

**ONLINE TENDER FOR PROCUREMENT OF
BUPRENORPHINE 0.4 MG FOR NATIONAL AIDS
CONTROL PROGRAM
FOR THE YEAR 2023-24**

Tender No: CMSS/PROC/2023-24/NACO/046
(National Competitive Bidding)
(FOR CLASS-1 & CLASS-2 LOCAL SUPPLIERS ONLY)

CENTRAL MEDICAL SERVICES SOCIETY

Ministry of Health & Family Welfare (Government of India)

2nd floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Road, Opposite Police
Station Chanakaya Puri, New Delhi-110021

Telephones: 011-21410905, 21410906

Email: - gmproc1@cmss.gov.in, agmproc2@cmss.gov.in

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**ONLINE BIDS ARE INVITED IN TWO PACKET BID SYSTEM FOR PROCUREMENT OF BUPRENORPHONE
0.4 MG FOR NACO.**

Manual bids shall not be accepted.

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

CRITICAL DATESHEET

Published Date	04.10.2023
Pre bid meeting	12.10.2023 (11:00 AM)
Last date & time to submit pre-bid queries	12.10.2023 (05:00 PM)
Bid Document Download End Date & time	26.10.2023(03:00PM)
Bid Submission End Date and Time	26.10.2023(03:00PM)
Last date of submission of original documents	27.10.2023(03:00PM)
Bid Opening Date and Time	27.10.2023(04:00PM)

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

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

Address for Communication :

Central Medical Services Society,
2nd Floor, Vishwa Yuvak Kendra,
Pandit Uma Shankar Dikshit Road,
Chanakyapuri, New Delhi-110021

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Online Tender for Procurement of Buprenorphine 0.4 MG for the year 2023-2024.

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

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

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

Tender Inviting Authority invites tender through online bid submission at CPPP website: <https://eprocure.gov.in/eprocure/app> for supply of Drugs to Central Medical Services Society for the year 2023-24.

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

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

1. LAST DATE FOR RECEIPT OF TENDER

Online Tenders (in two separate packets {Technical bid "Packet 1" and Price Bid "Packet 2"}) will be submitted online at CPPP website:

<https://eprocure.gov.in/eprocure/app> as per critical date sheet. The list of items along with their Technical Specifications are attached here as **Annexure-I**.

2. BID VALIDITY:

- i) The bid shall be valid for a period of 150 days from the date of opening of Packet-1 (Technical Bid).
- ii) In exceptional circumstances, the purchaser may request the consent of the bidder for an extension to the period of bid validity. The request and the responses there to shall be made in writing. The bid security provided under clause-9 shall also be suitably extended. A bidder may refuse the request without forfeiting his bid security. A bidder accepting the request and granting extension will not be permitted to modify his bid.

3. PRE-BID MEETING/CLARIFICATIONS:

- i) A prospective bidder, requiring any clarification of the bid documents may notify the purchaser in writing or email at the purchaser's mailing address indicated in the Invitation of bid. The purchaser shall respond in writing to any request for clarification of bid documents, which it receives not later than date mentioned in critical date sheet and prior to the pre-bid meeting. **Queries received after the pre-bid date mentioned in the critical date sheet will not be entertained.**
- ii) The Tenderers or their Official Representatives are invited to attend a pre- bid meeting which will take place as specified in critical date sheet/CPP Portal.
- iii) Any clarification issued by CMSS in response to query raised by prospective bidders shall form an integral part of bid documents and it may amount to an amendment of the relevant clauses of the bid documents.
- iv) The clarification if any will be uploaded at CPPP and on e-procurement website and bidder is expected to see the CMSS website for clarification before submitting the bid.

4. ELIGIBILITY CRITERIA

- a) Only Class- 1 local supplier and Class- II local supplier shall be eligible for participation. Bids from Class I/Class II supplier (MSE/Non MSE) as defined in Department of Pharmaceuticals under Ministry of Chemicals and Fertilizers order no F.No 31026/65/2020-MD dated 30.12.2021 shall be accepted. **Bids from firms/vendors other than Class- 1 and Class- II local supplier (MSE/Non MSE) shall be summarily rejected.**
- b) Tenderer shall be a manufacturer of quoted product and having valid own manufacturing license in the indicated pharmacopeia (in technical specification at Annexure IA) and Certificate of Pharmaceutical Product (COPP) as recommended by WHO in any of the pharmacopeia IP/BP/USP/IH (if the drug is not available in any pharmacopeia). The manufacturing license & COPP should be valid on the date of tender opening packet 1. In case of failure to submit the same, the bid shall not be considered any further.
- c) For all regulated products, the bidder should have at least two years i.e. 2020-21 and 2021-22 or 2021-22 & 2022-23 of manufacturing and marketing experience of the particular items as a manufacturer for each regulated product quoted in the tender. However, this would not apply to regulated products which have been licensed by DCG (I) in less than Two years ago. A permission from DCG (I) shall be required for all new regulated products to this effect.
- d) (i) Average Annual turnover for Tenderers in the last three years i.e., 2019-20, 2020-21 and 2021-22 or 2020-21, 2021-22 & 2022-23 shall not be less than the following: -

S.No.	Item Name	Turnover 100%	Turnover 50%
1	Buprenorphine 0.4 mg	4006491.494	2003245.747

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

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

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

- e) The bidder should not be blacklisted/ banned/ debarred (as whole) or for the tendered goods by CMSS, MoHFW and Department of Expenditure on the date of tender opening. Aforesaid debarred/banned/blacklisted bidder are not eligible to bid in the tender.
- f) Tenderer should quote at least for 50% of the tender quantity of each items quoted and the Tenderer shall have an annual production capacity not less than one and half times the quantity quoted for each schedule.
- g) For item, Tenderer should have supplied 40% of the quoted quantity of same or similar items during the last two financial years. Bidder should submit Purchase order copies and certificate duly issued by statutory auditor of the company on his letter head by certifying the quantities manufactured and marketed in trade, export, open market, sold to government institutions, private bodies etc. and the marketed quantities are not less than at least 40% of the quoted/ similar items.

