# ONLINE TENDER FOR PROCUREMENT OF Ethambutol -400mg & 800mg

Tender No: CMSS/PROC/2023-24/NTEP/047
(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: <a href="www.cmss.gov.in">www.cmss.gov.in</a>, Email- <a href="mailto:dgceocmss@cmss.gov.in">dgceocmss@cmss.gov.in</a>, <a href="mailto:gmproc1@cmss.gov.in">gmproc1@cmss.gov.in</a>, <a href="mailto:agmproc2@cmss.gov.in">agmproc2@cmss.gov.in</a>)

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#### CENTRAL MEDICAL SERVICES SOCIETY

Ministry of Health & Family Welfare (Government of India)

2<sup>nd</sup> 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: <u>gmproc1@cmss.gov.in</u> <u>agmproc2@cmss.gov.in</u>

## ONLINE BIDS ARE INVITED IN TWO PACKET BID SYSTEM FOR PROCUREMENT OF Ethambutol – 400mg & 800mg

#### Manual bids shall not be accepted.

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

#### **CRITICAL DATE SHEET**

Published Date	26.10.2023
Pre bid meeting	30.11.2023 at 12 noon
	Venue- Conference Hall, CMSS HQ New Delhi
Last date & time to submit pre-bid queries	30.10.2023 till 05:00 PM
Bid Document Download End Date & time	07.11.2023 till 03:00 PM
Bid Submission End Date and Time	08.11.2023 till 04:00 PM
Last date of submission of original documents	09.11.2023 till 01:00 PM
Bid Opening Date and Time	09.11.2023 at 02:00 PM

Bids shall be submitted online only at CPPP website: <a href="https://eprocure.gov.in/eprocure/app">https://eprocure.gov.in/eprocure/app</a>. 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 <a href="https://eprocure.gov.in/eprocure/app">https://eprocure.gov.in/eprocure/app</a>.

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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## Online Tender for Procurement & Supply of Ethambutol -400mg & 800mg

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)2<sup>nd</sup> floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Road, Opposite Police Station Chanakaya 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: <a href="https://eprocure.gov.in/eprocure/app">https://eprocure.gov.in/eprocure/app</a> for supply of Drugs to Central Medical Services Society for the year 2023-24.

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: <a href="https://eprocure.gov.in/eprocure/app">https://eprocure.gov.in/eprocure/app</a> 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. 2020-21 and 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: -

Schedule	Amount (in Rs.) for 100% quantity quoted	Amount (in Rs.) for 50% Quantity quoted
1	20,22,074	10,11,037
II	1,38,04,687	69,02,344

(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) The bidder should not be blacklisted/ banned/ debarred (as whole) or for the tendered goods by CMSS, MoHFW and Department of Expenditure on the date of tender opening. Aforesaid debarred/banned/blacklisted bidder are not eligible to bid in the tender.
- g) 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.
- h) 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.

Note: Bidder should submit Purchase order copies along with the copy of GST invoice and E-way bill against the proof of execution of order for every submitted Purchase Order. If GST invoice is not applicable for any Purchase Order, the affidavit to that effect on stamp paper of Rs. 100/- should be submitted.

#### 5. GENERAL CONDITIONS

- i. A complete set of tender document may be downloaded by any interested eligible bidder from website: <a href="https://eprocure.gov.in/eprocure/app">https://eprocure.gov.in/eprocure/app</a> 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: <a href="www.cmss.gov.in">www.cmss.gov.in</a> and <a href="https://eprocure.gov.in/eprocure/app">https://eprocure.gov.in/eprocure/app</a> 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:

- 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 (a) 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. Note: Bidder should submit Purchase order copies along with the copy of GST invoice and E-way bill against the proof of execution of order for every submitted Purchase Order. If GST invoice is not applicable for any Purchase Order, the affidavit to that effect on stamp paper of Rs. 100/- should be submitted.

- (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 WHO-GMP/GMP and Valid Certificate of Pharmaceutical Product (CoPP) as recommended by WHO in any Pharmacopeia IP/BP/USP/IH (if drug not available in any pharmacopeia).
- (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.
- (I) 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 23.02.2023 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, MoHFW and Department of Expenditure or the Firm/ Company (as whole) has not been debarred as a whole by these organizations"
- (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.

Note: All certificates issued by Chartered Accountant shall mandatorily include UDIN No.

