ONLINE TENDER FOR

(i) RATE CONTRACT FOR EMPANELMENT OF LABORATORIES FOR ANALYSIS OF DRUGS AND OTHER ITEMS FOR A PERIOD OF TWO YEARS.

(ii) FOR EMPANELMENT OF LABORATORIES FOR ANALYSIS OF DRUGS AND OTHER ITEMS FOR FUTURE REQUIREMENTS (ADDITIONAL DRUGS/INJECTIONS/NEEDLE/SYRINGE AND OTHER MEDICAL DEVICES/ FOR A PERIOD OF TWO YEARS.

Tender No: CMSS/2024-25/TL/DRUGS/017

CENTRAL MEDICAL SERVICES SOCIETY

Ministry of Health & Family Welfare (Government of India)
2nd floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Marg, Opposite Police Station, Chankaya Puri, New Delhi-110021
Telephones: 011-21410905, 21410906,
Email: - agmgacmss@cmss.gov.in, dgceocmss@cmss.gov.in

CENTRAL MEDICAL SERVICES SOCIETY
Ministry of Health & Family Welfare (Government of India)
2nd floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Marg, Opposite Police Station Chankaya Puri, New Delhi-110021
Telephones: 011-21410905, 21410906,

Telephones: 011-21410906 Fax: 011-23730120
Email: agmqacmss@cmss.gov.in, dgceocmss@cmss.gov.in

ONLINE TENDER FOR

(i) RATE CONTRACT FOR EMPANELMENT OF LABORATORIES FOR ANALYSIS OF DRUGS AND OTHER ITEMS FOR A PERIOD OF TWO YEARS.

(ii) FOR EMPANELMENT OF LABORATORIES FOR ANALYSIS OF DRUGS AND OTHER ITEMS FOR FUTURE REQUIREMENTS (ADDITIONAL DRUGS/INJECTIONS/NEEDLE/SYRINGE AND OTHER MEDICAL DEVICES/ FOR A PERIOD OF TWO YEARS.

(Manual bids shall not be accepted)

BID DOCUMENTS MAY BE DOWNLOADED FROM CPPP WEBSITE: https://eprocure.gov.in/eprocure/app as per the schedule as given in critical date sheet as under:

CRITICAL DATE SHEET

Published Date and Time	30.07.2024 (As per CPPP)
Bid Document Download Start Date And Time	30.07.2024 (As per CPPP)
Pre Bid Meeting	06.08.2024 (12.00 noon) Venue- Conference Hall, CMSS HQ, New Delhi
Last Date and Time for Clarification	06.08.2024 (05.00 PM)
Bid Submission Start Date and Time	07.08.2024 (09.00 AM)
Bid Submission End Date and Time	30.09.2024 (04.00 PM)
Last date of submission of original documents	30.09.2024 (04.00 PM)
Bid Opening Date and Time	01.10.2024 (04.00 PM)

Bids shall be submitted online only at CPPP website: **https://eprocure.gov.in/eprocure/app.** Bidder/Contractor is advised to follow their instructions provided in the 'Instructions to the Contractors/Bidder for the e-submission of the bids online through the Central Public Procurement Portal for e Procurement at **https://eprocure.gov.in/eprocure/app'.**

Bid documents may be scanned with100dpi with black and white option which helps in reducing size of this scanned document. Not more than one bid shall be submitted by one contractor or contractors having business relationship.

Address for Communication : Central Medical Services Society,
2nd floor, Vishwa Yuvak Kendra,
Pt. Uma Shankar Dikshit Marg,
Teen Murti Marg, Opposite Police
Station Chankaya Puri, New Delhi-110021

CONTENTS

Sr. No.	Description	Page No.
1.	Last Date for receipt of Tender	6
2.	Bid validity	6
3.	Pre bid Meeting/Clarifications	6
4.	Eligibility Criteria	7
5.	General Conditions	8
6.	Technical Bid – Packet 1	11
7.	Price Bid – Packet 2	13
8.	Opening of Packet 1 and Packet 2 of Tender	14
9.	Earnest Money Deposit	15
10.	Other Conditions	17
11.	Acceptance of Tender	17
12.	Security Deposit and Agreement	18
13.	Methodology for Placing Orders	19
14.	Analysis and Reporting Conditions	20
15.	Test Method	21
16.	Payment Provisions	21
17.	Penalties	22
18.	Deduction and other Penalties on account of Delays /Default/ Termination / Part Cancellation /short closure	23
19.	Force Majeure	24
20.	Saving Clause	25
21.	Prohibition of Influencing CMSS by the Bidder	25
22.	Resolution of Disputes	26
23.	Jurisdiction	26
24.	Annex-I (List of Drugs with Ref Specifications)	27-44
25.	Annex-II(Tender Forwarding Letter)	45-46

Sr. No.	Description	Page No.
26.	Annex-III (Details of EMD Submitted)	47
27.	Annex-IV (Proforma for Performance Statement)	48
28.	Annex-V (Annual Turnover Statement)	49
29.	Annex-VI (Check List)	50-51
30.	Annex-VII (Acceptance Letter)	52
31.	Annex-VIII (Microbiological Facility Details)	53
32.	Annex-IX (Mandate Form)	54-55
33.	Annex-X (The Price Bid)	56
34.	Annex-XI (Bank Guarantee for EMD)	57
35.	Annex-XII (Bank Guarantee for Security Deposit)	58
36.	Annex-XIII (Instruction for Online Bids Submission)	59-61
37.	Annex-XIV (No Deviation Certificate)	62
38.	Annex-XV (Near Relative Format)	63
39.	Annex-XVI (Notarized Undertaking by MSEs for EMD Exemption)	64
40.	Annex-XVII (Undertaking for land border sharing with India)	65
41.	Annex-XVIII (List of items quoted and their monthly analysis capacity and timeline)	66

ONLINE TENDER FOR

(i) RATE CONTRACT FOR EMPANELMENT OF LABORATORIES FOR ANALYSIS OF DRUGS AND OTHER ITEMS FOR A PERIOD OF TWO YEARS.
(ii) FOR EMPANELMENT OF LABORATORIES FOR ANALYSIS OF DRUGS AND OTHER ITEMS FOR FUTURE REQUIREMENTS (ADDITIONAL DRUGS/INJECTIONS/NEEDLE/SYRINGE AND OTHER MEDICAL DEVICES/ FOR A PERIOD OF TWO YEARS.

The CMSS, an autonomous Society of Ministry of Health & Family Welfare (Govt. of India), is responsible for procuring quality drugs, vaccines & contraceptives directly from the manufacturers through open tenders system and ensures timely supply of Drugs, Medicines, Vaccines & Contraceptives to all the States/ UT governments.

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

Tender Accepting Authority: DG&CEO, Central Medical Services Society (hereinafter referred as **CMSS,** unless the context otherwise requires)
Tender Inviting Authority invites tender through online bid submission at CPPP website: https://eprocure.gov.in/eprocure/app for rate contract for empanelment of laboratories for analysis of drugs/other items for a period of two years from the date of empanelment. The duration may be extended for another period of 12 months on the same term and conditions and rates. Bidder can apply for any item or all items listed.

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

-The EMD is Rs. 1,00,000 for participation in this tender (details at clause 9)

-Attention of bidder is invited towards checklist (Annexure VI) regarding documents to be attached with technical bid.

-Original Bank Guarantee/ Notarized undertaking by MSE companies Annexure XVI 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. (details at clause 6.2 (b))

1. LAST DATE FOR RECEIPT OF TENDER

Online Tenders (in two separate packets {Technical bid "Packet 1" and Price Bid "Packet 2"} will be submitted online at CPPP website: https://eprocure.gov.in/eprocure/app as per critical date sheet. The list of Drugs/other items to be tested along with their Technical Specification is attached here as **Annexure-I.**

2. BID VALIDITY:

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

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 shall be made in writing. The bid security/EMD provided under clause 9 shall also be suitably extended. A bidder may refuse the request without forfeiting his bid security. A bidder accepting the request and granting extension will not be permitted to modify his bid.

3. PRE BID MEETING/CLARIFICATIONS:

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

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

iii) Any clarification issued by CMSS in response to query raised by prospective bidders shall form an integral part of bid documents and it may amount to an amendment of the relevant clauses of the bid documents.

iv) The clarification if any will be uploaded at CPPP and on e-procurement website and bidder is expected to see the CMSS website for clarification before submitting the bid.

4. ELIGIBILITY CRITERIA: -

THOSE BIDDERS PARTICIPATE IN SR NO. 1, NO NEED TO REQUIRED SEPARATE DOCUMENTS FOR SR NO. 2.

i) Tenderer should be an analytical laboratory having own valid license under the Drugs& Cosmetics Act 1940 by any State Drug Control Department/ Central Drug Standard Control Organization.

ii) The Laboratory must be NABL accredited in accordance with standard ISO-17025 with quoted item listed in scope of NABL accreditation on tender opening date.

iii) Both the Licence and NABL should be valid on the date of tender opening.

iv) The Laboratory must be certified by state drug control department under the Drugs and Cosmetics Act 1940 for Good Laboratory Practices (GLP). GLP Certificate should be valid on the date of opening of tender.

v) The Laboratory should not have been convicted by FDA/ Drug controller of state in last two years.

vi) Lab should have all necessary instruments/equipment and required mandatory facilities for testing/analysis including microbiological testing.

vii) Lab should have a minimum three years' experience in the Laboratory services. P.O copies/Sample details/Invoices need to be attached for three such orders certified by CA indicating unique document identification number.

viii) Lab should have undertaken analysis of 500 samples testing annually in any of last three years as testing performance (List of Quoted dosage forms i.e. Tablets, Capsules, Injections, Syrup) for any Central & State Govt departments/private institutions certified by CA indicating unique document identification number.

ix) Lab should have 21 CFR compliant instruments and CMSS Samples need to be tested on 21 CFR compliant instruments

x) Lab should have an average Annual turnover of more than INR 2 crore for last 2 years i.e., 2021-22, 2022-23.

xi) Lab should be stand-alone laboratory independent and not an in-house facility part of manufacturing unit.

xii) In accordance with DoE guidelines vide OM No. F.1/20/2018/PPD dt. 02.11.2021 the bidder should not be debarred, in general or for the services tendered by CMSS, MoH&FW and DoE on the date of tender opening. Aforesaid debarred bidder are not eligible to bid.

xiii) Entities having beneficial ownership in land border sharing countries, as defind in Department of Expenditure Order No. F.7/10/2021-PPD date 23.02.2023, as amended from time to time, shall be eligible to bid only if are registered with competent authority in accordance with the provisions of the order.

xiv) In case any document submitted by the bidder or his authorized representative is found to be forged, false or fabricated, the bid will be rejected and Bid Security Deposit/EMD /Performance Security will be forfeited. Bidder may also be blacklisted/banned/debarred. Under taking shall be submitted by bidder.