Following drugs or its any formulation shall be considered as similar drugs:

a) The drugs listed at Serial No. 1, 3, 18, 20, 22, 34, 36, 37, 45 and 46 in Schedule H1- Annexure B and

b) The drugs notified as Essential Narcotic Drugs by GOI vide Gazetted Notification dtd. 05.05.2015.- Annexure C.

Annexures attached for reference.

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

- h) The manufacturer/supplier shall submit an undertaking of conformance to the rules and regulations laid down in the Narcotic Drugs and Psychotropic Substances ACT 1985 and its amendments, and the Drugs and Cosmetics Act 1940 and the rules thereof. The undertaking should be accompanied with all relevant documents and certificates. The bidders are requested to submit three years CBN Returns submitted to Central Bureau of Narcotics for the quoted drug. **CMSS may at its discretion seek compliance of above from CBN.**

5. GENERAL CONDITIONS

(i) FORGERY/FRAUD BY BIDDERS/SUPPLIER:

- a) Genuineness of the papers/documents/certificates/ declaration submitted with bid is the responsibility of the bidder. Also, the bidder should take utmost care in submitting undertakings/self-declaration/certificates along with its bid. If at any

stage it is found that the papers/documents/certificates/declaration/undertaking / self-certification submitted by the bidder are false/incorrect/suppressed/ misrepresented the actual fact or are not in order, are forged, manipulated, fabricated or altered, the bid or purchase order issued to the bidder is liable to be cancelled and further necessary action including forfeiture of its EMD/Security Deposit, debarring/blacklisting against the bidder will be taken. Purchaser may also initiate police/legal action and request concerned statutory authority for cancellation of license issued to supplier for tendered items.

- b) If any fraud, short supply of goods is detected on part of the bidder at any stage, the bid or work order/ Purchase order issued to the bidder is liable to be cancelled and further necessary action against the bidder including debarring/blacklisting will be taken.
- c) In any of above two cases, the CMSS is at liberty to make alternative purchase of the tendered items from other approved suppliers or in the open market or from any other Tenderer who might have quoted higher rates, at the risk and the cost of the supplier.

(ii) PATENT RIGHTS:

The supplier shall indemnify the purchaser against all third-party claims of infringement of patent, trade mark or industrial design rights arising from use of the goods or any part thereof.

In event of any such claim in respect of alleged breach of patent, registered designs, trademarks etc being made against TIA, the TIA shall notify the supplier of the same and the supplier shall at its own expenses take care of the same for settlement without any liability to the TIA.

(iii) TERMINATION FOR DEFAULT:

- i) The purchaser may, without prejudice to any other remedy for breach of contract, by written notice of default, sent to the supplier, terminate this contract in whole or in part.
- a) If the supplier fails to deliver any or all of the goods within the time period(s) specified in the contract, or any extension thereof granted by the purchaser.
- b) If the supplier fails to perform any other obligation(s) under the contract, and
- c) If the supplier, in either of the above circumstances, does not remedy his failure within a period of 15 days (or such longer period as the purchaser may authorize in writing) after receipt of the default notice from the purchaser.

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

(iv) TERMINATION FOR INSOLVENCY:

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

(v) SET OFF:

Any sum of money due and payable to the supplier (including security deposit refundable to him) under this contract may be appropriated by the purchaser and set off the same against any claim of the purchaser for payment of a sum of money arising out of this contract or under any other contract made by the supplier with the Purchaser.

- (vi)** Purchaser reserves the right to debar/blacklist a bidder for a suitable period in case he fails to honour his bid/contract without sufficient grounds.

(vii) BID SUBMISSION:

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

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

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

(viii) NEAR RELATIVE CERTIFICATE:

The bidder should give a certificate that none of his/her near relative as defined below is working in CMSS where he is going to apply for the tender. In case of Proprietorship firm certificate will be given by the proprietor. For partnership firm

certificate will be given by all the partners and in case of limited company by all the Directors of the company excluding Govt. of India/Financial Institutions nominees and independent non-official part time directors appointed by Govt. of India or the Governor of the state. Authorised signatory of bid may also sign this bid on behalf of the entire directors/ partners/ proprietor. Due to any breach of conditions by the company or firm or any other person the tender will be cancelled and bid security will be forfeited at any stage whenever it is noticed and CMSS will not pay any damage to the company or firm or the concerned person. The company or firm or the person will also be debarred for further participation for quoted item in the concerned unit.

The near relatives for this purpose are defined as:

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

An undertaking as specified in Annexure-XVI to be submitted.

6. TECHNICAL BID – “PACKET1”

- (a) Those indenting to participate in the tender (herein called Tenderer) should first ensure that they fulfil all the eligibility criteria and All documents should be valid on the date of tender opening packet 1:
- 6.1 The Tenderer should electronically submit the soft copies of following documents in Technical Bid“Packet1”. (All the documents submitted should be a signature and stamp of the Tenderer)."
- 6.2 (a) DD/FDR/RTGS/NEFT e-receipt or Bank Guarantee (if applicable) in respect of EMD as per Clause 9 of this Tender document or in case of MSE, a copy of their valid registration certificate in support of their being an MSE and a notarised undertaking given in Annexure VIII.
- (b) Tender Forwarding letter as per **Annexure-II**.
- (c) The Tenderer should furnish the Manufacturing License valid on tender opening for each items quoted been duly renewed up to date and the items quoted shall be clearly highlighted in the license. Original documents should be produced for verification when demanded. If the tendered drug is in Indian Pharmacopoeia (IP), then the manufacturing license has to be submitted in IP only.
- (d) Duly notarized general power of Attorney (on non-judicial stamp paper of worth Rs. 50/-) in favour of authorized signatory in case of partnership firm (to be signed by all partners) / proprietorship firm or board resolution in case of a company to sign the bid and bind the bidder. The signature of authorized

signatory should be duly attested. In case of proprietorship on its letter head of firm declares himself as proprietor with specimen signature.