- 6.3 (a) The above-mentioned documents are to be submitted in soft copy electronically on the CPPP portal <a href="https://eprocure.gov.in/eprocure/app">https://eprocure.gov.in/eprocure/app</a> 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 1st July 2020 therefore following firms will be exempted from submission of EMD.

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

LOA Submission -15 days
Rate Valid -365 days
Delivery period -60 days
Shelf life -365 x 3 Years

B.G. Extension -<u>60 days</u>

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 3<sup>rd</sup> 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.
- 13.10Subject 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-1**.
- 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 60<sup>th</sup> 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
- i) report number
- k) Date of Analysis
- 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-1.** 

- 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.
<b>24. JURISDICTION</b> 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.
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### Annexure -I

# CENTRAL MEDICAL SERVICES SOCIETY NEW DELHI- 110021

# Online Tender of Procurement of Ethambutol – 400mg & 800mg

### LIST OF PRODUCT & THEIR TECHNICAL SPECIFICATIONS

Sch. No.	Item Name	Total Tentative Quantity	· · · · ·	Technical	Distribution Criteria	Inspection Methodology (PDI/Non- PDI)	Consignee Location
'	PC - 45 (Ethambutol - 400 mg)		strip of 10 tablets	Annexure-IA	l	1st Lot – Pre- Dispatch Inspection	CMSS Warehouses
"	PC - 10 (Ethambutol - 800 mg)		strip of 10 tablets		70:30 as per clause no. 13	and rest Lot Non-PDI (Inspection at Delivery Stages)	

# (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 & II

**TRANCHE I (25%)-** To be delivered within 60 days from the date of issue of LOA. **TRANCHE II (25%)-** To be delivered within 61-90 days from the date of issue of LOA. **TRANCHE III (25%)-** To be delivered within 120-150 days from the date of issue of LOA. **TRANCHE IV (25%)-** To be delivered within 180-210 from the date of issue of LOA.

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

### Product Code 45: Ethambutol-400mg

### A. Specific requirements

Product Code 45 (PC-45) is for Ethambutol - 400mg. The drug contained in the product shall have valid registration in the country of manufacture and shall meet all requirements of the licensing authority of the country of manufacture. The drug contained in the product shall also have valid registration in India and shall meet all the requirements of the licensing authority in India.

### **Description:**

Ethambutol 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.

Ethambutol Tablet contain Ethambutol Hydrochloride.

Each tablet shall contain - Ethambutol Hydrochloride-400mg, Pharmacopeia\* (IP/BP/USP/any other International Pharmacopeia)

The quality Ethambutol Hydrochloride tablet 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<sup>3</sup> bacteria and not more than 10<sup>2</sup> fungi per gram
- -Absence of Escherichia coli.

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

Each batch should be accompanied with a certificate from the manufacturer that the drugs meet the specified requirements.

### B. Labelling:

### General requirements of the labels:

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

### Labelling on Strip of Blisters:

The label shall indicate the content of Ethambutol Hydrochloride in each tablet.

All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact.

The label shall incorporate manufacturing license no., batch no., date of mfg., date of expiry of the individual drug and storage requirements.

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

### Labelling on Millboard/Greyboard Box:

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

The label shall incorporate manufacturing license no., batch no., date of mfg., date of expiry of the drug and storage requirements along with the number of the strips packed in the millboard/greyboard Box. The label shall include Bar Code and be tear proof, to be pasted on smooth surface to enable it to be read by Bar Code reader / Hand held device (Tablet computer / Smartphone). 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 - 45 ETHAMBUTOL-400mg (10x10 TABLETS)

Each Blister Strip contains 10 Tablets of Ethambutol-400 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.

"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- 45
Ethambutol-400mg 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.

"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  $5/6^{\rm th}$  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
	25 °C ± 2 °C/60% RH ± 5% RH
Long Term Stability	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
- 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

XX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX										

### 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):

rate	Temperature	Relative Humidity	gsm/24h	Vapour <sup>-</sup>	Fransmission
thermoformed			Ther	moformed	Not
thermolornied	(°C)	% RH			
0.00	20	85	gsm/24 h	0.15	
0.06	38	90	gsm/24 h	0.7	

Shrinkage longitudinally

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



# 5 - Ply Shipper



### Product Code 10: Ethambutol-800mg

### A. Specific requirements

Product Code 10 (PC-10) is for Ethambutol -800mg. The drug contained in the product shall have valid registration in the country of manufacture and shall meet all requirements of the licensing authority of the country of manufacture. The drug contained in the product shall also have valid registration in India and shall meet all the requirements of the licensing authority in India.