5. GENERALCONDITIONS:- SR NO. (I) AND (II) BOTH

I. A complete set of tender documents may be downloaded by any interested eligible bidder from website: https://eprocure.gov.in/eprocure/appas 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 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. 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.

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

VI. **FORGERY/FRAUD BY BIDDERS:**

(a) Genuineness of the papers/documents/certificates/declaration submitted with bid is the responsibility of the bidder. If at any stage it is found that the papers/ documents/certificates/declaration submitted by the bidder are not in order, are forged, manipulated, fabricated or altered, the bid or purchase order issued to the bidder is liable to be cancelled and further necessary action including forfeiture of its EMD/Security Deposit, debarring/blacklisting against the bidder will be taken.

Purchaser may also initiate police/legal action and request concerned statutory authority for cancellation of license issued to supplier for tendered items.

(b) If any fraud, 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:**

(a) The bidder 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.

(b) 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:**

(a) 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.

i. If the bidder fails to inspection any or all of the CMSS location within the time period(s) specified in the contract, or any extension thereof granted by the purchaser.

ii. If the bidder fails to perform any other obligation(s) under the contract, and

iii. If the bidder, 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.

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 bidder 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 bidder (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 Laboratory /Agency for a suitable period in case he fails to honor 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) 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.

(c) 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. Authorized 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 XV to be submitted.

6. TECHNICAL BID – "PACKET 1"

Those indenting to participate in the tender (herein called Tenderer) should first ensure that they fulfill all the eligibility criteria:

6.1 The Tenderer should electronically submit the soft copies of following documents in Technical Bid "Packet 1". (All the documents submitted should bear signature and stamp of the Tenderer)."

a) RTGS/NEFT/DD or Bank Guarantee (if applicable) in respect of EMD as per Clause 9 of this tender document as per **Annexure-III.** or in case of MSE, a copy of their valid registration certificate in support of their being an **MSE and a notarized undertaking given in Annexure XVI.**

b) Duly notarized general power of Attorney (on non-judicial stamp paper of worth Rs. 50/-) in favour of authorized signatory, authorizing an officer of the Tenderer should be enclosed with the tender and such authorized officer of the Tenderer should sign the tender documents. 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.

c) Tender Forwarding letter as per **Annexure-II.**

d) Tenderer should submit valid license under the Drugs& Cosmetics Act 1940 by any State Drug Control Department/ Central Drug Standard Control Organization

e) Tenderer should submit Self-Attested copy of latest inspection certificates of NABL certificate in accordance with standard ISO-17025 with quoted item listed in scope of NABL accreditation.

f) Tenderer should submit GLP certificate by state drug control department under the Drugs and Cosmetics Act 1940 for Good Laboratory Practices.

g) Non-Conviction Certificate issued by the FDA/ Drugs Controller of the State certifying that the Laboratory has not been convicted in year 2022 and 2023.

h) List of 21 CFR compliant instruments with instrument ID on which CMSS Samples shall be analyzed.

i) The list of sophisticated instruments available in the laboratory along with their numbers and details of make /model.

j) Micro Biological facilities available in the laboratory provide the details as per Annexure-VIII.

k) Performance Statement to establish 3 years' i.e., 2021-22, 2022-23 and 2023-24 as per format in Annexure-IV.

l) P.O copies/Sample details/Invoices of last three years substantiating that bidder has experience of 500 samples annually in any of last three years i.e., 2021-22, 2022-23 or 2023-24 in laboratory testing should be submitted duly certified by CA indicating its unique document identification number.

m) Annual turnover statement for 2 years i.e., 2021-22 and 2022-23 should be furnished in the format given in Annexure-V duly certified by the company Auditor.

n) Copies of the Annual reports including the Audited Balance Sheet for FY 2021-22 and 2022-23.

o) **A Checklist (Annexure-VI) 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.**

p) The tender shall be signed by the authorized official of the Tenderer in all pages with office seal.

q) **All the documents enclosed with the tender document should also be signed by the authorized official of the Tenderer.**

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

s) Bidders are requested to mention total monthly batches which they are handle to deliver timely test reports.

t) Bidder should submit an undertaking In accordance with DoE guidelines vide OM No. F.1/20/2018/PPD dt. 02.11.2021 the bidder should not be debarred and disqualified, in general or for the services tendered by CMSS, MoH&FW and DoE on the date of tender opening. Aforesaid debarred bidder are not eligible to bid.

u) No Deviation Certificate as per **Annexure-XIV**.

v) Near Relative Certificate as per **Annexure–XV.**

w) Undertaking for Land Border Sharing with India as per **Annexure-XVII**

x) List of items quoted and their monthly analysis capacity and timeline as per **Annexure-XVIII**

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

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

7. PRICE BID-"Packet 2"

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

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

ii) Format of the Schedules of price bid is available in Annexure-X.

iii) The bidder shall quote only in INRs as per price schedule given in Annexure-X for all the items quoted by him schedule of requirement.

iv) The price quoted shall be all inclusive prices per sample and shall include all taxes and duties and other incidental expenditure for furnishing report to CMSS.

v) The rate quoted in Price Schedule Annexure-X 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 or the rates quoted in original bid.

7.2 GST (Goods and Service Tax)/other statutory Taxes/Levies

i) The bidder may quote for GST as per applicability in accordance with relevant Government notification.

ii) Any variation upwards/downwards as a result of statutory variation in GST/ other taxes/duties/levies for supplies during original specified delivery schedule of goods shall be allowed.

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

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

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

8. OPENING OF "PACKET 1"i.e. 'TECHNICAL BID AND "PACKET 2" i.e. FINANCIAL BID' OFTENDER CLARIFICATION OF BIDS SUBMITTED:

i) 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.

ii) Presence of authorized official of the Tenderer is not necessary at the time of opening of Technical Bid - "Packet 1" as opening is online.

iii) 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.

iv) 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.

v) 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.

vi) 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.

vii) "Packet 2" will be opened only for tenderers, who are found **techno-commercially** eligible on satisfying the criteria for technical evaluation and Laboratory/Agency 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.

viii) 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: - for Sr no. (i) and (ii)

9.1. The Earnest Money Deposit (EMD) is payable by all Tenderers, **for Sr no. (i) And Sr no. (ii)** an amount of Rs **1,00,000** as indicated in **Annexure-III** need to be deposited. Same EMD amount to be deposited for any one quoted item/all items. UNLESS EXEMPTED under clause 9.2 The Tenderers are required to furnish 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, FD receipt, Banker's cheque or Bank Guarantee or RTGS/NEFT** in the following Bank Account**:**

Beneficiary Name	**: Central Medical Services Society**
A/C No.	**: 50100729160644**
Bank Name	**: HDFC Bank**
Branch	**: SAFDARJUNG ENCLAVE-DEER PARK, New Delhi**
IFSC Code	**: HDFC0000503**

b) The Bank Guarantee can also be accepted as a mode of payment and the named beneficiary shall be **Central Medical Services Society**. The Bank guarantee shall be

issued by a bank (Nationalized or Scheduled Bank) in India to make it enforceable and acceptable to the purchaser. The Bank Guarantee shall be in the format as per **Annex-XII** provided in the tender document.

c) Bank Guarantee shall remain valid for 60 days beyond the validity period for the bid and will be extended accordingly beyond any extension subsequently requested by purchaser.

The applicable EMD amount has been indicated in **Annexure-III.**

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-XVI) to the effect that in the event of non-fulfillment or non-observance of any of the conditions stipulated in the tender, the MSE Unit shall pay a penalty, equivalent to the Earnest Money Deposit to offset the loss incurred by the Tender Inviting Authority consequent on such breach of any bid condition.

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

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

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

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

Note: Traders will not get benefit of MSE Firms

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

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

(ii) The Earnest Money Deposit (EMD) furnished by all unsuccessful tenderers will be returned as early as possible after the expiration of the period of tender validity but not later than 30 days of the award of the contract.

9.4 FORFEITURE OF EMD (If applicable):

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

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

10. OTHER CONDITIONS

(i) The details of items are shown in **Annexure-I**. ***The quantity shown in Annexure-I is not a fixed quantity and it is only a tentative requirement and may increase or decrease*** by the CMSS, at its discretion, depending on the actual requirements. Though the tentative quantity shall be indicated in the agreement, the CMSS may confirm the requirement after issuance purchase orders. The Tenderers shall perform analysis of the items only on the basis of the periodical order issued by the CMSS.

(ii) To ensure completion of analysis in time without any interruption, the Tender Inviting Authority reserves the right to empanel more than one Laboratory for each item. Minimum 02 labs for each item would be empanelled.

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

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

(v) The Tenderer shall allow inspection of the Laboratory at any time by a team of Experts/Officials nominated by the Tender Inviting Authority for the purpose. The Tenderer shall extend necessary cooperation to such team in inspection of the

analytical process, quality control measures adopted etc., in the analysis of the items quoted. If Laboratory does not allow for any such inspection, their tenders will be rejected during the currency of the contract.

11. ACCEPTANCE OF TENDER

(i) Technically responsive tenders will be evaluated based only on the "All Inclusive Price", i.e. Rate per Unit inclusive of all taxes, duties & any other incidental charges as given in **Annexure-X by the tenderer.**

(ii) CMSS reserves the right to accept or reject the tender for the analysis of any one or more items tendered for in the tender without assigning any reason.

(iii) CMSS or its authorized representative(s) has the right to inspect the Laboratories 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.