- (e) Tenderer should have supplied 40% of the quoted quantity of same or similar items during the last two financial years. Bidder should submit Purchase order copies and certificate duly issued by statutory auditor of the company on his letter head by certifying the quantities manufactured and marketed in trade, export, open market, sold to government institutions, private bodies etc. and the marketed quantities are not less than at least 40% of the quoted/ similar items.

Following drugs or its any formulation shall be considered as similar drugs:

a) The drugs listed at Serial No. 1, 3, 18, 20, 22, 34, 36, 37, 45 and 46 in Schedule H1- Annexure B and

b) The drugs notified as Essential Narcotic Drugs by GOI vide Gazetted Notification dtd. 05.05.2015.- Annexure C.

Annexures attached for reference.

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

- (f) Market standing certificate issued by the Licensing Authority as a Manufacturer for each item quoted for atleast last 2 years i.e., 2020-21 and 2021-22 or 2021-22 & 2022-23 and the submitted CBN return for 2020-21 and 2021-22 of quoted product shall be required for compliance of Tender Clause 4 (d). However, this would not apply to regulated products which have been licensed by DCG (I) less than two years ago.
- (g) Non-Conviction Certificate issued by the FDA/ Drugs Controller of the State certifying that the firm/company (as well as the manufacturer firm in case of non-manufacturer bidders) has not been convicted and the products quoted have not been cancelled during last two years i.e., 2020-21 and 2021-22 or 2021-22 & 2022-23.
- (h) Capacity certificate issued by the licensing authority should be submitted.
- (i) Performance Statement to establish 2 years market standing as per format given in **Annexure-IV**.
- (j) Annual turnover statement for 3 years i.e., 2019-20, 2020-21 & 2021-22 or 2020-21 2021-22 & 2022-23 should be furnished in the format given in **Annexure-V** duly certified by the Chartered Accountant.
- (k) Copies of the audited Annual reports including the Balance Sheet and Profit and Loss Account along with all the annexure for the last three years i.e., 2019-20,

2020-21 and 2021-22 or 2020-21, 2021-22 & 2022-23 duly certified by a practicing Chartered Accountant.

- (l) i) Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life. However, For the drugs recently introduced in the country (introduced in the last two years, the requirement for Long Term (Real Time) Stability Data of the quoted product in specified packing for atleast 3 batches, to support shelf life shall be waived off. Pont no (iii) shall be applicable.

ii) Only for the drugs introduced in Indian Pharmacopeia in the recent past (last years), Long Term Stability Data for previously approved Pharmacopeia or In House Standards shall be accepted, as the case may be.
iii) Accelerated Stability data for a period of 6 months in specified packing for at least 3 batches and available long Term (Real Time) stability data as available for the quoted product shall be submitted.
iv) Certificate of Analysis of one batch of the quoted product should be submitted.
- (m) List of items quoted (the name and item code of the items quoted) and relevant pharmacopoeia annual production for the last 3 years as per the **Annexure-VI**.
- (n) A Checklist (**Annexure-VII**) indicating the documents submitted with the tender document and their respective page numbers shall be enclosed with the tender document. The documents should be serially arranged.
- (o) Each page of submitted bid (along with tender document) be properly page numbered and shall be signed by the authorized signatory of the Tenderer with office seal.
- (p) All the documents enclosed with the tender document should also be signed by the authorized signatory of the Tenderer.
- (q) No Deviation Certificate as per **Annexure-XV**.
- (r) Near Relative Certificate as per **Annexure-XVI**.
- (s) Tenderer should submit a certificate from the statutory auditor or cost auditor of the company (in the case of companies) or from a practicing cost accountant or practicing chartered accountant (in respect of suppliers other than companies) giving the percentage of local content at the time of submission of bid as per **Annexure-XVII**.
- (t) Vendors are requested to fulfil the requirements of Ministry of Finance, Department of Expenditure, Procurement Policy Division Office Memorandum No.- 6/9/2020-PPD dated 24.08.2020.
- (u) Tenderer should submit an Undertaking on Letter head to Compliance to Ministry of Finance, DOE order No- 6/18/2019-PPD dated 23.07.2020 as per **Annexure-XVIII**.
- (v) Tenderer should submit an undertaking that

“I/ We do hereby declare that our firm has not been blacklisted/ banned/debarred by CMSS, MoHFW and Department of Expenditure or the Firm/ Company (as whole) has not been debarred as a whole by these organizations”

- (w) Para wise compliance of technical specification of the quoted items.
- (x) The tenderers are requested to submit an undertaking on their letterhead for compliance to the Artwork enclosed for the items quoted by them. No further approval for Artwork would be provided by CMSS to any bidder.
- (y) A valid WHO-GMP/GMP and Valid Certificate of Pharmaceutical Product (CoPP) as recommended by WHO in any Pharmacopeia IP/BP/USP/IH (if drug not available in any pharmacopeia).
- (z) Manufacturers must have CBN Registration Number and CBN Return for the last three years for the quoted product and the same should be submitted with the technical bid. The manufacturer/supplier shall submit an undertaking of conformance to the rules and regulations laid down in the Narcotic Drugs and Psychotropic Substances ACT 1985 and its amendments, and the Drugs and Cosmetics Act 1940 and the rules thereof. The undertaking should be accompanied with all relevant documents and certificates.