### **Description:**

Ethambutol 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.

Ethambutol Tablet contain Ethambutol Hydrochloride.

Each tablet shall contain - Ethambutol Hydrochloride-800mg, Pharmacopeia\* (IP/BP/USP/any other International Pharmacopeia)

The quality Ethambutol Hydrochloride tablet 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<sup>3</sup> bacteria and not more than 10<sup>2</sup> fungi per gram
- -Absence of Escherichia coli.

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

Each batch should be accompanied with a certificate from the manufacturer that the drugs meet the specified requirements.

### B. Labelling:

### General requirements of the labels:

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

### Labelling on Strip of Blisters:

The label shall indicate the content of Ethambutol Hydrochloride in each tablet.

All labelling should be in weatherproof ink and shall withstand immersion in water and remain intact.

The label shall incorporate manufacturing license no., batch no., date of mfg., date of expiry of the individual drug and storage requirements.

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

### **Labelling on Millboard/Greyboard Box:**

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

The label shall incorporate manufacturing license no., batch no., date of mfg., date of expiry of the drug and storage requirements along with the number of the strips packed in the millboard/greyboard Box. The label shall include Bar Code and be tear proof, to be pasted on smooth surface to enable it to be read by Bar Code reader / Hand held device (Tablet computer / Smartphone). 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 - 10 ETHAMBUTOL-800mg (10x10 TABLETS)

Each Blister Strip contains 10 Tablets of Ethambutol-800 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.

"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- 10 Ethambutol-800mg 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.

"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  $5/6^{\rm th}$  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
	25 °C ± 2 °C/60% RH ± 5% RH
Long Term Stability	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:

- 10) Product Name/content
- 11) Product Strength
- 12) Batch Number
- 13) Date of Manufacturing
- 14) Date of Expiry
- 15) Manufacturer Address
- 16) Manufacturer License number
- 17) Storage conditions requirement
- 18) 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.

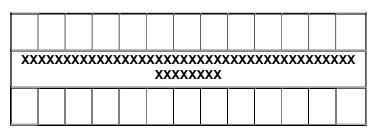
### Aluminium-PVC Blister:

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):

rate	Temperature	Relative Humidity	gsm/24h	Vapour Tı	ransmission
thermoformed			Ther	moformed	Not
triermoiormed	(°C)	% RH			
0.06	20	85	gsm/24 h	0.15	
0.06	38	90	gsm/24 h	0.7	
U-4					