(iv) The acceptance of the tenders will be communicated to the lowest / matched Tenderers in writing, as per format of the Acceptance Letter given in **Annexure-VII.**

12. SECURITY DEPOSIT AND AGREEMENT

(i) **Security Deposit: for Sr no. (i)&(ii)**

On being intimated about the acceptance of the tender the L1/Matched tenderer shall pay a Security Deposit of Rs.5,00,000 /- of contract to be awarded within 7 days, in the form of only **NEFT/RTGS/*Banker's Cheque /Demand Draft/Bank Gaurantee*** in favor of Central Medical Service Society. The Security Deposit in any other form like Cash/ Postal-Order will not be accepted.

(ii) 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.

(iii) The Tenderer shall not, at any time, assign, or make over the contract or the benefit thereof or any part thereof to any person or persons what so ever.

(iv) 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 as provided by the tenderer.

(v) If the lowest/matched tenderer fails to execute the agreement and/or to deposit the required security deposit within the time specified or withdraws the tender, after the intimation of the acceptance of the tender or owing to any other reasons to undertake the contract, the contract will be cancelled and the Earnest Money Deposit deposited by the tenderer along with the tender shall stand forfeited by the CMSS and the firm will also be liable for all damages sustained by the CMSS apart from blacklisting and other penal actions.

13. METHODOLOGY FOR PLACING ORDERS

For placing orders the following procedures will be adopted:

(i) After the Price Bid opening (Packet 2), the lowest offer will be declared as the L1 tenderer. In present case, items wise L1 tenderer will be identified.

(ii) The Tenderer, who has been declared as Lowest Tenderer for certain item(s), shall within 15 days of the acceptance of the tender execute necessary Agreement for the analysis of the items as specified in the Tender Document after depositing the required amount as Security Deposit and on execution of the Agreement such Tenderer shall perform analysis on receipt of Orders for Analysis.

(iii) If two or more than two Tenderers are declared as lowest testing for the same item(s), 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 is eligible for the placement of Orders for Analysis for such item(s) for which they are declared as lowest.

(iv) CMSS will inform the lowest rate to other Tenderers in the order of their price bid i.e. L2 will be asked to match the L1 price and L3 will be given this offer only if L2 refuses and the Tenderers who agree to match lowest rate, will be considered as Matched Lowest Tenderer and so on.

(v) In order to maintain supplies / smooth testing of samples, the CMSS may empanel Laboratories for every product. The CMSS will limit the value of orders to the testing capacity of Laboratory.

(vi) If the lowest Laboratory has failed to analyze the required Drugs within the stipulated time or within the extended time, as the case may be, CMSS will cancel such Analysis orders and on cancellation, CMSS will place Analysis Orders with the Matched Lowest Tenderer or to the other Tenderers at the risk and cost of the defaulted Laboratory.

(vii) CMSS at its discretion may empanel single or two labs at L1 rates and CMSS will give business based on randomly selected laboratory by E-aushadhi IT based web system or CMSS reserve the right to divide the business among the empaneled laboratory to have secrecy.

(viii) If any medicines and other items indent received in future sealed financial quotation from the technically as well as commercial qualified laboratories shall be asked for testing of such new medicines and L1 laboratory will be selected.

14. ANALYSIS AND REPORTING CONDITIONS

a) On empanelment and entrustment of the job, the Analytical Laboratory should furnish the test reports within the time specified below (stipulated time period):-

I. The labs should mandatorily receive the samples in the IT enabled E-Aushadhi web system of CMSS within **3 days** of delivery of samples at laboratory as per Indian post/courier (as verified by docket details).

II. QC reports to be released within 10 days from receipt of the sample as explained in clause 14(I), in case of Tablets, Capsules, Powder and other non-sterile items.

III. QC reports to be released within 15 days from receipt of the sample as explained in clause 14(I), **in the case of Tenofovir 300 mg+Lamivudine 300 mg+Dolutegravir 50 mg (TLD)tablet and Zidovudine 60/300mg , Lamivudine 30/150 mg & Nevirapine 50/200mg / Tablets.**

IV. QC reports to be released within 21 days from receipt of the sample as explained in clause 14(I), in the case of Injectables and other sterile items.

V. Samples need to be tested on 21 CFR compliant instruments.

VI. Reports should be uploaded by the laboratory on the web based IT system of CMSS (E-Aushadhi) and simultaneously scanned copy to be emailed to CMSS Head office.

VII. The hard copy of the duly signed COA should be couriered to the Head office.

VIII. In case of failure of a sample, the result should be communicated immediately to CMSS warehouse and HO by phone & email. The Hard copy of COA should be immediately sent to CMSS H.Q. via email.

IX. If laboratory fails to perform the services within the time frame incorporated as stipulated above CMSS shall without prejudice to other rights and remedies available under contract, deduct the contract charges, as liquidated damages a sum equivalent to 2.0 % testing charges per day (all inclusive) on delayed services until actual performance subject to a maximum LD of 10 % of the testing charges.

X. In case a lab repeatedly defaults on timely furnishing reports as stipulated above, CMSS reserves right to initiate action including forfeiture of security deposit and/or

debarring or disqualification of testing lab in accordance with instructions contained in DoE guidelines vide OM No. F.1/20/2018/PPD dt. 02.11.2021.

b) In all report where there is some value assigned to result then the report should mention the actual value and permissible limits. In case of dissolution, uniformity of weight / content the minimum and maximum values are to be provided. "COMPLIES" or "PASSES" in the result column of the report will be treated as incomplete report, if the result has some value. However, in case sterility test result as 'COMPLIES' / 'PASSES' will be acceptable.

c) Every test report must have remarks i.e. of Standard Quality or Not of Standard Quality. Reports should be sent on Form-39 as specified in Drugs and Cosmetics Act, 1940 and Rules there under, 1945.

d) Certificate of analysis (COA) should be in A4 size paper of good quality and should have serial no. of the test, Description (name) of the test, Specifications and Result and test method.

e) COAs should be attached along with Spectra, Chromatographs or other instrument print outs if applicable.

f) If in any circumstances (like break down of instrument, non-availability of reference standard etc.) the Analytical Laboratory is unable to undertake analysis for a sample, the same should be reported within 24 hours of receipt of such a sample by FAX or Email and the sample should be returned to the Pharmacist of the CMSS warehouse from whom the sample has been received.

g) If any sample is received in a damaged/open/tempered condition by the laboratory, the sample should not be analyzed and the information should be sent immediately to the Pharmacist of the CMSS warehouse from whom the sample has been received.

h) Deliberate omission of any test will be viewed seriously and shall invite action against the laboratory as deemed fit by CMSS.

15. TEST METHOD

(i) All the tests are to be performed as per pre-defined specifications and test methods. If the product monograph is available in current Indian Pharmacopoeia (IP) then the product should be analysed as per the individual monograph given in IP and the tests mentioned under general requirements of the product's dosage form in IP.

(ii) If the product monograph is not available in current IP but it is available in immediate previous edition of IP, then that IP monograph and general requirements under the product's dosage form should be used for test method.

(iii) If the product monograph is not available either in current IP an in immediate previous edition of IP then other pharmacopoeias like British Pharmacopoeia (BP), European Pharmacopoeia (Eu.Phr.), United States Pharmacopoeia (USP), **The International Pharmacopoeia (WHO),** Japanese Pharmacopoeia, Chinese Pharmacopoeia or other Pharmacopoeia/ Standard mentioned in Annexure-I should be used.

(iv) **Microbiological test is compulsory in Anti TB drugs and STI/RTI kits.**

(v) **Leak test should also be performed in case of Blister packs/strips packs in Anti TB drugs as additional test.**

16. PAYMENT PROVISIONS

(i) No advance payments towards costs of analysis of drugs will be made to the Tenderer.

(ii) The payment towards analysis of drugs or other items as indicated in the tender 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-IX) to make the payment through RTGS/ Core Banking/ NEFT and the change of Bank Account during the Validity of the tender will not be entertained normally.

(iii) All bills/Invoices should be raised in duplicate and the bills should be drawn in the name of CENTRAL MEDICAL SERVICES SOCIETY Ministry of Health & Family Welfare (Government of India) 2nd floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Marg, Opposite Police Station Chankaya Puri, New Delhi-110021or in the name of any other authority as may be designated.

(iv) Payment shall be made only on completion of analysis of items ordered in individual order for analysis. The CMSS shall endeavor to make payment within 30 days of receipt of bill.

(v) No advance payment towards any analysis will be made. No payment will be made for incomplete analysis or incomplete report.

(vi) Where there is a statutory requirement for tax deduction at source, such deduction towards income tax and other taxes as applicable will be made from the bills payable at rates as notified from time to time by Government of India.

17. PENALTIES:

(i) If the successful tenderer fails to execute the agreement and payment of security deposit within the time specified or withdraws the tender after intimation of the

acceptance of the tender has been sent to or owing to any other reasons, it is unable to undertake the contract, the empanelment will be cancelled and the Earnest Money Deposit or/and Performance Guarantee if any deposited by the tenderer will also be forfeited and it should be liable for all damages sustained for reasons of breach of tender conditions. Such damages shall be assessed by the DG & CEO, CMSS whose decision shall be final.

(ii) Non performance of any tender or empanelment conditions will debar or disqualify a laboratory in accordance with instructions contained in DoE guidelines vide OM No. F.1/20/2018/PPD dt. 02.11.2021.

(iii) To assess the correctness of the test results being given by the Empanelled laboratory, at random samples could also be sent simultaneously to the Government Analyst or other empanelled laboratory for testing and if any variation is found the result would be informed to empanelled laboratory. If there is any variation in the analytical reports furnished by the empanelled laboratory with the Government Laboratory for 3 times in assay, dissolution, impurities, sterility, Endotoxins etc. critical tests, in a year, the empanelled laboratory will be debarred or disqualified in accordance with instructions contained in DoE guidelines vide OM No. F.1/20/2018/PPD dt. 02.11.2021.

(iv) If it is revealed that the analytical Laboratory is involved in any form of fraud and collusion with the suppliers of CMSS, the Analytical Laboratory will be debarred or disqualified in accordance with instructions contained in DoE guidelines vide OM No. F.1/20/2018/PPD dt. 02.11.2021. The tenderers shall also be liable for action under criminal law and the matter will be notified to the concerned Department for penal action against them.

(v) The DG & CEO will be at liberty to terminate the empanelment of any laboratory either wholly or in part at one month's notice. The tenderer will not be entitled for any compensation whatsoever in respect of such termination.