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

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

(c) Conditional Bids shall be summarily rejected

7. PRICE BID- “Packet 2” :

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-XX**.
- iii) The supplier shall quote as per price schedule given in **Annexure-XX** for all the items quoted by him as per schedule of requirement.
- iv) The price quoted shall be the landed price per unit at the specified locations on DDP basis and shall include all taxes and duties including transportation and other incidental expenditure for delivery at CMSS warehouses.
- v) The rate quoted in Price Schedule **Annexure-XX** should be for a unit as given in specifications as detailed in the tender document. The bidder is not permitted to change / alter specification or unit size in the box.

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

- i. The bidder may quote for GST as per applicability in accordance with relevant Government notification.
- ii. Any variation upwards/down wards 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 benefits 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.
- v. 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.
- vi. Breakup of the quoted price indicating the various components like Ex Work, GST, Transportation cost etc. has to be submitted, if desired by the TIA before placing the order

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

- 8.1 To assist in the examination, evaluation and comparison of bids, the purchaser may, at his discretion ask the bidder for the clarification in its bid. The request for the clarification and response shall be in writing. However, no post bid clarification at the initiative of the bidder shall be entertained. Documents issued after the date of tender opening will not be accepted.
- 8.2 Tenderers are advised to submit all the required documents as per tender terms and conditions. Failure to submit shall result in rejection of bids. Clarifications (if required) to assist in the evaluation of bids will be asked by the purchaser only once. The tenderer is requested to reply in the given time by purchaser.

- 8.3 The purchaser shall evaluate the bids to determine whether they are complete, whether any computational errors have been made, whether required sureties have been furnished, whether the documents have been properly signed and whether the bids are generally in order.
- 8.4 Prior to the detailed evaluation, pursuant to clause above, the purchaser will determine the substantial responsiveness of each bid to the bid documents for purposes of these clauses. A substantially responsive bid is one, which confirms to all the terms and conditions of the bid documents without material deviations. The purchaser's determination of bid's responsiveness shall be based on the contents of the bid itself without recourse to extrinsic evidence.
- 8.5 A bid determined as substantially non-responsive will be rejected by the purchaser and shall not subsequent to the bid opening be made responsive by the bidder by correction of the non-conformity.
- 8.6 The purchaser may waive any minor infirmity or non-conformity or irregularity in a bid, which does not constitute a material deviation, provided such waiver does not prejudice or affect the relative ranking of any bidder. Such minor infirmity will be identified by the TEC and clarification in this regard may be called for.
- 8.7 Technical Evaluation Summary will be uploaded on CPPP Portal. The bidders are intimated that representations, if any, may be sent before price bid opening as per schedule indicated in uploaded summary. Any representations received after the indicated date and time would not be entertained **under any circumstances**. No new document would be allowed to be submitted at this stage.
- 8.8 "Packet 2" will be opened only for tenderers, who are found **techno-commercially** eligible on satisfying the criteria for technical evaluation and plant inspection **(wherever necessary)** based on the documents submitted in "Packet 1". Presence of authorized official of Tenderers is not necessary in opening of "Packet 2" as opening is online.
- 8.9 Arithmetical errors shall be rectified on the following basis. If there is a discrepancy between the unit price and total price that is obtained multiplying the unit price and quantity, the unit price shall prevail and total price shall be corrected by the purchaser. If there is a discrepancy between words and figures, the amount in words shall prevail.

9. EARNEST MONEY DEPOSIT

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

Beneficiary Name: Central Medical Services Society

A/C No.: 32719062216

Bank Name: SBI Bank

Branch: Nirman Bhawan, Maulana Azad Road, New Delhi

IFSC Code: SBIN0000583

- (b) Bank Guarantee (**as per Annexure-XIV**) can also be accepted as a mode of payment and the named beneficiary shall be Central Medical Services Society. The Bank guarantee shall be issued by a bank (Nationalized or Scheduled Bank) in India to make it enforceable and acceptable to the purchaser. The Bank Guarantee shall be in the format as per **Annexure-XIV** provided in the tender document. EMD shall remain valid for 45 days beyond the validity period for the bid and will be extended accordingly beyond any extension subsequently requested by purchaser.
- (d) The applicable EMD amount has been indicated in **Annexure-III** and is for 100% and 50% quantity of the schedule. If quoted quantity is anywhere between 50% to 100% of the quantity of schedule, the applicable EMD may be calculated by the tenderer by proportionately reducing the amount applicable to 100% quantity.

9.2 EXEMPTION FROM PAYMENT OF EARNEST MONEY DEPOSIT TO MSME (MICRO & SMALL ENTERPRISES)

- (i) (The MSE Units will be required to furnish a notarized undertaking (as per **Annexure-VIII**) to the effect that in the event of non-fulfillment or non-observance of any of the conditions stipulated in the tender, the MSE Unit shall pay a penalty, equivalent to the Earnest Money Deposit to offset the loss incurred by the Tender Inviting Authority consequent on such breach of any bid condition.
- (ii) Vide Gazette no. CG-DL-E-26062020-220191 dt. 26.06.2020, Ministry of MSME have revised criteria for classifying the enterprises as Micro, small and medium enterprises with effect from 1st July 2020 therefore following firms will be exempted from submission of EMD.
- a) Micro and Small Enterprises as per classification given in MSME Notification dtd. 26.06.2020 registered under "Udyam Registration" w.e.f. 01.07.2020 will be granted exemption from payment of Earnest Money Deposit. Udyam Registration Certificate has to be produced in support of above.