Shrinkage longitudinally

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



# 5 - Ply Shipper



# Annexure-1B

# **CONSIGNEE LIST**

Consignee list and Schedule of Requirement (SOR) for the Procuremer							nt of Tab Etha	mbutol-400n	ng & 800mg		
SN	State Name		1	thambutol - 4 UOM - Tablets	s			U	nambutol - 80 OM - Tablets	- 3	
21/	State Name	Total	1st Tranche	2nd Tranche	3rd Tranche	4th Tranche	Total indented	1st Tranche	2nd Tranche	3rd Tranche	4th Tranche
		indented	(25%)	(25%)	(25%)	(25%)	Quantity	(25%)	(25%)	(25%)	(25%)
1	Andaman and Nicobar Islands	4,500	1,200	1,200	1,200	900	10,600	2,700	2,700	2,700	2,500
2	Andhra Pradesh	1,43,600	35,900	35,900	35,900	35,900	5,71,200	1,42,800	1,42,800	1,42,800	1,42,800
3	Arunachal Pradesh	7,500	1,900	1,900	1,900	1,800	44,500	11,200	11,200	11,200	10,900
4	Assam	13,900	3,500	3,500	3,500	3,400	94,000	23,500	23,500	23,500	23,500
5	Bihar	2,24,200	56,100	56,100	56,100	55,900	4,60,700	1,15,200	1,15,200	1,15,200	1,15,100
6	Chandigarh	11,900	3,000	3,000	3,000	2,900	45,500	11,400	11,400	11,400	11,300
7	Chhattisgarh	36,100	9,100	9,100	9,100	8,800	63,900	16,000	16,000	16,000	15,900
8	Dadra and Nagar Haveli and Daman and Diu	300	100	100	100	-	2,800	700	700	700	700
9	Delhi	2,36,600	59,200	59,200	59,200	59,000	4,96,500	1,24,200	1,24,200	1,24,200	1,23,900
10	Goa	10,600	2,700	2,700	2,700	2,500	45,400	11,400	11,400	11,400	11,200
11	Gujarat	1,75,300	43,900	43,900	43,900	43,600	5,44,000	1,36,000	1,36,000	1,36,000	1,36,000
12	Haryana	1,02,300	25,600	25,600	25,600	25,500	3,03,300	75,900	75,900	75,900	75,600
13	Himachal Pradesh	54,000	13,500	13,500	13,500	13,500	1,84,500	46,200	46,200	46,200	45,900
14	Jammu And Kashmir	14,800	3,700	3,700	3,700	3,700	75,100	18,800	18,800	18,800	18,700
15	Jharkhand	37,700	9,500	9,500	9,500	9.200	1,95,100	48,800	48,800	48.800	48.700
16	Karnataka	1.48.800	37,200	37,200	37,200	37,200	5.38.600	1.34.700	1.34.700	1.34.700	1,34,500
17	Kerala	1,34,800	33,700	33,700	33,700	33,700	4,51,700	1,13,000	1,13,000	1,13,000	1,12,700
18	Ladakh	· · ·		-	-	_	3,300	900	900	900	600
19	Lakshadweep	-	-	-	-	-	100	100	100	100	-200
20	Madhya Pradesh	1,30,100	32,600	32,600	32,600	32,300	5,70,000	1,42,500	1,42,500	1,42,500	1,42,500
21	Maharashtra	4.68.200	1.17.100	1.17.100	1.17.100	1.16.900	17.99.600	4.49.900	4.49.900	4.49.900	4.49.900
22	Manipur	4,100	1,100	1,100	1,100	800	18,700	4,700	4,700	4,700	4,600
23	Meghalaya	23,300	5,900	5,900	5,900	5,600	90,000	22,500	22,500	22,500	22,500
24	Mizoram	28,200	7,100	7,100	7,100	6,900	35,200	8,800	8,800	8,800	8,800
25	Nagaland	5,700	1,500	1,500	1,500	1,200	19,800	5,000	5,000	5,000	4,800
26	Odisha	74,900	18,800	18,800	18,800	18,500	89,300	22,400	22,400	22,400	22,100
27	Puducherry	9,300	2,400	2,400	2,400	2,100	25,600	6,400	6,400	6,400	6,400
28	Punjab	71,200	17,800	17,800	17,800	17,800	2,81,400	70,400	70,400	70,400	70,200
29	Rajasthan	1.28.600	32,200	32,200	32,200	32,000	6.60.100	1.65,100	1.65,100	1,65,100	1,64,800
30	Sikkim	16,600	4,200	4,200	4,200	4,000	24,500	6,200	6,200	6,200	5,900
31	Tamil Nadu	1,52,600	38,200	38,200	38,200	38,000	8,07,500	2,01,900	2,01,900	2,01,900	2,01,800
32	Telangana	53,100	13,300	13,300	13,300	13,200	2,80,400	70,100	70,100	70,100	70,100
33	Tripura	6,500	1,700	1,700	1,700	1,400	15,700	4,000	4,000	4,000	3,700
34	Uttar Pradesh	5,39,600	1,34,900	1,34,900	1,34,900	1,34,900	24,56,300	6,14,100	6,14,100	6,14,100	6,14,000
35	Uttarakhand	36,700	9,200	9,200	9,200	9,100	94,400	23,600	23,600	23,600	23,600
36	West Bengal	2,40,100	60,100	60,100	60,100	59,800	8,19,400	2,04,900	2,04,900	2,04,900	2,04,700
	Total	33,45,700	8,37,900	8,37,900	8,37,900	8,32,000	1,22,18,700	30,56,000	30,56,000	30,56,000	30,50,700