(vi) In all matters pertaining to the tender, the decision of the DG & CEO, CMSS shall be final and binding.

(vii) In the event of any dispute arising out of the tender such dispute would will be dealt with in line with clause 22 of this tender document.

18. DEDUCTION &OTHER PENALTIES ON ACCOUNT OF DELAYS/ DEFAULT/ TERMINATION/ PART CANCELLATION/SHORT CLOSURE:

(i) The CMSS, without prejudice to any other contractual rights and remedies available to it (the CMSS), May, by written notice of default sent to the supplier, terminate the contract in whole or in part, if the supplier fails to perform any contractual

obligation(s) within the time period specified in the contract, or within any extension thereof granted by the purchaser.

(ii) In the event of the CMSS terminates the contract in whole or in part, the CMSS may procure the services similar to those cancelled, with such terms and conditions and in such manner as it deems fit and the testing laboratory shall be liable to the CMSS for the extra expenditure, if any, incurred by the CMSS for arranging such services.

(iii) Unless otherwise instructed by the CMSS, the testing laboratory shall continue to perform the contract to the extent not terminated.

(iv) If the testing laboratory becomes bankrupt or otherwise insolvent, the CMSS reserves the right to terminate the contract at any time, by serving written notice to the testing laboratory without any compensation, whatsoever, to the testing laboratory, subject to further condition that such termination will not prejudice or affect the rights and remedies which have accrued and/or will accrue thereafter to the CMSS.

(v) The CMSS reserves the right to terminate the contract, in whole or in part for its convenience, by serving a three months written notice on the testing laboratory at any time during the currency of the contract. The notice shall specify that the termination is for the convenience of the CMSS. The notice shall also indicate interalia, the extent to which the testing laboratory's performance under the contract is terminated, and the date with effect from which such termination will become effective.

(vi) The services (testing of samples) which are complete and ready in terms of the contract for delivery and performance within thirty days after the testing laboratory's receipt of the notice of termination, shall be accepted by the CMSS following the contract terms, conditions and prices. For the remaining services, the CMSS may decide:

(vii) To get any portion of the balance completed and delivered at the contract terms, conditions and prices; and/or

(viii) To cancel the remaining portion of the services and compensate the supplier by paying an agreed amount for the cost incurred by the supplier towards the remaining portion of the services.

19. FORCE MAJEURE:

(i) Notwithstanding the provisions contained in clauses 14 and 15 the testing laboratory shall not be liable for imposition of any such sanction so long the delay and/or failure

of the testing laboratory in fulfilling its obligations under the contract is the result of an event of Force Majeure.

(ii) For purposes of this clause, Force Majeure means an event beyond the control of the testing laboratory and not involving the testing laboratory's fault or negligence and which is not foreseeable and not brought about at the instance of the party claiming to be affected by such event and which has caused the non – performance or delay in performance. Such events may include, but are not restricted to, acts of the CMSS either in its sovereign or contractual capacity, wars or revolutions, hostility, acts of public enemy, civil commotion, sabotage, fires, floods, explosions, epidemics, quarantine restrictions, strikes excluding by its employees, lockouts excluding by its management, and freight embargoes.

(iii) If a Force Majeure situation arises, the testing laboratory shall promptly notify the CMSS in writing of such conditions and the cause thereof within seven days of occurrence of such event. Unless otherwise directed by the CMSS in writing, the testing laboratory shall continue to perform its obligations under the contract as far as reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event.

(iv) If the performance in whole or in part or any obligation under this contract is prevented or delayed by any reason of Force Majeure for a period exceeding sixty days, either party may at its option terminate the contract without any financial repercussion on either side.

(v) In case due to a Force Majeure event the CMSS is unable to fulfill its contractual commitment and responsibility, the CMSS will notify the testing laboratory accordingly and subsequent actions taken on similar lines described in above sub-paragraphs.

20. 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 in tended to be done in pursuance of the tender.

21. PROHIBITION OF INFLUENCING CMSS BY THE BIDDER:

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

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

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

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

22. 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.

23. JURISDICTION

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

For Sr. no. (i) Rate contract for empanelment of laboratories for analysis of drugs and other items for a period of two years.

***ANNEX*URE – I**

S.No.	Drug Name	Ref Specification	Approx No. of batches
1.	Inj. Medroxyprogesterone Acetate IP .Each vial contains Medroxyprogesterone Acetate IP 150 mg/ml including 1 Sterile Disposable Single Syringe 2 ml with Needle + Alcohol Swab	IP and IS 10258(3):2021/ISO 7886-3:2020) for Syringe, IS 10654:2002 for needle	200
2.	Tabs-Tenofovir 300 mg	IP	200
3.	Tabs-Entecavir IP 0.5 mg ,1 mg	IP	200
4.	Syrup- Zidovudine IP 50 mg	IP	200
5.	Tabs-Tenofovir 300 mg+ Lamivudine 300 mg+ Dolutegravir 50 mg (TLD)	IP	750
6.	Tabs- Dolutegravir 50 mg	IP	200
7.	Tabs- Darunavir 600 mg	IP	200
8.	Tabs- Ritonavir 100 mg	IP	200
9.	Tabs-Delamanid 50 mg	IH	200
10.	Inj. Benzathine Penicillin (2.4 Million Unit) with water for Injection 10 ml.	IP	200
11.	IFA Tabs / Syrups (Ferrous sulphate and Folic acid tablets IP)	IP	500
12.	Buprenorphine 0.4 mg/ 2mg [330]	IP	200
13.	Syrup Nevirapine [264]	IP	200
14.	Zidovudine 300mg , Lamivudine 150 mg & Nevirapine 200mg / Tablets [115]	IP	200
15.	Tablet Ivermectin 3mg [305]	IP	500
16.	Zidovudine 60 mg, Lamivudine 30 mg & Nevirapine 50 mg / Tablets [118]	IP	200
17.	Ambisome Inj. 50 mg / Vials [75]	IP	200
18.	Artesunate Injections/Kits (Artesunate Injection IP with Sodium Bicarbonate Injection IP, Sodium Chloride Injection IP) (Along with Disposable Syringe And Needle)]	IP and IS 10258(3):2021/ISO 7886-3:2020) for Syringe, IS 10654:2002 for needle	200
19.	Amphotericin-B for Injection for Kala-Azar / Vials [76]	IP	200
20.	STI/RTI Kit- 1 contains Azithromycin 1gm and Cefixime 400 mg (1 tablet each) [331]	IP	200
21.	STI/RTI Kit- 2 contains Secnidazole 1 gm- 2 tablets and Fluconazole 150 mg- 1 tab [332]	IP	200
22.	STI/RTI Kit- 3 contains Azithromycin 1 gm- 1 tab [333]	IP	200
23.	STI/RTI Kit- 4 contains Azithromycin 1 gm 1 tab. and Doxycycline 100 mg 30 tabs/Caps [334]	IP	200
24.	STI/RTI Kit- 5 contains Acyclovir 400 mg - 21 tab	IP	200
25.	STI/RTI Kit- 6 contains Cefixime 400 mg- 1 tab., Doxycycline 100 mg 28 tabs/Caps and Metronidazole 400 mg 28 tabs	IP	200
26.	STI/RTI Kit- 7 contains Azithromycin 1 gm 1 tab. and Doxycycline 100 mg 42 Tabs/Caps	IP	200

9) Delamanid IH Specification and STP

S. No.	Test	Specification	Method Reference (Pharmacopeia / In-house)
01	Description	Yellow, round film coated tablets debossed with "DLM" and "50" on one side.	In-house
02	Identification		In-house
	A. For Delamanid (By HPLC with diode array detector)	The UV spectrum of the major peak of the Sample Preparation corresponds to that of the Standard Preparation, as obtained in the 'Assay method for Delamanid'.	
	B. For Tocopherol (By HPLC)	The retention time of the Tocopherol peak in the chromatogram of the test preparation should correspond to that in the chromatogram of the standard preparation as obtained in the 'Assay method for Tocopherol'.	
03	Colorant Identification [£]	A blue color should develop	Ph. Eur. 2.3.1, Reaction C
04	Impurities/Degradation products (By HPLC)		In-house
	SFO-67121	Not more than 0.2% w/w	
	Other individual impurity	Not more than 0.2% w/w	
	Total Impurities	Not more than 0.8% w/w	
05	Uniformity of Dosage Units (By Content Uniformity)	Complies with IP General Chapter 2.5.4 The Acceptance Value (AV) should be not more than 15.0.	In-House

S. No.	Test	Specification	Method Reference (Pharmacopeia / In-house)
06	Dissolution (By UV)	Not less than 75% (Q) of the labeled amount of Delamanid $C_{25}H_{25}F_3N_4O_6$ should be dissolved in 30 minutes.	In-house
07	Assay (By HPLC)		In-House
	A. For Delamanid	Delamanid tablets contain not less than 47.50 mg and not more than 52.50 mg of Delamanid $C_{25}H_{25}F_3N_4O_6$, (95.0% w/w – 105.0% w/w of labeled amount of Delamanid)	
	B. For Tocopherol	Delamanid tablets contain not less than 3.6 mg and not more than 4.4 mg of Tocopherol (90.0% w/w – 110.0% w/w) of target amount (4.0 mg per tablet) of Tocopherol	
08	Microbiological Test #		IP 2.2.9
	A. Microbial Enumeration Tests		
	a. Total Aerobic Microbial Count (TAMC)	Not more than 1000 CFU/g	
	b. Total Combined Yeasts / Moulds Count (TYMC)	Not more than 100 CFU/g	
	B. Test for specified Micro-organisms		
	a. *Escherichia Coli*	Must be absent / g	

1.0 DESCRIPTION:

Procedure:

Put 10 tablets on butter paper and observe the size, shape, color and marking. Compare the sample appearance to specification description. The tablet should be free of foreign matter or surface defects, including sticking, discoloration or disfiguration.

2.0 IDENTIFICATION:

A. For Delamanid (By HPLC with diode array detector):

Proceed as directed under the test, Assay method for Delamanid tablets

Procedure:

Use Photodiode array detector (Wavelength: 242 nm, spectrum range of measurement 210-450 nm).