Note: Traders will not get benefit of MSE Firms

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

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

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

9.4 FORFEITURE OF EMD (if applicable)

- (i) The Earnest Money Deposit (EMD) will be forfeited/vendor would be required to deposit the equivalent EMD amount as per Notarised Undertaking by MSE bidder, if the Tenderer withdraws or amends, impairs or derogates from the tender in any respect within the period of validity of his Tender.
- (ii) The Earnest Money Deposit (EMD) will be forfeited/ vendor would be required to deposit the equivalent EMD amount as per Notarised Undertaking by MSE bidder, in case of the lowest/ matched bidder, fails to execute the contract agreement and / or deposit the Security Deposit within the stipulated time. Additionally, actions as stipulated in clause no. 18.1 will also be taken.
- (iii) In both the above cases, the bidder will not be eligible to participate in the tender for same item for two years from the date of issue of letter of acceptance. The bidder will not approach the court against the decision of the CMSS in this regard.

10. OTHER CONDITIONS:

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

- (i) Central Medical Services Society (CMSS) will have the right to increase or decrease up to 25% of the quantity of goods and/or services specified in the schedule of requirements without any change in the unit price or other terms and conditions at the time of award of contract.
- (ii) In exceptional situation where the requirement is of an emergent nature and/ or it is necessary to ensure continued supplies from the existing vendors, the purchaser reserves the right to place repeat order up to 50% of the quantity of the goods and/or services contained in the running tender/contract up to a period of twelve months from the earliest date of Long Term agreement (LTA) at the same rate or a rate negotiated (downwardly) with the existing vendors considering the reasonability of rates based on prevailing market conditions and the impact of reduction in duties and taxes etc.
- (iii) The delivery of the additional quantity (as per ii above) shall be scheduled after the completion of the delivery of the original tendered quantity or on mutual consent between the supplier and CMSS.

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

- (ii) Any upward/downward revision (only during scheduled delivery period) in statutory taxes, levies will be allowed and benefit will pass on to supplier/purchaser.
 - (iii) Any increase in taxes and other statutory duties/levies after the expiry of the delivery date shall be to the supplier's accounts. However, the benefit of any decrease in these taxes/duties shall be passed on to the purchaser by the supplier.
 - (iv) The delivery of the additional quantity shall be scheduled after the completion of the delivery of the original tendered quantity.
- 10.3 In accordance to the notification the participating Micro and Small Enterprises (MSEs) in a tender, quoting price within the band of L 1 + 15% would be allowed to supply a portion of the requirement by bringing down their price to the L 1 price, in a situation where L 1 price is from someone other than an MSE. In exercising of the powers conferred in Section 11 of the Micro, Small and Medium Enterprises Development (MSMED) Act 2006, the Government has notified a new Public Procurement Policy for Micro & Small Enterprises effective from 9th November 2018. The policy mandates that 25% of procurement of annual requirement of goods and services by all Central Ministries / Public Sector Undertakings will be from the Micro and Small Enterprises. Government has also earmarked a sub target of 4% procurement of goods & services out of 25% from MSEs owned by SC/ST entrepreneurs and 3% to micro and small enterprises owned by women.
- 10.4 For quoted items, the Department of Pharmaceuticals under Ministry of Chemicals and Fertilizers has issued guidelines for implementation of the provisions of public procurement (Preference to Make in India) order (PPO) 2017 as desired by DPIIT vide order no **F.No. 31026/65/2020-MD dated 30.12.2020**. The relevant provisions of DoP order dt. 30.12.2020 and all subsequent orders from time to time will apply in the instant case. Bidders are requested to submit a declaration indicating percentage of local content as per **Annexure-XII**.

11. ACCEPTANCE OF TENDER

- 11.1 Technically responsive tenders will be evaluated based only on the "landed price" (all-inclusive price), i.e., Rate per Unit inclusive of all taxes, duties, transportation & other charges.
- 11.2 The evaluation for ranking shall be carried out on the basis of "all inclusive" prices of the goods offered for each schedule separately.
- 11.3 The purchaser reserves the right to accept or reject any bid, and to annul the bidding process and reject all bids, at any time prior to award of contract without assigning any reason whatsoever and without thereby incurring any liability to the affected bidder or bidders on the grounds of purchaser's action.

- 11.4 (i) CMSS or its authorized representative(s) has the right to inspect the factories of Tenderers, before accepting the rate quoted by them or before releasing any purchase order(s) or at any point of time during the continuance of tender and also has the right to reject the tender or terminate/ cancel the purchase orders issued and/or not to place further order, based on adverse reports brought out during such inspections. In such situation CMSS reserves the right to take other actions against the tenderer including forfeit of security deposit, debarring/blacklisting for appropriate period.
- (ii) The Tenderer shall allow inspection of the factory at any time by a team of Experts/ Officials nominated by the Tender Inviting Authority for the purpose. The Tenderer shall extend necessary cooperation to such team in inspection of the manufacturing process, quality control measures adopted etc., in the manufacture of the items quoted. If Company/ Firm does not allow for any such inspection, their tenders will be rejected during the currency of the contract.
- 11.5 The acceptance of the tenders will be communicated to the lowest / matched tenderers in writing (through email), as per format of the Acceptance Letter given in **Annexure-IX**.

12. SECURITY DEPOSIT AND AGREEMENT

12.1 Security Deposit:

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

On being intimated about the acceptance of the tender the L1/Matched tenderer shall pay a Security Deposit at the rate of 3% of the total value of goods to be awarded. The Security Deposit amount, is to be deposited in the form of NEFT/RTGS/Fixed Deposit Receipt/Demand Draft (payable at New Delhi)/Bank Guarantee in favor of Central Medical Service Society.

