs._____ Lakhs.

Date:
Seal:

Signature of Auditor/Chartered Accountant
(Name in Capital)

Annexure-VI

LIST OF ITEMS QUOTED & THEIR PRODUCTION CAPACITY

1. Name of the firm :

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

3. Details of Endorsement for all products quoted :

Sch No	Item Code	Drug/Goods Name	UOM	Quantity Tendered	Quantity quoted	Manufacturing Capacity	Quantity Manufactured **8**		Average Quantity Manufactured
							2020-21	2021-22	
1	**2**	**3**	**4**	**5**	**6**	**7**	**8A**	**8B**	**9**
I		Isoniazid - 300mg	Tab	61,51,700					
II		Levofloxacin - 250mg	Tab	65,89,200					
III		Levofloxacin - 500mg	Tab	67,93,900					
IV		Pyrazinamide -500mg	Tab	1,01,94,700					
V		Pyrazinamide-750mg	Tab	64,94,800					
VI		Rifampicin - 150mg	Cap	25,19,200					
VII		Rifampicin - 300mg	Cap	25,65,200					
VIII		Rifampicin - 450mg	Cap	8,29,600					
IX		Clofazimine-50mg	Tab	1,65,300					
X		Clofazimine-100mg	Cap/Tab	49,72,400					
				TOTAL					

Date: Authorized Signatory:

Annexure-VII

CHECK LIST

Packet 1

		Pg. No. in bid	
1.	Checklist – Annexure-VII- (Clause 6.2 p)	Yes	No
2.	EMD (as per Annexure-XIII) (Clause 6.2 a)	Yes	No
3.	Certificate by MSME/ SSI units in support of being a MSE/ SSI unit. (Clause 6.2 a)	Yes	No
4.	Tender Forwarding Letter (Annexure-II) (Clause 6.2 b)	Yes	No
5.	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 6.2 c)	Yes	No
6.	Power of Attorney duly signed & Authorization letter nominating a responsible person of the tenderer to transact the business with the Tender inviting Authority. (Clause 6.2 d)	Yes	No
7.	Purchase Order Copy (Clause 6.2 e)	Yes	No
8.	Market Standing Certificate (Clause 6.2 f) and Valid WHO-GMP Certificate (valid on the date of tender opening) & COPP (Clause 6.2 i)	Yes	No
9.	Non-Conviction Certificate issued by the Drugs Controller (Clause 6.2 g)	Yes	No
10.	Manufacturing Capacity Certificate (Clause 6.2 h)	Yes	No
11.	Performance Statement (Annexure-IV) (Clause 6.2 j)	Yes	No
12.	Annual Turnover Statement for 3 Years (Annexure-V) (Clause 6.2 k)	Yes	No
13.	Copies of Annual Audit Reports including Balance Sheet & Profit & Loss Account for last three years (Clause 6.2 l)	Yes	No
14.	Certificate of Incorporation in case of companies/copy of partnership deed in case of partnership firm/ Declaration in case being a proprietary firm. (Clause 6.2 m)	Yes	No

15.	Long term stability data (Clause 6.2 n)	Yes	No
16.	List of items quoted and their production capacity – Annexure-VI (Clause 6.2 o)	Yes	No
17.	No Deviation Certificate (Annexure-XV) (Clause 6.2 s)	Yes	No
18.	Near Relative Certificate (Annexure-XVI) (Clause 6.2 t)	Yes	No
19.	Certificate for local content (Clause 6.2 u)	Yes	No
20.	Undertaking to compliance i.r.o Ministry of Finance, Department of Expenditure, Procurement Policy Division No- 6/18/2019-PPD dated 23.07.2020 (Annexure-XIX) (Clause 6.2 v & w)	Yes	No
21.	Undertaking that Firm is not being blacklisted or debarred from any Govt. Agency (Clause 6.2 x)	Yes	No
22.	Para-wise compliance of technical specification of the quoted item (Clause 6.2 y)	Yes	No
23.	Annexure-XII (Mandate Form)	Yes	No
24.	The bidders are requested to submit an undertaking on their letterhead for compliance to the Artwork enclosed for the items quoted by them. No further approval for Artwork would be provided by CMSS to any bidder.	Yes	No

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

Annexure-VIII

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, goods for the year 2022-23 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 Clause 9.2 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 clause 9.2 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)