B. For Tocopherol (By HPLC):

Procedure:

Proceed as directed under the test, "Assay method for Tocopherol". Compare the retention time of the Tocopherol peak from sample solution with that from the 'standard solution'. The retention time of the Tocopherol peak in the chromatogram of sample solution corresponds to that in the chromatogram of the standard solution.

3.0 COLORANT IDENTIFICATION:

Perform the test according to the modified test method of "Reaction C" in 2.3.1 IDENTIFICATION REACTIONS OF IONS AND FUNCTIONAL GROUPS, IRON of European Pharmacopoeia:

1. Grind the film-coated tablets to a powder without excessive force (do not grind the filmcoated layer to a powder) and sieve through a 850 µm sieve. Take 0.5 g of the retained portion on the sieve, add 6 mL of hydrocholoric acid (1 in 2) solution.
2. Shake this mixture for 5 minutes in a water bath setting at 70°C. Cool to room temperature and centrifuge this mixture if necessary.
3. Filter through a membrane filter with a pore size of 0.45 µm. Take 2 mL of the filtrate, add 1 mL methanol and 1 mL of potassium ferrocyanide solution. A blue precipitate is formed.

4.0 IMPURITIES/DEGRADATION PRODUCTS (BY HPLC):

Note: Carry out the procedure protected from light, using light-protected glass wares.

Cleaning of the HPLC system including column and cleaning effectiveness check

Cleaning method of HPLC including column:

Use a mixture of acetonitrile/water/acetic acid (900:100:10) as cleaning solution and clean over night

Cleaning effectiveness check:

Dissolve about 20 mg of delamanid reference material in a mixture of acetonitrile/water (3:2) to make exactly 50 mL. Use as the stock solution for system suitability. Inject 10 µL of the solution and the absence of a unknown peak around the relative retention time of 0.8 (around the retention time of 29 minutes) indicates that the cleaning is effective. If the unknown peak is detected for the first injection, repeat the injection of the solution a few time. After the injections, if the unknown peak is no longer detected, the cleaning should be considered effective. If not, change the column. Note that the unknown peak tends to become smaller as the injection of the solution is repeated.

Reagents:

a.	Sodium octanesulfonate	:	AR grade or equivalent.
b.	Glacial acetic acid	:	HPLC grade or equivalent.
c.	Acetonitrile	:	HPLC grade or equivalent.
d.	Water	:	HPLC (Milli-Q water) or equivalent.

5 mM sodium octanesulfonate solution : Dissolve about 4.4 g of sodium octanesulfonate in 4000 mL of water and mix.

Mobile Phase A: Prepare a mixture of 5 mM sodium octanesulfonate solution and glacial acetic acid (100:1) and mix well.

Mobile phase B: Prepare a mixture of acetonitrile and glacial acetic acid (100:1) and mix well.

Diluent:

Prepare a mixture of acetonitrile and water in the ratio 3:2 v/v respectively, mix well.

Chromatographic Condition:

Column	:	Stainless steel column (4.6 mm id × 25 cm) packed with octadecylsilanized silica gel (3 µm particle in diameter), Unison UK-C18 or equivalent
Flow rate	:	0.9 mL/ min
Wavelength	:	254 nm
Column temperature	:	40°C ± 2°C
Injection volume	:	15 µL

Gradient programme:

Time (minutes)	Mobile phase A (%v/v)	Mobile phase B (%v/v)
0	70	30
60	20	80
60.1	70	30
70	70	30

Time span of measurement:

60 minutes after the solvent peak

Standard solution:

1. Weigh accurately and transfer about 20 mg of Delamanid reference standard/ working standard, into a 50 mL volumetric flask, dissolve and dilute to volume with diluent.
2. Take exactly 1 mL of this solution into a 100 mL volumetric flask and dilute to volume with diluent.

Note: Standard solution is stable for 10 days in Amber glass, airtight container room temperature at laboratory (15-25°C).

System suitability solution:

Take exactly 2 mL of the standard solution into a 20 mL volumetric flask and dilute to volume with diluent.

Note: System suitability solution is stable for 10 days in Amber glass, airtight container room temperature at laboratory (15-25°C).

Sample Solution:

1. Grind the tablets to a powder. Weigh accurately and transfer about 0.21 g of the powder (corresponding to about 20 mg of Delamanid drug substance ($C_{25}H_{25}F_3N_4O_6$)) into a 50 mL volumetric flask, add 40 mL diluent and then shake well for 10 minutes.
2. Dilute to volume with diluent and filter through a 0.45 µm PTFE filter. Discard the first not less than 3 mL of the filtrate.

Note: Sample solution is stable for 10 days in Amber glass, airtight container room temperature at laboratory (15-25°C)

Placebo Solution preparation:

Note: If placebo is not available for preparation of placebo solution, then refer RRT table of placebo mentioned under 'Note' section point No.3

1. Weigh accurately and transfer an amount of the placebo powder equivalent to about 20 mg of Delamanid drug substance ($C_{25}H_{25}F_3N_4O_6$)) into a 50 mL volumetric flask, add 40 mL diluent and then shake well for 10 minutes.
2. Dilute to volume with diluent and filter through a 0.45 µm PTFE filter. Discard the first not less than 3 mL of the filtrate.

Procedure:

Inject blank, standard solution (for 6 times), system suitability solution, placebo solution preparation and sample solution into the chromatograph. Record the chromatograms and measure the peaks' responses (Refer Typical chromatograms).

System suitability:

From Standard solution:

1. The number of theoretical plates and the symmetry factor of the peak of Delamanid should be not less than 200000 and not more than 2.0, respectively.
2. The relativc standard deviation of the peak area of Delamanid should be not more than 3%.

From System suitability solution:

Confirm that the peak area of Delamanid obtained from 15 µL of System suitability solution is 7% - 13% of that from 15 µL of the Standard solution.

Note:

1. Determine the peak areas of Delamanid and impurities/degradation products by automatic integration method and calculate the amount of each impurity by the area percentage method.

2. Use the peak areas of all related substances after multiplying by their relative response factor defined below.

S. No.	Name of the Impurity	RRT	RRF
1	SFO-67121	0.25	0.6
2	DM-6706	0.61	3.1
3	DM-6705	0.81	1.6
4	Delamanid	1.0	-
5	Others	-	1.0

3. During Calculation of impurity results following placebo peak RRT shall be considered as placebo peak in the sample chromatogram;

S. No.	Placebo Peak at RRT
1	0.103
2	0.112
3	0.120
4	0.216
5	0.244
6	0.260
7	0.280
8	0.355
9	0.400

The above RRT peak shall be considered as placebo peak and excluded in the results calculation.

Calculation:

$$\text{Any Individual Impurity (\% w/w)} = \frac{\text{Peak area of individual impurity}}{\text{Sum of the peak areas of delamanid and individual impurities}} \times \text{RRF} \times 100$$

5.0 UNIFORMITY OF DOSAGE UNITS (CONTENT UNIFORMITY):

Proceed as directed in the General test procedure, "Uniformity of Dosage Units – IP." GTP No.: GTP017#.

Note: Carry out the procedure protected from light, using light-protected glass wares.

Reagents:

Ammonium formate	:	AR grade or equivalent
Acetonitrile	:	HPLC grade or equivalent
Water	:	Milli-Q water or equivalent
Methanol	:	HPLC grade or equivalent

Chromatographic condition:

Column	:	Stainless steel column (4.6 mm id × 7.5 cm) packed with octylsilanized silica gel (3 µm particle in diameter),Inertsil C8-3 or equivalent
Flow rate	:	1 mL/ min
Wavelength	:	242 nm
Injection Volume	:	10 µL
Column Temperature	:	40°C ± 2°C
Run time	:	20 minutes

Mobile Phase:

Prepare a mixture of methanol and 0.1 M ammonium formate solution in the ratio of 13:7 v/v respectively.

0.1M Ammonium Formate Solution Preparation:

Dissolve about 6.306 gm of Ammonium Formate to 1000 mL of water and mix.

Diluent: Prepare a mixture of water and acetonitrile in the ratio of 1:1 v/v respectively.

Internal standard solution: Pentyl benzoate in acetonitrile (1 in 125).

Standard solution:

1. Weigh accurately and transfer about 50 mg of Delamanid reference standard/WS into a 50 mL volumetric flask, add exactly 5 mL of the internal standard solution and dissolve in acetonitrile.
2. Dilute to volume with acetonitrile.
3. Further dilute 8 mL of this solution to 50 mL with the diluent and mix.

Note: Standard solution is stable for 7 days in glass airtight container at room temperature.

Sample solution:

1. Transfer one tablet into a 50 mL volumetric flask, add 4 mL of water and disintegrate the tablet with sonication and shaking. Add exactly 5 mL of the internal standard solution and add 30 mL acetonitrile. Shake well for 10 minutes and dilute to volume with acetonitrile.
2. Further dilute 8 mL of this solution to 50 mL with the diluent and mix. Centrifuge, if necessary and filter the supernatant through a 0.45 µm PTFE filter, discard the first 3 mL of the filtrate.

Note: Sample solution is stable for 7 days in glass airtight container at room temperature.

Procedure:

Inject Blank, Standard solution (six times) and Sample Solution into the chromatograph, record the chromatograms and measure the peak responses. (Refer Typical chromatograms).

System Suitability:

From standard solution:

1. The relative standard deviation of the peak area ratio of Delamanid to the internal standard should be not more than 1.0%.
2. The resolution between Delamanid and internal standard peaks should be not less than 4.

Calculation:

$$\text{Assay of Delamanid (\% of Label claim)} = \frac{A_T}{A_S} \times \frac{W_S}{50} \times \frac{8}{50} \times \frac{50}{1} \times \frac{P}{8} \times \frac{100}{100} \times \frac{}{LC}$$

Where,

A_T = Peak area ratio of Delamanid to the internal standard in the chromatogram of Sample solution.

A_S = Average peak area ratio of Delamanid to the internal standard in the chromatogram of standard solution.

W_S = Weight of Delamanid standard taken, in mg, for standard solution.

P = % Potency of Delamanid, on as is basis.

LC = Label Claim of Delamanid per tablet, in mg.