Beneficiary Name: Central Medical Services Society

A/C No. 32719062216

Bank Name: SBI Bank

Branch: Nirman Bhawan, Maulana Azad Road, New Delhi

IFSC Code: SBIN0000583

- 12.2 The Performance Bank Guarantee shall be valid for **1260** days from the date of commencement.

LOA Submission	15 days
Rate Valid	365 days
Delivery period	90 days
Shelf life	365 x 2 Years
B.G. Extension	<u>60 days</u>
	<u>1260 days</u>

- 12.3 The lowest/matched tenderer shall execute an Agreement on a non-judicial stamp paper of value of Rs.100/- (stamp duty to be paid by the Tenderer) within 15 days from the date of the intimation from CMSS informing that his tender has been accepted. The Specimen form of Agreement is available in **Annexure-X**.
- 12.4 The proceeds of the performance security shall be payable to the purchaser as compensation for any loss resulting from the supplier's failure to complete its obligations under the contract.
- 12.5 The performance security bond will be discharged by the purchaser after completion of the supplier's performance obligations including any warranty obligations under the contract.
- 12.6 Failure to deposit the performance security will attract clause 9.4.

13. METHODOLOGY FOR PLACING ORDERS

For placing orders the following procedures will be adopted:

- 13.1 After the Price Bid opening, the lowest offer will be declared as the L1 tenderer. CMSS reserves right to negotiate prices with L1 bidder in justified cases.
- 13.2 The Tenderer, who has been declared as Lowest Tenderer for certain item(s), shall within the tender issue of LOA (letter of acceptance) execute necessary Agreement for the supply of the allocated quantity of such items as specified in the Tender Document after depositing the required amount as Security Deposit and on execution of the agreement such Tenderer shall supply goods on receipt of Purchase Orders. The format of LOA, agreement, Purchase Order is attached at **Annexure –IX, X, XI** respectively. Generally speaking, the draft art work should be given in technical specifications however, in those cases where draft artwork not given in tender specifications, the vendor must need to coordinate with respective programme division of ministry to freeze (get approval) for the art work. No extension would be given on this pretext.
- 13.3 If two or more than two Tenderers are declared as lowest suppliers for the same item(s) (i.e. emerge L1), such Tenderers shall execute necessary agreement as specified in the Tender Document on depositing the required amount as Security Deposit and on execution of the agreement such Tenderer will be eligible for placement of Purchase Orders for equal proportion of tendered quantities (50:50 or 33.33:33.33:33.33) for such item(s) for which they are declared as lowest (L1).
- 13.4 CMSS will counter offer the lowest rate (L1 rate) to other Tenderers in the order of their ranking i.e. L2, L3 and soon will be asked to match the L1 price.
- 13.5 CMSS will counter offer the lowest rate (L1 rate) to other Tenderers in the order of their ranking i.e. L2, L3 and soon will be asked to match the L1 price.

- i. In order to maintain uninterrupted supplies, the CMSS will place orders with minimum of two suppliers for tendered product with 70% of the orders given to L1 and the balance 30% to the next Matched Lowest Tenderer.
 - ii. In case there is no L2 /matched bidder, balance quantity up to extent of quoted quantity or at most for balance 50% quantity can be offered to L1 bidder. Quantity beyond quoted quantity will be ordered on mutual consent.
 - iii. In case, L2 bidder/matched bidder refuses to accept the offered quantity, balance quantity up to extent of quoted quantity or at most for balance 50% quantity can be offered to L1 bidder. Quantity beyond quoted quantity (and including quantity in consideration in Clause No. 10.1 (i)) will be ordered on mutual consent.
 - iv. In case L1 bidder has quoted for 50% quantity, the balance quantity will be offered to L2 and L3 bidders for 30% and 20% quantity respectively.
 - v. In case there is no L3/ matched bidder at 3rd position (i) above may be followed or balance 50% quantity may be offered to L2/matched bidder in case L1 does not agree to supply 70% of tendered quantity.
 - vi. In case of requirement of large quantities, CMSS may place orders with 3 suppliers in the ratio of 50:30:20, which will be indicated in the tender document at **Annexure-I**.
- 13.6 If the lowest supplier has failed to supply the required items within the stipulated time or within the extended time, as the case may be, CMSS may cancel such purchase orders and on cancellation, CMSS may place Purchase Orders with the Matched Lowest Tenderer or to the other tenderers at the risk and cost of the defaulted supplier.
- 13.7 The supplier shall complete the supply of the items required by CMSS at the consignee destination mentioned in the schedule, within minimum required period as stipulated in order from the date of the orders.
- 13.8 The supplier shall supply the items at the specified destination and submit a copy of the Purchase Order, Delivery Challan and other relevant documents at the same destinations.
- 13.9 After supply of items at the specified destinations, the supplier shall submit Invoice (Original), Certificate of analysis (Batch Wise) and other relevant documents etc., at the Head Office, CMSS for claiming payment.
- 13.10 Subject to para (13.6) to para (13.9) above, CMSS will process the invoices submitted by the supplier and the payments against supply will be made within 60 days from the date of submission of all relevant documents to the CMSS provided the items supplied has been declared of STANDARD QUALITY, by the Empanelled Laboratory of CMSS.

14 SUPPLY / DELIVERY CONDITIONS

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

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

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

(b) With the prior approval of CMSS, the supplier may continue to supply the unexecuted quantity after 60th day or after the delivery dates/schedule as mentioned in order with Liquidated Damages as specified in Clause 18 of the tender conditions on the delayed supplies.

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

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

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

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

14.6A Certificate of Analysis/ Performance Evaluation Report from manufacturer's own Quality Control Lab covering each batch delivered is to be submitted along with shipping documents.