Annexure-IX

Central Medical Services Society

2nd Floor, Vishwa Yuvak Kendra, Pandit Uma Shankar Dixit Marg, Teen Murti Road, Opp. Police Station, Chanakyapuri, New Delhi- 110021, Tel: 011-214109005 011-21410906

Email: gmproc1@cmss.gov.in

LETTER OF ACCEPTANCE

No: CMSS/PROC/2023-24/NTEP/029 Date _____

To,

M/s _____

Address: _____

Attn: _____

Phone: _____

Email _____

(Kind Attn: _____(Name), _____ Designation)

Sub: Acceptance of Tender for supply of DR-TB Drugs to CMSS

Ref: 1) CMSS Tender No. **CMSS/PROC/2023-24/NTEP/029** opened on _____

2) Your Ref. No. _____ dated _____ in response to above mentioned tender.

Dear Sir,

I am pleased to inform you that your offer in response to above mentioned tender for supply of ARV DRUGS FOR NACO has been accepted for following items:

Sch No.	Items Description	Quantity	Unit	Ex-Works per Unit (Rs.)	GST (%)	GST (Rs)	Transport & any other charges (Rs.)	Total unit price (all incl) (Rs.)	Grand Total (Rs.)
1									
2									
								Grand Total	

2. You are requested to deposit Security Deposit @ 3% of the total value by NEFT/ RTGS/ Bank Guarantee/Demand Draft/ Banker's Cheque and enter into an Agreement, as per the format given in **Annexure-X** of the Tender document, within 15 days from the date of receipt of this letter. The Security Deposit shall be valid for 1260 days from the date of commencement.

3. Please convey your acceptance to this LOA within 03 days of issue, else it will be presumed that you are not keen to accept the LOA and CMSS may proceed for allocation of quantity to other bidder and with other actions stipulated in referred Tender document.

4. All other terms and conditions will be applicable as per Tender document no. CMSS/PROC/2023-24/NACO/021and subsequent amendments to it.

Anjana
GM/Procurement

Annexure A to LOA No:
Supplier: M/s _____

Annexure-A

LIST OF MANUFACTURING LICENSES & SITE ADDRESSES					
Sr. No.	**Item Code**	**Item Description**	**Manufacturing Site Address**	**Manufacturing License No.**	**Remarks**
1					
2					
3					

Annexure-X

LONG TERM AGREEMENT (LTA) NO.: CMSS/PROC/2023-24/NTEP/LTA/027

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 DR-TB Drugs used under NTEP** in the Tender Reference No. **CMSS/PROC/2023-24/NTEP/029 , 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 DR-TB Drugs used under NTEP**, 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/2023-24/NTEP/029** from CMSS to the Supplier, to quote for the cost of supply of the Products to CMSS.

Long Term Agreement, as abbreviated to Agreement or LTA, means this Agreement between the Parties, to provide Products, including its Annexure, however with due consideration of the order of precedence among the LTA and individual Annexure.

Parties means CMSS and the Supplier, their successors and assigns and where not repugnant to the context, their servants or agents.

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:

1. **LTA DOCUMENTS:**

The following documents shall be deemed to form and be read and construed as part of this Agreement, viz.:

(a) This LTA
(b) The Notice Inviting Tender
(c) Terms and Conditions of Tender Document as given in Tender No: **CMSS/PROC/2023-24/NTEP/029** dt. _____
(d) The Minutes of Pre-Bid meeting and corrigendum issued.
(e) Schedule of Requirement.
(f) The Technical Specification
(g) The Supplier's Offer including Enclosures, Annexure etc.
(h) Any other document listed in the supplier's bid and replies to queries, clarifications issued by the purchaser, such confirmations given by the tenderer which are acceptable to the purchaser and the entire Addendum issued as forming part of the contract.
(i) The Letter of Acceptance issued by the purchaser.

2. **PURPOSE OF LTA:**

2.1 The Purchaser hereby covenants to pay the Supplier in consideration of the provision of the goods, the Contract Price at the times and in the manner prescribed by this Agreement.

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

Sch No.	Items Description	Quantity	Unit	Ex-Works per Unit (Rs.)	GST (%)	GST (Rs)	Transport & any other charges (Rs.)	Total unit price (all incl) (Rs.)	Grand Total (Rs.)
1									
2									
								Grand Total	

2.3 The supplier agrees that his supplies are subject to terms and conditions details

contained in LTA documents mentioned above. The supplier appreciates that the supplies are meant for public health system in the country and hence will agree to supply the goods of good quality as per standards in a timely manner as specified as per tender terms and conditions. The supplier has already given its no deviation (clause-by-clause compliance) for the subject terms and conditions.