6.0 DISSOLUTION (By UV):

Reagents:

Sodium lauryl sulfate	:	J.T. Baker make or equivalent
Hydrochloric acid	:	AR grade or equivalent
Sodium chloride	:	AR grade or equivalent
Ethanol	:	HPLC grade or equivalent
Water	:	HPLC grade, Milli-Q water or equivalent

Dissolution parameters:

Medium	:	0.30% sodium lauryl sulfate (SLS) solution
Volume	:	900 mL
Apparatus	:	IP Apparatus-II (Paddle)
RPM	:	50
Temperature	:	37 ± 0.5°C
Time point	:	As specified in specification.

Note:

1. Carry out the analysis under sodium-vapor lamp (protect from light), using light-protected (low actinic glass) glass wares.
2. After preparation, dissolution medium shall be kept in closed container to avoid exposure to open environment.
3. Dissolution medium to be prepared and used as quickly as possible (preferably within 1 hr.).
4. Preferably prepare dissolution medium 10 liter or more.
5. Tablets to be weighed just before start of dissolution run (not more than 5 minutes before) i.e. after achieving the temperature of dissolution medium in bowl, tablet weighing activity shall be started, to avoid the exposure of tablets to open environment.

Dissolution medium (0.30% sodium lauryl sulfate (SLS) solution): Preparation given for 10000 mL volume of dissolution medium.

- Take 10000 mL Milli-Q water in a suitable container.
- Take glass beaker having capacity of 5 liter, transfer about 3000 mL Milli-Q water in beaker and take out 2000 mL water in another container for rinsing of the used beaker from above 10000 mL.
- Weigh accurately 30 g of SLS in suitable container, and transfer weighed SLS slowly in beaker having 3000 mL water with stirring using rod to avoid lumps formation, rinse the container of SLS used for weighing twice with water (kept separate for rinsing) and ensure that SLS dissolved completely.
- Sonicate the above solution for 10-15 minutes with intermittent stirring using rod and ensure physically that SLS dissolved completely.
- Mix the above prepared SLS solution in remaining quantity of water, rinse the glass beaker twice with water (kept separate for rinsing) and mix well with vigorous shaking using rod.
- Do not remove foam generated after stirring, allow dissolution medium to settle.
- Dissolution medium shall be Degassed using degasser (Using SLS mode ON) before use for analysis.

Solvent mixture : Dissolve 2.0 g of sodium chloride in 7.0 mL of concentrated hydrochloric acid and water and dilute with water to make 1000 mL. Add 3.0 g of sodium lauryl sulfate to this solution and dissolve.

Diluent as blank: Prepare a mixture of Ethanol and Solvent mixture (1:9)

Standard solution:

Weigh accurately about 50 mg of Delamanid reference standard/WS, add 100 mL of 95% ethanol and dissolve. Dilute with solvent mixture to make exactly 1000 mL.

Sample solution:

1. Transfer 900 mL of the dissolution medium into each of the dissolution vessels. Equilibrate the medium to 37°C± 0.5°C.
2. Transfer one tablet into each of the dissolution vessels and immediately start the run.
3. At end of the specified time, withdraw 10 mL of the sample from each of the dissolution vessels.
4. Filter the sample solution through 10µ full flow filter and use the filtrates.

Procedure:

Measure the UV absorbance of dissolution medium as blank (for autozero), Diluent as blank, standard solution (six times) and sample solution (once) at 335 nm and 450 nm with a UV spectrophotometer equipped with a flow cell (cell length: 10 mm).

Calculations:

$$\% \text{ Drug Dissolved} = \frac{A_{SPL\,(335)} - A_{SPL\,(450)}}{A_{STD\,(335)} - A_{STD\,(450)}} \times \frac{W_{STD}}{1000} \times \frac{900}{LC} \times \frac{P}{100} \times 100$$

Where:

$A_{SPL\,(335)}$	=	Absorbance of Delamanid in the sample solution at 335 nm
$A_{SPL\,(450)}$	=	Absorbance of Delamanid in the sample solution at 450 nm
$A_{STD\,(335)}$	=	Average absorbance of Delamanid in the standard solution at 335 nm
$A_{STD\,(450)}$	=	Average absorbance of Delamanid in the standard solution at 450 nm
W_{STD}	=	Weight of Delamanid RS/WS in mg.
LC	=	Label Claim of Delamanid per tablet, in mg.
P	=	Potency of Delamanid standard in %, on as is basis.

7.0 ASSAY (BY HPLC):

Note: Carry out the procedure protected from light, using light-protected glass wares.

A. For Delamanid:

Reagents:

Ammonium formate	:	AR grade or equivalent
Acetonitrile	:	HPLC grade or equivalent
Water	:	Milli-Q water or equivalent
Methanol	:	HPLC grade or equivalent

Chromatographic condition:

Column	:	Stainless steel column (4.6 mm id × 7.5 cm) packed with octylsilanized silica gel (3 µm particle in diameter),Inertsil C8-3 or equivalent
Flow rate	:	1 mL/ min
Wavelength	:	242 nm **For Delamanid (By HPLC with diode array detector): Use a diode array detector in the range of 210 nm - 450 nm.**
Injection Volume	:	10 µL
Column Temperature	:	40°C ± 2°C
Run time	:	20 minutes

Mobile Phase:

Prepare a mixture of methanol and 0.1 M ammonium formate solution in the ratio of 13:7 v/v respectively.

0.1M Ammonium Formate Solution Preparation:

Dissolve about 6.306 gm of Ammonium Formate to 1000 mL of water and mix.

Diluent: Prepare a mixture of water and acetonitrile in the ratio of 1:1 v/v respectively.

Internal standard solution: Pentyl benzoate in acetonitrile (1 in 125).

Standard solution:

1. Weigh accurately and transfer about 50 mg of Delamanid reference standard/WS into a 50 mL volumetric flask, add exactly 5 mL of the internal standard solution and dissolve in acetonitrile.
2. Dilute to volume with acetonitrile.
3. Further dilute 8 mL of this solution to 50 mL with the diluent and mix.

Note: Standard solution is stable for 7 days in glass airtight container at room temperature.

Sample solution:

1. Take not less than 20 tablets, weigh accurately and grind to a fine powder.
2. Weigh accurately and transfer about 0.54 g of the powder (corresponding to about 50 mg of Delamanid drug substance ($C_{25}H_{25}F_3N_4O_6$)) into 50 mL volumetric flask, add exactly 5 mL of the internal standard solution.
3. Add 35 mL acetonitrile and shake well for 10 minutes. Dilute to volume with acetonitrile. Further dilute 8 mL of this solution to 50 mL with the diluent and mix.
4. Centrifuge, if necessary and filter the supernatant through a 0.45 µm PTFE filter, discard the first 3 mL of the filtrate.

Note: Sample solution is stable for 7 days in glass airtight container at room temperature.

Procedure:

Inject Blank, Standard solution (six times) and Sample Solution (Two times) into the chromatograph, record the chromatograms and measure the peak responses. (Refer Typical chromatograms).

System Suitability:

From Standard solution:

1. The relative standard deviation of the peak area ratio of Delamanid to the internal standard should be not more than 1.0%.
2. The resolution between Delamanid and internal standard peaks should be not less than 4.

Calculation:

$$\text{Assay of Delamanid (mg per tablet)} = \frac{A_T}{A_S} \times \frac{W_S}{50} \times \frac{8}{50} \times \frac{50}{W_T} \times \frac{50}{8} \times \frac{P}{100} \times A_{WT}$$

$$\text{Assay of Delamanid (\% of label claim)} = \frac{\text{Reported Assay value in mg/tablet (Rounded of value)}}{LC} \times 100$$

Where,

A_T	=	Average peak area ratio of Delamanid to the internal standard in the chromatogram of Sample solution.
A_S	=	Average peak area ratio of Delamanid to the internal standard in the chromatogram of standard solution.
W_S	=	Weight of Delamanid standard taken, in mg, for standard solution.
W_T	=	Weight of tablet powder taken in mg, for sample solution.
LC	=	Labeled amount of Delamanid per tablet, in mg.
P	=	% Potency of Delamanid standard, on as is basis.
A_{WT}	=	Average weight of tablet in mg

B. For Tocopherol:

Reagents:

Anhydrous ethanol	:	Commercial grade
Water	:	Milli-Q water or equivalent
Methanol	:	HPLC grade or equivalent

Chromatographic condition:

Column	:	Stainless steel column (4.6 mm id × 15 cm) packed with octadecylsilanized silica gel (5 µm particle in diameter), TSKgel ODS-80Ts or equivalent

Flow rate	:	**1 mL/ min**
Wavelength	:	**292 nm**
Injection Volume	:	**20 µL**
Column Temperature	:	**35°C**
Run time	:	**20 minutes**

Mobile Phase:

Prepare a mixture of methanol and water in the ratio of 49 : 1 v/v respectively.

Standard solution:

1. Weigh accurately about 50 mg of tocopherol reference standard in a 50 mL volumetric flask.
2. Dissolve in anhydrous ethanol. Dilute to volume with anhydrous ethanol.
3. Further dilute 5 mL of this solution to 50 mL with anhydrous ethanol.

Sample solution:

1. Weigh accurately not less than 20 tablets and calculate the average weight of the tablet.
2. Take not less than 10 tablets, weigh accurately and grind to a fine powder.
3. Weigh accurately about 0.67 g of the powder (corresponding to about 5 mg of tocopherol) and add exactly 50 mL of anhydrous ethanol. Shake well for 10 minutes.
4. Filter the supernatant through a 0.45 µm PTFE filter. Discard the first 1 mL of the filtrate.

Note:

1. Add anhydrous ethanol slowly with intermittent shaking and ensure to completely disperse the powder and check that powder should not be stuck to the wall or bottom of the volumetric flask.
2. Shake the test solution for 10 minutes on rotatory shaker at 200 RPM.

System Suitability solution: Dissolve 50 mg each of tocopherol and tocopherol acetate in 50 mL of anhydrous ethanol.

Procedure:

Inject Blank, Standard solution (six times), System Suitability solution and Sample Solution into the chromatograph, record the chromatograms and measure the peak responses (Refer Typical chromatograms).

System Suitability:

From Standard solution:

The relative standard deviation of peak area of tocopherol should be not more than 1.0%.

From System Suitability solution:

Resolution between tocopherol and tocopherol acetate should be not less than 2.6.