The Certificate of Analysis shall include:

- a) Generic name of the product
- b) Batch No.
- c) Pharmacopeial Reference and/ or In-house method
- d) Batch quantity
- e) Date of manufacture
- f) Expiry date
- g) Date of test
- h) Description

- i) All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharmacopoeia and/or In-house method. Both the actual results and the limits for the individual tests should be given
- j) Conclusion
- k) Qualified signatures
as applicable
OR/And

The Performance Evaluation Report shall include:

- a) Product name
- b) Lot/Batch Number
- c) Date of manufacture
- d) Date of Expiry
- e) Manufacturer's name
- f) Number of samples tested
- g) Testing principle

Information about reference used

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

The abovementioned batch shall be manufactured in accordance with the applicable GMP/QMS regulations.

- 14.7 All the Tenderers are required to supply the product(s) with printed text "FWP SUPPLIES – NOT FOR SALE" in red-colour on the strips, blisters, vials, ampoules & bottles and also on the external packings. The type/thickness of packing materials used in Blister packs may also be specified. Goods received without this print will not be accepted by CMSS/Consignee. Affixing of rubber stamp shall not be accepted. However, the approved art work will prevail.
- 14.8 If at any time the Tenderer has, in the opinion of the CMSS, delayed the supply of items due to one or more reasons related to Force Majeure events such as riots, mutinies, wars, fire, storm, tempest or other exceptional events at the manufacturing premises, the time for supplying the items may be extended by the CMSS at its discretion for such period as may be considered reasonable. However, such extension shall be considered only if a specific written request is made by the Tenderer within 10 days from the date of occurrence of such event. The exceptional events do not include scarcity of raw material, increase in the cost of raw material, electricity failure, labour disputes/ strikes, insolvency, and closure of the factory/ manufacturing unit on any grounds etc.
- 14.9 The supplier shall not be liable to pay LD/ penalty and forfeiture of security deposit for the delay in executing the contract on account of the extension of supply period on the ground of force majeure events.

15. PACKING

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

- 15.2 The Weight, Volume & Dimensions of shipping cartons & intermediate packaging carton may be mentioned.
- 15.3 The packing shall be of a sturdy quality to provide adequate protection of the product for carriage to final destination, **PAN INDIA** including remote locations under adverse climatic and storage conditions and high humidity. Used cartons should never be used.
- 15.4 Products with specific temperature requirements will be packed and stored and delivered in appropriate conditions.
- 15.5 The packaging unit should be strong, able to be stacked to a height of 4 pallets as static storage and 2 pallets during transport, and resistant to puncturing.
- 15.6 Special attention of suppliers is invited to ensure the material is of good quality and is free from development of fungus/termites. In case fungus/termites develops within 15 days of delivery at specified locations, suppliers at their own cost would lift the entire batch from various locations and supply fresh replaced batches. For LD purposes the date of receipt of replaced batches would count. In addition, the expenses on pest control to be undertaken by CMSS would be borne by the tenderer.

16. QUALITYCONTROL

- 16.1 Quality Control is an essential part of the current procurement and it is the responsibility of the supplier to ensure quality assurance as per specifications/bid document. The products should conform to the standards as specified in Annexure-I of the Tender document.
- 16.2 The bidder/ supplier understand that the tendered item/items is/are critical health goods and the quality parameters of supplied goods are to be ensured during complete specified shelf life as indicated in technical specification/bid document/ official compendium. Bidder/Supplier also appreciate that failure in quality checks is serious default as it may derail entire programme and can also risk the life of users of supplied health goods.
- 16.3 CMSS will embark on stringent quality checks to ensure that tendered goods meet required standards throughout specified shelf life. For this purpose, CMSS reserves the right to carry necessary inspections/tests at any of, or any combination of or/ all of following stages:
- (a) At Pre-Dispatch stage.
Pre-dispatch inspection for passing the quality of the goods, would be done before direct shipment to the consignees from supplier Warehouses (in India).
 - (b) At Delivery Stage: inspection done once the goods reach at consignee location and before taking over supplied goods in inventory.
 - (c) Post Delivery Surveillance: The Drugs/goods shall have the active ingredients and all other parameters at the prescribed level as indicated in official compendiums or technical specifications throughout the shelf-life period of the drugs/ goods. Quality Monitoring Activities may also be organized by CMSS post-delivery.
- 16.4 CMSS may engage the services of a Quality Control Agent & Quality Control Testing Laboratories for the purpose of Inspection & Quality Control.
- 16.5 **Inspection Methodology:**

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

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

In case of failure of batches during or at any stage(indicated at 16.5), the testing charges would be claimed for the defaulting vendor.

- 16.6 The supplies will be deemed to be completed only upon receipt of the quality certificates from the laboratories.
"Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be deemed to be rejected goods.
- 16.7 **At any of Inspection/testing stage**, samples which do not meet quality requirement/specifications shall render the relevant batches liable to be rejected. If the sample is declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be deemed to be rejected goods and the cost of entire batch paid will be recovered whether consumed fully/ partially. Besides action may also be initiated for debarring/blacklisting against supplier for suitable period.
- 16.8 In the event of the samples of Drugs/goods supplied fails in quality tests or found to be not as per specifications at any of testing stages (as mentioned in clause no. 16.3), depending upon the type, nature and seriousness of failure, consequences resulting from such default, availability of alternate sources, the CMSS is at liberty to either:
- (i) Ask the supplier to replace the entire quantity of relevant batches, in addition to imposition of penalty @ 25% of batch supply cost or
 - (ii) To make alternative purchase of the items of Drugs from other approved suppliers or in the open market or from any other Tenderer who might have quoted higher rates, at the risk and the cost of the supplier.
 - (iii) In addition to (i) or (ii) above, action to debar/blacklist the supplier for suitable period, as decided by CMSS may also be initiated. In addition to forfeiture of Performance Security Deposit.
 - (iv) In addition, the FDA/ Drugs Control Authority of concerned State will be informed for initiating necessary action on the Tenderer in their state. Security deposit will also be forfeited without any intimation.