3 . Manufacturing License and Site

License and Site Address: As per Annexure A.

IN WITNESS where of the parties here to have caused this Agreement to be executed in accordance with their respective laws the day and year first above written.

Signed, Sealed and Delivered by the said..... (For the Purchaser)

in the presence of .....

Signature

Name

Address

Signed, Sealed and Delivered by the Said ..... (For the Supplier)

in the presence of .....

Signature

Name

Address

Annexure A to LTA No:

Supplier: M/s

Annexure-A

Annexure A to LTA No:
Supplier: M/s

LIST OF MANUFACTURING LICENSES & SITE ADDRESSES					
Sr. No.	**Item Code**	**Item Description**	**Manufacturing Site Address**	**Manufacturing License No.**	**Remarks**
1					
2					
3					

Annexure-XI

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/2023-24/NTEP/029 **Dated:** _____

To,

M/s _____
Address: _____
Attn: _____
Phone: _____
Email _____

Subject: **Purchase Order for supply of PROCUREMENT OF DR-TB Drugs used under NTEP**

Ref : Long Term Agreement No: CMSS/PROC/2023-24/NTEP/027 /LTA/..... dated_____

Dear Sir,

Please supply following quantities for the items specified as per the technical specifications and terms & conditions of the Long Term Agreement referred above:

Sr. No.	Item Code	Item Description	Quantity Accepted by the Purchaser	Unit	Ex Works Price per Unit (Rs)	GST (%)	GST (Rs)	Transportation Charges (Rs)	Rate Per Unit (Landed Price)(Rs)	Total Value (Rs)	Destination
1											As per Annex 1
2											As per Annex -1

1. All the Terms & Conditions of the Agreement signed by you on acceptance of your tender are applicable.
2. Delivery Period: As per Annexure A of the tender document

3. Manufacturing license as per Annexure A and site address as per Annexure B.
4. Payment Terms: Within 75 days of supplies in respect of items requiring sterility tests and within 60 days of supplies for other items.

(Anjana)
General Manager (Procurement)

Copy to :

1. General Manager (LSC), CMSS
2. General Manager (QA), CMSS
3. General Manager (Finance), CMSS
4. All Consignees (CMSS Warehouses) concerned.

Annexure-A

Annexure A to PO No:
Supplier: M/s

CONSIGNEE-LIST						
Sr. No.	**Item Description**	**Consignee Location**	**Consignee Address**	**Quantity**	**UOM**	**Remarks**
1						
2						
3						

Annexure-B

Annexure B to PO No:
Supplier: M/s

LIST OF MANUFACTURING LICENSES & SITE ADDRESSES					
Sr. No.	**Item Code**	**Item Description**	**Manufacturing Site Address**	**Manufacturing License No.**	**Remarks**
1					
2					
3					

Annexure-XII

MANDATE FORM

01	Company Name	
02	Postal Address of the company with Telephone No., Fax No. and Mail ID.	
03	Name of the Managing Director / Director / Manager Mobile No. / Phone No. E-mail ID.	
04	Name and Designation of the authorized company official Mobile No. E-mail ID	

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

Mandate Form contd..

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

(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

Annexure-XIII

Bank Guarantee for EMD (Format)

(if applicable)

[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……
Furthermore, 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 under take to pay you any sum or sums not exceeding in total an amount of *[insert **amount in figures**]*(*[insert **amount inwords**]*) 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)]

Annexure-XIV

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**]*[1] 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_____,[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."

Annexure-XV

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.

Signature (with Stamp)

Annexure-XVI

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-XVII

Format of Local Content Declaration

Tender Reference No: Date:

I _____, S/o, D/o, W/o _____, Resident of _____do hereby solemnly affirms and declares as under:-

The local content is _____% for the _____ (quoted item of M/s _____.

That I on behalf of M/s _____will agree to abide by the terms and conditions of the Ministry of Chemicals & Fertilizers, DOP, Government of India issued vide notification no. **31026/65/2020-MD dated 30.12.2020** and DPIIT order no. P- 45021/2/2017- PPBE- II dated 16.09.2020 and calculations for local content have been done in accordance with Sr. No. 1 of DOP order no. **31026/65/2020-MD dated 30.12.2020**.