# Annexure-1C

The details of CMSS warehouses are given below:-

	CMSS Warehouse & Mapped States								
Sr	Warehouse	States/UT's covered by							
No	Location	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.						
	'	Chandigarh							
Ī		Punjab	1						
Ī		Haryana	Central Medical Services Society						
5	Chandigarh	Himanchal Pradesh	Godown no. B014/3433, Near Vivekanand School,						
		Jammu & Kashmir,	Godown area, Village Bhabat, Thana-Zirakpur, Dist: SAS						
		Leh Ladakh	Nagar-140603(Punjab)						
		Uttarakhand							
		Tamil Nadu							
		Pondicherry							
6	Chennai	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.						
		Assam							
		Arunachal Pradesh	EPIP Complex, Amingaon, Guwahati-781031						
		Meghalaya							
9	Guwahati	Nagaland							
		Sikkim							
		Manipur	7						
		Mizoram							
10	I be all a serila as al	Telangana	Dalais at Carrelle later was Names at the Head and a set 500001						
10	Hyderabad	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						
		Maharastra							
		Goa	Canton OO No am ADAC Emilia to desta Atrada de						
14	Navi Mumbai	Dadra and Nagar Haveli	Sector-20 Near APMC Fruit Market , VashiNavi Mumbai-400613						
		Daman and Diu							
15	Patna	Bihar	Bazar Sammittee , Katra Bazar, Patna city-800008						
16	Raipur	Chattisgarh	Rawabhata , Raipur -493221						
17	Ranchi	Jharkhand	Po-Hehal , Ratu Road , Dist-Ranchi-834005						
18	Trivandrum	Kerala	Kinfra Apparel Park, Thumba, Palliphura(PO),						
10	IIIVariarum	Lakshadweep	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

<u>Sub: Acceptance of Terms & Conditions of Tender.</u>

# Tender No: CMSS/PROC/2023-24/NTEP/047

Name of Tender: - Online tender for Procurement of Ethambutol – 400mg & 800mg

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	Quantit y Quoted	% of the Bid Quantit y	Amount of EMD Payable (in INR) for 100% quantity	Amount of EMD Payable (in INR) for 50% quantity	Amoun t of Bid Securit y
I	PC - 45 (Ethambutol - 400 mg)	Strip of 10 tablets	3,34,570			1,01,104	50,552	
II	PC - 10 (Ethambutol - 800 mg)	Strip of 10 tablets	12,21,870			6,90,234	3,45,117	

# **Annexure-IV**

# PROFORMA FOR PERFORMANCE STATEMENT

# (FOR A PERIOD OF LAST 2 YEARS)

ame of Bidder with Address	_
Manufacturer with Address	
ender No	
r. No. of the Product	
ame of the Product	

SI.	Name of Product	Quantity manufactured and marketed Year Year 2020-21 2021-22		UOM	Name and full address of the Purchaser	

### Note:

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

Signature of Tenderer Signature of Statutory Auditor

Name in Capitals

Name in Capitals

Date: Date Seal: Seal

UDIN No.

# Annexure-V

# **ANNUAL TURN OVER STATEMENT**

		e statement is true and correct.
SI. No.	Financial Year	Turnover in Lakhs (Rs)
1. 2. 3.	2019-2020 2020-2021 2021-2022	- - -
	<u> Total - Rs</u>	Lakhs.
Average Turnov Rs		ee years mentioned above -
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	Ite	Drug/Go	UOM	Quantity	Quant	Manufact	Quar	ntity	Average	
No	m	ods		Tendered	ity	uring	Manufa	ctured	Quantity	
	Со	Name			quote	Capacity	8		Manufac	
	de				d		2020-21	2021-	tured	
								22		
1	2	3	4	5	6	7	8A	8B	9	
I		PC - 45	Strip of							
		(Ethamb	10	3,34,570						
		utol -	tablets							
		400 mg)								
II		PC - 10	Strip of							
		(Ethamb	10	12,21,870						
		utol -	tablets	, ,,,,,						
		800 mg)	tablets							
		1		TOTAL						

Date:	Authorized Signatory:
DOIE.	AUIDONEG SIGNORY.