Calculation:

$$\text{Assay of Tocopherol (mg per tablet)} = \frac{A_T}{A_S} \times \frac{W_S}{50} \times \frac{5}{50} \times \frac{50}{W_T} \times \frac{P}{100} \times A_{WT}$$

$$\text{Assay of Tocopherol (\% of label claim)} = \frac{\text{Reported Assay value in mg/tablet (Rounded of value)}}{LC} \times 100$$

Where,

A_T	=	Peak area of Tocopherol in the chromatogram of Sample solution.
A_S	=	Average peak area of Tocopherol in the chromatogram of Standard solution.
W_S	=	Weight of Tocopherol standard taken, in mg, for standard solution.
W_T	=	Weight of tablet powder taken in mg, for sample solution.
LC	=	Labeled amount of Tocopherol per tablet, in mg.
P	=	% Potency of Tocopherol standard, on as is basis.
A_{WT}	=	Average weight of tablet in mg

8.0 MICROBIOLOGICAL TEST:

Procedure:

Proceed as directed under the General Test Procedure "Microbial Contamination in nonsterile products" GTP No.: GTP036#.

For Sr. no. (ii) For empanelment of laboratories for analysis of drugs and other items for future requirements (i.e. for additional drugs/injections/needle/syringe and other medical devices) for a period of two years.

1. The laboratory which will be empaneled for Sr. (i) shall also be empaneled for Sr. (ii) based on meeting technical as well as commercially requirement as per clause no. 4.
2. For any future needs (i.e. for a new drugs/injections/needle/syringe and other medical devices) sealed financial quotes only would be asked from such empaneled (technically qualified) laboratories to award the work to L1, L2 labs & more, if rates quoted are reasonable and justified. However, laboratory should have /possess required certifications for the drugs in question.

ANNEXURE-II

TENDER FORWARDING LETTER

(To be given on Company Letter Head)

Date:

To,

DG&CEO,

Central Medical Services Society

1, Red Cross Road

New Delhi - 110001

Sub: Acceptance of Terms & Conditions of Tender.

Tender No: _____

Name of Tender: - Online tender for……

Dear Sir,

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

_____

_____

As per your advertisement, given in the above-mentioned website(s).

2. I / We hereby certify that I / we have read the entire terms and conditions of the tender Documents from Page No. _____ To _____ (Including all documents like annexure(s), Schedule, 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 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 in accordance with DoE guidelines vide OM No. F.1/20/2018/PPD dt. 02.11.202.

6.1 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 /performance security absolutely.

Yours Faithfully,

(Signature of the Bidder, with Official Seal)

ANNEXURE-III

DETAILS OF E.M.D. SUBMITTED for Sr no. (i) and Sr no. (ii)

We herewith submit the E.M.D. of Rs.1,00,000 in the form of Demand Draft / RTGS/NEFT/Banker's Cheque or Bank Guarantee bearing No._____ Dated: _____ drawn on _____ Bank _____Branch in favor of CMSS for the following items of drugs: **refer Annexure-I.**

List of Items:

Signature & Seal

ANNEXURE-IV

PROFORMA FOR PERFORMANCE STATEMENT

(FOR A PERIOD OF LAST 3 YEARS i.e., 2021-22, 2022-23 and 2023-24)

Name of the Laboratory: _____
Address: _____
No. of QC analyst: _____
List of Qualified Instrument:

Sr. No.	Samples Analyzed (List of quoted dosage form)	No. of Samples Analyzed	Tentative Analysis Timeline per batch
1			
2			
3			
4			
5			
6			

Name:

Designation:

Date:

Signature and seal of the Tenderer_____

Date:
Seal:

Signature of Auditor/ Chartered Accountant
(Name in Capital)

ANNEXURE-V

ANNUAL TURN OVER STATEMENT

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

Sl. No.	***Financial Year***	***Turnover in Lakhs Rs***
1.	2021-2022	-
2.	2022-2023	-
	Total	- Rs. _____.

Average Turnover Per Annum in the last two years mentioned above-

Rs._____.

Date:
Seal:

Signature of Auditor/ Chartered Accountant
(Name in Capital)

ANNEXURE – VI

CHECK LIST

Sr. No.	List of Documents	Yes	No	Page No.
1.	A Checklist (Annexure-VI) indicating the documents submitted with the tender document and their respective page number			
2.	Authorization letter nominating two responsible persons of the tenderer to transact the business with the Tender inviting Authority			
3.	Tender document and other documents of submitted bid are properly page numbered and signed by the authorized signatory of the Tenderer with office seal. The documents are serially arranged.			
4.	List of items quoted and their Monthly Analysis capacity and Timeline Annexure-XVIII			
5.	Duly attested photocopy of License approved by the Licensing Authority.			
6.	Duly attested copy of NABL certificate in accordance with standard ISO-17025 having quoted item listed in scope of NABL accreditation on tender opening date.			
7.	Duly attested photocopy of Good Laboratory Practice (GLP) certificate under the Drugs and Cosmetics Act 1940 by state drug authority.			
8.	Non-Conviction Certificate issued by the FDA/ Drugs Controller of the State certifying that the Laboratory has not been convicted in year 2022 and 2023.			
9.	Undertaking that Firm is not blacklisted or debarred from any Govt. Agency (Clause 4f, 6 s)			
10.	The Tender Forwarding Letter Annexure - II			
11.	Details of EMD Submitted Annexure-III			
12.	Performa for Performance Statement Annexure-IV			
13.	P.O copies/Sample details of 500 samples annually in any of last three years i.e., 2021-22, 2022-23 and 2023-24 duly certified by CA indicating its unique identification number.			
14.	Annual Turnover Statement i.e., 2021-22 and 2022-23 Annexure-V			
15.	Copies of Balance Sheet & Profit & Loss Account for last two years i.e., 2021-22 and 2022-23			
16.	Microbiological Facility Details Annexure-VIII			
17.	Mandate Form Annexure-IX			
18.	The Price Bid Annexure-X			
19.	Bank Guarantee for EMD Annexure-XI			
20.	Bank Guarantee for Security Deposit Annexure-XII			
21.	No Deviation Certificate Annexure-XIV			
22.	Near Relative Certificate Annexure-XV			
23.	Original Notarised undertaking by MSE companies Annexure XVI for Exemption of EMD in physical form deposited			
24.	Undertaking for land border sharing with India Annexure-XVII			
25.	The instrument such as power of attorney, resolution of board etc. authorizing an officer of the tenderer duly signed by the Authorized signatory of the Laboratory and such authorized officer of the tenderer should sign the tender document.			

26.	List of Sophisticated instruments with numbers and make/model			
27.	List of 21 CFR compliant instruments with instrument ID on which CMSS Samples shall be analyzed.			
28.	Udyam Registration certificate			
29.	Copy of Original cancelled cheque with Mandate Form			

NOTE:

Bidders are requested to submit all documents with the bid as shown as checklist (Annexure - VI). 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-VII

ACCEPTANCE LETTER FORMAT

(In CMSS Letter-Head)

To,
M/s:
Address:

Kind Attn:

Sub: Acceptance of Tender for analysis of Drugs and other items of CMSS for 2 years 2024-26.

Ref: 1) CMSS Tender No……., dated _____
2) Your Ref. No. _____

Dear Sir,

I am pleased to inform you that the above referred Tender for analysis of Drugs and other items for CMSS during the year 2024-26 have been accepted for following items:

Sr. No.	Item Code	Name of Item	All Inclusive Price	Total Value
1				
2				
3				
4				

You are requested to pay Security Deposit of Rs. 5.00 lakh by Demand Draft or Banker's Cheque, within 7 days from the date of receipt of the letter and enter into an Agreement, within 15 days from the date of receipt of the letter. Non fulfillment to do so within the stipulated period will be treated as breach of tender terms & liable for forfeiture of EMD.

Thank you,
For Central Medical Services Society

(DG& CEO)

ANNEXURE -VIII

FACILITIES IN THE MICROBIOLOGICAL SECTION

I. LIST OF STOCK CULTURES AVAILABLE-

II. LIST OF EQUIPMENT / APPARATUS Date of installation Total number
(Ex. INCUBATORS ETC.)

Signature:

Name:

Designation:

Date:

Name of the Laboratory:

Office Seal:

ANNEXURE -IX

MANDATE FORM

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

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

Mandate Form contd..

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

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

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

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

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

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

ANNEXURE-X

PACKET -2
PRICE –BID

CENTRAL MEDICAL SERVICES SOCIETY
NEW DELHI – 110001

TENDER FOR RATE AGREEMENT OF DRUGS FOR THE YEAR……

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

(Below sheet is only for reference)

Validate | Print | Help | ise BoQ

Tender Inviting Authority: DG & CEO, CMSS

Name of Work:RATE CONTRACT FOR EMPANELMENT OF LABORATORIES FOR ANALYSIS OF DRUGS AND OTHER ITEMS FOR A PERIOD OF TWO YEARS.