That the information furnished hereinafter is correct to best of my knowledge and belief and I on behalf of M/s _____undertake to produce relevant records before the procuring entity or any authority so nominated by the Department of Pharmaceuticals, Government of India for the purpose of assessing the local content.

(Name of Firm/ Entity)

Authorized Signatory/ Statutory Auditor/ Chartered Accountant

(with Company Seal/Stamp)

(Refer Clause **9 of DPIIT** Order dtd. **16.09.2020**)

Annexure-XVIII

UNDERTAKING

(On Company's Letter Head)

We,.....(name of bidder), having offices at

……..are participating in Bid No.

…… Dated.....

We equivocally and irrevocably undertake that,

i) Compliance of DOE, MOF order No. 6/18/2019–PPD dated:- 23.07.2020 and No.F.7/10/2021-PPD (1), dated 2302.2023 or any other subsequent revised order in said matter.

ii) Compliance of Public Procurement Order 2017- revision, issued vide No. P-45021/2017-PP (BE-II) Dated:- 16/9/2020 or any other subsequent revised order in said matter.

If at any stage of tendering process, non-compliance of above orders - observed/found we will be liable for stringent actions as per the tender terms and condition including suspension/debarment from any bidding in CMSS/MoHFW tenders for twoyears.

M/s_____

Witness

For Self and Firm/Company Limited

1.

Signature & Seal of company

Annexure-XIX

CONSIGNEE RECEIPT CERTIFICATE

(To be given by consignee's authorized representative)

The following store(s) has/have been received in good condition:

1) P.O No. & date:_____
2) Supplier's Name:_____
3) Consignee's Name & Address with telephone No. & Fax No. : _____

   _____

   _____
4) Name of the items/equipment supplied:_____
5) Quantity of items/equipment Supplied:_____
6) Date of Receipt of items/equipment by the Consignee:_____
7) Name and designation of Authorized Representative of Consignee :_____
8) Signature of Authorized Representative of Consignee with date:_____
9) Counter Signed by Director/MS/Dean of the concerned Hospital/Institute:_____
10) Seal of the Consignee:_____

Annexure-XX

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 tenderer s 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 haveto 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, inadvance, 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 with100dpi 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 maybe 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 theportal), 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 withalother 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

……

Annexure-XXI

Format of Price Bid

Validate | Print | Help | Item Wise BoQ

Tender Inviting Authority: DG & CEO, CMSS

Name of Work:TENDER FOR PROCUREMENT OF DR TB Drugs FOR NTEP FOR THE YEAR 2023-24

Tender No: CMSS/PROC/2023-24/NTEP/29

Bidder Name :	

PRICE SCHEDULE

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

NUMBER #	TEXT #	TEXT #	NUMBER #	TEXT #	TEXT	NUMBER #	NUMBER	NUMBER	NUMBER
Sl. No.	Name of the Item	Location	Quantity in Tender	Units	Quantity Offered	EX Works price per unit in Rs.	GST (In Rs.)	Transportation and any Other Charges in Rs. (Till Consignee Locations) on DDP basis, All Inclusive and firm & fixed	Total Unit Price With GST(In Rs.) (Col 7+ Col 8+Col 9)
1	2	3	4	5	6	7	8	9	10
1.01	Isoniazid 300 mg	1. Annex-I A	61,51,700	Tablets					₹ 0.0000
1.02	Levofloxacin 250 mg	2. Annex-I A	65,89,200	Tablets					₹ 0.0000
1.03	Levofloxacin 500 mg	3. Annex-I A	67,93,900	Tablets					₹ 0.0000
1.04	Pyrazinamide 500 mg	4. Annex-I A	1,01,94,700	Tablets					₹ 0.0000
1.05	Pyrazinamide 750 mg	5. Annex-I A	64,94,800	Tablets					₹ 0.0000
1.06	Rifampicin 150 mg	6. Annex-I A	25,19,200	Capsules					₹ 0.0000
1.07	Rifampicin 300 mg	7. Annex-I A	25,65,200	Capsules					₹ 0.0000
1.08	Rifampicin 450 mg	8. Annex-I A	8,29,600	Capsules					₹ 0.0000
1.09	Clofazimine 50 mg	9. Annex-I A	1,65,300	Tablets					₹ 0.0000
1.1	Clofazimine 100 mg	10. Annex-I A	49,72,400	Tablets/Capsules					₹ 0.0000