	CHECK LIST		Annexure-VII
	Packet 1 Pg. No. in bid		
	. g		
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
l	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 6.21)	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	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 (Annexure-VII). NO CLARIFICATIONS may be sought from bid		

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)

			, Proprietor / Partner /
			(Proprietary
			nis Undertaking for myself and on
		(Propriet	tary Concern / Firm / Company
	Ltd.).		
	2. Whereas, CMSS	(Tender Inviting Authority) has	s invited Tender for supply of Drugs
			and in pursuant to the conditions
		er documents. M/s	
	(Proprietary C	Concern/ Firm / Company	y Ltd.), having its Office at
		is exempted fr	rom payment of Earnest Money
	Deposit as indi	cated in the Clause 9.2 of ten	
	3. And whereas, i	in pursuant to the conditions ir	n Clause Nos. 9.2, 9.3 & 9.4 of the
		· · · · · ·	e forfeited by the Tender Inviting
	•	•	nditions and for non-performance
	of the obligation	on under tender document.	
	4. In consideration	n of exempting M/s	
	• • •		from payment of Earnest Money
	•	cated in the clause 9.2 of tend	
	tender inviting	um without any demur on rece authority	eipi oi demana issued by the
	1011001 1111111119	domonny.	
		M/s _	
		For Self and F	Firm / Company Ltd.
			, ,
			Signature and Seal
<u>Witne</u>	<u>ss:-</u>		
(1)			
(2)			

# **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: <a href="mailto:gmproc1@cmss.gov.in">gmproc1@cmss.gov.in</a>, <a href="mailto:agmproc2@gmail.com">agmproc2@gmail.com</a>

### LETTER OF ACCEPTANCE

No: (	CMSS/PROC/	2023-24/1	NTEP/04	17				Date.	
To,									
M/	S								
	ldress:								
	n:								
Ph	one:								
Em	nail								
(Ki	nd Attn:		(No	ame),			Designation)		
Re Dear	2) Your Ref. Sir, I am pleased for supply of	ender No. No. d to inforr	CMSS/ dat m you t JGS FO	'PROC/20 ed hat your R NACO	023-24 ir offer i	1/NTER	P/047 oper onse to above conse to above accepted for	e mentione e mentior following it	ed tender. ned tender ems:
Sch	ltems	Quantit	Unit	Ex-	GST	GST	Transport &	Total unit	Grand Total
No.	Description	У		Works	(%)	(Rs)	any other	price (all	(Rs.)
				per Unit			charges (Rs.)	incl) (Rs.)	
				(Rs.)			(KS.)		
1									
2									

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.

**Grand Total** 

 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 Page 69 of 90 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/NTEP/047 and 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	Manufacturin g License No.	Remarks				
1									
2									
3									

# Annexure-X

LONG TERM AGREEMENT (LIA) NO.: CM35/PROC/2023-24/NTEP/047/LTA/
E- STAMP CERTIFICATE NO.:
LTA Validity: From to
TERMS OF AGREEMENT
THIS AGREEMENT made the
WHEREAS the Purchaser is desirous that certain Goods and ancillary services viz; Procurement of Ethambutol-400mg & 800mg in the Tender Reference No. CMSS/PROC/2023-24/NTEP/047 , Dt
<b>WHEREAS</b> the Supplier confirms that it is qualified, ready, willing and able to supply/services the <b>Procurement of Ethambutol- 400mg &amp; 800mg</b> , in accordance with the terms and conditions of this Agreement.
1. <u>DEFINITIONS</u>
Commencement Date means
Expiry Date means
<b>Products</b> , 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.
<b>Tender</b> means Tender No. Tender No: <b>CMSS/PROC/2023-24/NTEP/047</b> 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/047 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.

Sc	Items	Quantity	Unit	Ex-Works	GST	GST	Transport	Total unit	Gran
h	Descripti			per Unit	(%)	(Rs)	& any	price (all	d
No	on			(Rs.)			other	incl) (Rs.)	Total
							charges		(Rs.)
							(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 accordance with their respective laws the day and year	
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							

#### **CENTRAL MEDICAL SERVICES SOCIETY**

Ministry of Health & Family Welfare (Government of India)

2<sup>nd</sup> 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: CMS	SS/PROC/2023-24/NTEP/047	Dated:		
То,				
Address: Attn: Phone:				
Subject: Ref :		y of Ethambutol – 400mg & 800mg No: CMSS/PROC/2023-24/NTEP/047/LTA/		
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 Cod e	Item Descrip tion	Quanti ty Acce pted by the Purch aser	Unit	Ex Works Price per Unit (Rs)	GST (%)	GST (Rs)	Trans portat ion Char ges (Rs)	Rate Per Unit (Lande d Price)(R s)	Tota I Val ue (Rs)	Destin ation
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	Consigne e Location	Consignee Address	Quantity	UOM	Remark s		
1								
2								
3								

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.	Remark s		
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 <u>attach the original cancelled</u> <u>cheque</u> 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	S	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
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:
<ul><li>(a) has withdrawn its Bid during the period of bid validity specified by the Tenderer in the Form of Bid; or</li><li>(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.</li></ul>
(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.