Tender No: CMSS/2024-25/TL/DRUGS/017

Bidder Name :	

PRICE SCHEDULE

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

NUMBER	TEXT *	TEXT *	NUMBER	TEXT *	NUMBER *	NUMBER	NUMBER
Sl. No.	Name of the Item	Location	Approximate No. of Batches (Batches may increase	Units	Testing Charge per Batch in Rs.	GST (In Rs.)	Total Charge per batch With GST(In Rs.) (Col 7+ Col 8)
1	2	3	4	5	7	8	9
1.01	Inj. Medroxyprogesterone Acetate IP .Each vial contains Medroxyprogesterone Acetate IP 150 mg/ml including 1 Sterile Disposable Single Syringe 2 ml with Needle +	1.Annex-I	500	Nos.			₹ 0.0000
1.02	Tabs-Tenofovir 300 mg	2.Annex-I	500	Nos.			₹ 0.0000
1.03	Tabs-Entecavir IP 0.5 mg ,1mg	3.Annex-I	500	Nos.			₹ 0.0000
1.04	Syrup- Zidovudine IP 50 mg	4.Annex-I	500	Nos.			₹ 0.0000
1.05	Tabs-Tenofovir 300 mg+ Lamivudine 300 mg+ Dolutegravir 50 mg (TLD)	5.Annex-I	500	Nos.			₹ 0.0000
1.06	Tabs- Dolutegravir 50 mg	6.Annex-I	500	Nos.			₹ 0.0000
1.07	Tabs- Darunavir 600 mg	7.Annex-I	500	Nos.			₹ 0.0000
1.08	Tabs- Ritonavir 100 mg	8.Annex-I	500	Nos.			₹ 0.0000
1.09	Tabs-Delamanid 50 mg	9.Annex-I	500	Nos.			₹ 0.0000
1.1	Inj. Benzathine Penicillin (2.4 Million Unit) with water for Injection 10 ml.	11.Annex-I	500	Nos.			₹ 0.0000
1.11	IFA Tabs / Syrups (Ferrous sulphate and Folic acid tablets IP)	12.Annex-I	500	Nos.			₹ 0.0000
1.12	Buprenorphine 0.4 mg/ 2mg [330]	13.Annex-I	500	Nos.			₹ 0.0000
1.13	Syrup Nevirapine [264]	14.Annex-I	500	Nos.			₹ 0.0000
1.14	Zidovudine 300mg + Lamivudine 150		500	Nos.			₹ 0.0000

***Annexure*-XI**

Bank Guarantee for EMD (Format)

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

_____

*[insert **Bank's Name**, and **Address** of Issuing Branch or Office]*
Beneficiary: *[insert **Name and Address of Purchaser**]*
Date: _____
BIDGUARANTEE No.: _____

We have been informed that *[insert **name of the Tenderer**]* (hereinafter called "the Tenderer") has submitted to you its bid dated (hereinafter called "the Bid")for the execution of *[insert **name of contract**]*under Tender No……
Further more, we understand that, according to your conditions, bids must be supported by a EMD.

At the request of the Tenderer ,we *[insert **name of Bank**]* hereby irrevocably under take to pay you any sum or sums not exceeding in total an amount of *[insert **amount in figures**]*(*[insert **amount inwords**]*) upon receipt by us of your first demand in writing accompanied by a written statement stating that the Tenderer is in breach of its obligation(s) under the bid conditions, because the Tenderer :

(a)has withdrawn its Bid during the period of bid validity specified by the Tenderer in the Form of Bid; or
(b) having been notified of the acceptance of its Bid by the Purchaser during the period of bid validity, (i)fails or refuses to execute the Contract Form, if required, or(ii)fails or refuses to furnish the security deposit, in accordance with the Instructions to Tenderer s.
(c) does not accept the correction of the Bid Price
(d)This guarantee will expire: (a) if the Tenderer is the successful tenderer ,upon our receipt to copies of the contract signed by the Tenderer and the performance security issued to you upon the instruction of the Tenderer ; or(b) if the Tenderer is not the successful tenderer ,upon the earlier of (i) our receipt of a copy of your notification to the Tenderer of the name of the successful tenderer ;or (ii) Forty five days after the expiration of the Tenderer 's Bid.

Consequently, any demand for payment under this guarantee must be received by us at the office on or before that date.
This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No. 758.

_____
[signature(s)]

Annexure-XII

Security Bank Guarantee (Format)

_____ *[insert: **Bank's Name, and Address of Issuing Branch or Office**]*

Beneficiary: _____ *[insert: **Name and Address of Purchaser**]*
Date: _____

PERFORMANCE GUARANTEE No.: _____

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

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

At the request of the Supplier, we *[insert: **name of Bank**]* hereby irrevocably undertake to pay you any sum or sums not exceeding in total an amount of *[insert: **amount in figures**]* (___) *[insert: **amount in words**]*[1] upon receipt by us of your first demand in writing accompanied by a written statement stating that the Supplier is in breach of its obligation(s) under the Tender , without your needing to prove or to show grounds for your demand or the sum specified therein.

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

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

_____

[signature(s)]

ANNEXURE-XIII

Instructions for Online Bid Submission

The bidders 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 bidders 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: https://eprocure.gov.in/eprocure/app

REGISTRATION

1) Bidders are required to enroll on the e-Procurement module of the Central Public Procurement Portal (URL: https://eprocure.gov.in/eprocure/app) by clicking on the link "**Online bidder Enrollment**" on the CPP Portal which is free of charge.
2) As part of the enrolment process, the bidders will be required to choose a unique username and assign a password for their accounts.
3) Bidders 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 bidders 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 bidder. Please note that the bidders are responsible to ensure that they do not lend their DSC's to others which may lead to misuse.
6) Bidder then logs in to 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 bidders 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 bidders 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 bidders 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 bidders through SMS / e-mail in case there is any corrigendum issued to the tender document.

3) The bidder 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) Bidder should take into account any corrigendum published on the tender document before submitting their bids.

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

3) Bidder, in advance, should get ready the bid documents to be submitted as indicated in the tender document / schedule and generally, they can be in PDF / XLS / RAR / DWF/JPG formats. Bid documents may be scanned with 100 dpi 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 bidders. Bidders can use "My Space" or ''Other Important Documents'' area available to them to upload such documents. These documents may be directly submitted from the "My Space" area while submitting a bid, and need not be uploaded again and again. This will lead to a reduction in the time required for bid submission process.

SUBMISSION OF BIDS

1) Bidder 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. Bidder will be responsible for any delay due to other issues.

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

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

4) Bidder 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) Bidders 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 bidders. Bidders are required to download the BoQ file, open it and complete the white colored (unprotected) cells with their respective financial quotes and other details (such

as name of the bidder). No other cells should be changed. Once the details have been completed, the bidder should save it and submit it online, without changing the filename. If the BoQ file is found to be modified by the bidder, the bid will be rejected.

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

7) All the documents being submitted by the bidders 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 Layer 128 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 asymmetric encryption using buyers/bid openers' public keys. Overall, the uploaded tender documents become readable only after the tender opening by the authorized bid openers.

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

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

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

ASSISTANCE TO BIDDERS

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- XIV

No Deviation Certificate

This is to certify that the product(s) Analysis _____ by our Laboratory,. _____ is as per the given IP/BP/USP PHARMACOPOEIA/INHOUSE SPECIFICATION OR AS PER TECHNICAL SPECIFICATIONS in the tender document & there is no deviation in relation to any conditions/requirements specified in the tender document.

Signature (with Stamp)

Annexure-XV

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. Authorized 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-XVI

NOTARISED UNDERTAKING BY MSE COMPANIES

(In 20- Rupees stamp paper)

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

2. Whereas, CMSS (Tender Inviting Authority) has invited Tender for analysis of drugs and other items in pursuant to the conditions in the tender documents. M/s _____ (Proprietary Concern/ Firm / Company Ltd.), having its Office at _____ _____ is exempted from payment of Earnest Money Deposit as indicated in the **Annexure-III** of tender document.

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

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

M/s _____

For Self and Firm / Company Ltd.
Signature and Seal

Witness:-
(1)
(2)

Annexure-XVII

UNDERTAKING FOR LAND BORDER SHARING WITH INDIA

"We have read the clause regarding restrictions on procurement from entities having beneficial ownership of a country which shares a land border with India and on sub-contracting to contractors from such countries, as stipulated vide Department of Expenditure Order No F.7/10/2021-PPD (1), dated 23.02.2023 as amended till date of bid submission, and solemnly certify that we fulfil all requirements in this regard and are eligible to be considered. We certify that:

a) *we are not from such a country or, if from such a country, we are registered with the Competent Authority (copy enclosed). and;*
b) *we shall not subcontract any work to a contractor from such countries unless such contractor is registered with the Competent Authority.*

Signature (with Stamp)

Annexure-XVII

LIST OF ITEMS QUOTED AND THEIR MONTHLY ANALYSIS CAPACITY AND TIMELINE

S.No.	Drug Name	Monthly Capacity	Testing Timeline
1.	Inj. Medroxyprogesterone Acetate IP .Each vial contains Medroxyprogesterone Acetate IP 150 mg/ml including 1 Sterile Disposable Single Syringe 2 ml with Needle + Alcohol Swab		
2.	Tabs-Tenofovir 300 mg		
3.	Tabs-Entecavir IP 0.5 mg ,1 mg		
4.	Syrup- Zidovudine IP 50 mg		
5.	Tabs-Tenofovir 300 mg+ Lamivudine 300 mg+ Dolutegravir 50 mg (TLD)		
6.	Tabs- Dolutegravir 50 mg		
7.	Tabs- Darunavir 600 mg		
8.	Tabs- Ritonavir 100 mg		
9.	Tabs-Delamanid 50 mg		
10.	Inj. Benzathine Penicillin (2.4 Million Unit) with water for Injection 10 ml.		
11.	IFA Tabs / Syrups (Ferrous sulphate and Folic acid tablets IP)		
12.	Buprenorphine 0.4 mg/ 2mg [330]		
13.	Syrup Nevirapine [264]		
14.	Zidovudine 300mg , Lamivudine 150 mg & Nevirapine 200mg / Tablets [115]		
15.	Tablet Ivermectin 3mg [305]		
16.	Zidovudine 60 mg, Lamivudine 30 mg & Nevirapine 50 mg / Tablets [118]		
17.	Ambisome Inj. 50 mg / Vials [75]		
18.	Artesunate Injections/Kits (Artesunate Injection IP with Sodium Bicarbonate Injection IP, Sodium Chloride Injection IP) (Along with Disposable Syringe And Needle)]		
19.	Amphotericin-B for Injection for Kala-Azar / Vials [76]		
20.	STI/RTI Kit- 1 contains Azithromycin 1gm and Cefixime 400 mg (1 tablet each) [331]		
21.	STI/RTI Kit- 2 contains Secnidazole 1 gm- 2 tablets and Fluconazole 150 mg- 1 tab [332]		
22.	STI/RTI Kit- 3 contains Azithromycin 1 gm- 1 tab [333]		
23.	STI/RTI Kit- 4 contains Azithromycin 1 gm 1 tab. and Doxycycline 100 mg 30 tabs/Caps [334]		
24.	STI/RTI Kit- 5 contains Acyclovir 400 mg - 21 tab		
25.	STI/RTI Kit- 6 contains Cefixime 400 mg- 1 tab., Doxycycline 100 mg 28 tabs/Caps and Metronidazole 400 mg 28 tabs		
26.	STI/RTI Kit- 7 contains Azithromycin 1 gm 1 tab. and Doxycycline 100 mg 42 Tabs/Caps		

Signature (with Stamp)