[signature(s)]

at the office on or before that date.

No. 758.

Consequently, any demand for payment under this guarantee must be received by us

This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication

#### Security Bank Guarantee (Format)

	[insert: Bank's Name, and Address of Issuing Branch or Office]
Beneficiary: Date:	[insert: Name and Address of Purchaser]
PERFORMANCE GUAR	ANTEE No.:
received a Letter of	ned that [insert: <b>name of Supplier</b> ] (hereinafter called "the Supplier") has Acceptance No. [insert: <b>reference number of the Letter of Acceptance</b> ] for entering into a Rate Agreement with you, for the supply of [insert:
guarantee is required At the request of the you any sum or sums r amount in words] <sup>1</sup> upon statement stating that	erstand that, according to the conditions of the Tender, a performance a post acceptance of letter of Acceptance.  Supplier, we [insert: name of Bank] hereby irrevocably undertake to pay not exceeding in total an amount of [insert: amount in figures] () [insert: on receipt by us of your first demand in writing accompanied by a written at the Supplier is in breach of its obligation(s) under the Tender, without e or to show grounds for your demand or the sum specified therein.
_	expire no later than the $\_\_$ day of $\_\_\_$ , $2\_\_$ , $^2$ and any demand must be received by us at this office on or before that date.
•	ect to the Uniform Rules for Demand Guarantees, ICC Publication No. oparagraph (ii) of Sub-article 20(a) is hereby excluded

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."

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.

## Annexure-XV

## No Deviation Certificate

This is to certify that the product(s) quoted by our firm, M/ is as per the given technical specifications in the tended document & there is no deviation in relation to any conditions/requirements specifie	er
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:			
The local content is%	_do hereby solemnly	y affirms and declares as	under:-	of M/s
That I on behalf of M/s  the Ministry of Chemicals & Ferti 31026/65/2020-MD dated 30.12 16.09.2020 and calculations for of DOP order no. 31026/65/2020	lizers, DOP, Governme	ent of India issued vide r er no. P- 45021/2/2017- l een done in accordance	notification PPBE- II do	no. ated
That the information furnished he I on behalf of M/s procuring entity or any author Government of India for the pur	undertake to ty so nominated by	produce relevant recor the Department of Pho- local content.	ds before	the cals,
Aut	norized Signatory/ Stc	atutory Auditor/ Chartere (with Compan		
	(Refer	Clause <b>9 of DPIIT</b> Order d	td. <b>16.09.2</b>	<b>020</b> )

## **UNDERTAKING**

# (On Company's Letter Head)

We,	(name of bidder), having offices at
	are participating in Bid No.
	Dated
We equ	ivocally 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.
observe condition	iny stage of tendering process, non-compliance of above orders -ed/found we will be liable for stringent actions as per the tender terms and on including suspension/debarment from any bidding in CMSS/MoHFW for twoyears.
	M/s
Witness	For Self and Firm/Company Limited
1.	
	Signature & Seal of company

## **CONSIGNEE RECEIPT CERTIFICATE**

# (To be given by consignee's authorized representative)

10) Seal of the Consignee:\_\_\_\_\_

The fo	llowing 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  Consignee:	by the
7)	Name and designation of Authorized Representative of :	Consignee
8)	Signature of Authorized Representative of Consignate:	gnee with
9)	Counter Signed by Director/MS/Dean of the Hospital/Institute:	concerned

#### **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: <a href="https://eprocure.gov.in/eprocure/app">https://eprocure.gov.in/eprocure/app</a>) 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 with 100dpi with black and white option which helps in reducing size of the scanned document.
- 4) To avoid the time and effort required in uploading the same set of standard documents which are required to be submitted as a part of every bid, a provision of uploading such standard documents (e.g. PAN card copy, annual reports, auditor certificates etc.) has been provided to the tenderers. Tenderer scan use "My Space" or "Other Important Documents" area available to them to upload such documents. These documents 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