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

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

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

17. PAYMENT PROVISIONS

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

17.2 The payment towards supply of items to CMSS will be made either by means of Cheque or through RTGS (Real Time Gross Settlement System)/ Core Banking/ NEFT. The Tenderer shall furnish the relevant details in original **(Annexure-XII)** to make the payment through RTGS/Core Banking/NEFT. The payment will be in INR only.

17.3 All bills/ Invoices should be raised in duplicate and the bills should be drawn in the name of Central Medical Services Society, 2nd Floor, Vishwa Yuvak Kendra, Pandit Uma Shankar Dikshit Road, Chanakyapuri, New Delhi-110021 or in the name of any other authority as may be designated. Suppliers have to mention e- aushadhi PO No. and tranche/ lot on the invoice.

17.4 Payments for supply will be made only after completion of supply of Items ordered in the individual Purchase Order PROVIDED quality reports are acceptable. The CMSS shall endeavour to make payment within 75 days in respect of items requiring sterility tests and within 60 days in respect of items requiring non- sterility test from the date of submission of invoice or from the date of receipt of material, whichever is later along with all the relevant documents of tender.

17.5 Lot/Tranche/PO wise Part payments for supply will be considered only after completion of supply of atleast 50% quantity ordered in the individual Purchase Order/Lot/Tranche PROVIDED original consignee receipts (or on GeM by consignee for the receipt, with original CRC to be submitted before next payment is released) are produced and the quality pass reports of Standard Quality on samples testing are received from approved laboratories of CMSS.

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

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

17.7 The supplier shall submit the following documents while claiming payments for supplies:

- (a) Delivery challan along with the supplies (POD)
- (b) Packing list
- (c) Certificate of analysis along with the supplies (for each batch supplied).
- (d) Itemized Invoice/ Bill in duplicate to CMSS Head Office.
- (e) Such other documents as required by CMSS.
- (f) Bidders are requested to submit their Original Invoice along with copies of Lorry Receipt/ Delivery challans and original Consignee Receipt Certificate (CRC) or such CRC to be uploaded on GeM by the consignee (if applicable) (with originals to be submitted before next payment is processed) as per format given in the tender document Annexure duly signed & stamped with other necessary documents for smooth processing of payment.

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

18. LIQUIDATED DAMAGES AND OTHER PENALTIES:

18.1 DELAYS IN SUPPLIER'S PERFORMANCE:

- (a) Delivery of the goods and performance of services shall be made by the supplier in accordance with the time schedule specified by the purchaser in its LOA/purchase order. In case the supply is not completed in the stipulated delivery period, as indicated in the LOA/purchase order or in case of non-submission of Security Deposit within the stipulated time, purchaser reserves the right either to short-close/cancel this LOA/purchase order and/or recover liquidated damage charges. The cancellation/short-closing of the LOA/Purchase order shall be at the risk and responsibility of the supplier and purchaser reserves the right to purchase balance-unsupplied quantity at the risk and cost of the defaulting vendor. This purchase at the risk and cost of the defaulting vendor can be at the same L1 cost of the tender or at higher cost and can be met through other vendors available in the present tender/contract or through any vendor from the open market. Any additional cost towards this risk purchase will be entirely borne/adjusted from running bills/demanded from the defaulting vendor.
- (b) Repeated/habitual delays by the supplier in the performance of its delivery obligations shall render the supplier liable to any or all of the following sanctions; imposition of liquidated damages, forfeiture of its performance security, and/or termination of the contract for default and purchaser reserves the right to purchase balance-unsupplied quantity at the risk and cost of the defaulting vendor.
- (c) If the suppliers are not completed in the extended delivery period, the purchase order may be short closed without any compensation to supplier and the performance security shall be forfeited.
- (d) Quantum of liquidated damages assessed and levied by the purchaser shall be final and not challengeable by the supplier.

- (e) Purchaser reserves the right to debar/blacklist the supplier for a suitable period who habitually failed to supply the goods/services in time. The decision of purchaser will be final and binding.
- 18.2 If the supply reaches the designated consignee places or CMSS Warehouse after scheduled delivery date mentioned in LOA/P.O, liquidated damages will be levied @ 2.5% per week to be applied proportionately on per day basis up to a maximum of 10% of P.O. Cost, irrespective of the fact that whether the CMSS has suffered any damage/ loss or not, on account of delay in effecting supply. If the last scheduled delivery day happens to be a holiday the supply will be accepted on the next working day without any penalty.
- 18.3 If the supply is received in damaged condition, it shall not be accepted. In case of damage in the packing only, the supply may be accepted subject to purchaser's decision and after levying a penalty which may be upto 5% of cost of package received with damaged packing.
- 18.4 Timely supply is the essence of contract/ Purchase order. The drugs/medicines/items ordered are meant for key National programmes & delay in supply can have the adverse impact on patients can derail the critical National level Disease Control Programme.

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

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

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

- a. The supplier will not dispatch/supply stocks/goods after the last date of scheduled delivery of the Lot/Tranche without PO amendment issued by procurement wing.
- b. CMSS Warehouses/Direct consignees would not accept any stock/goods of any Lot/tranche beyond scheduled delivery period in absence of delivery extension PO amendment. E-Aushadhi software functionality has been made that CMSS WHs would not be able to receive the goods (GRN creation barred). These consignees will accept the stocks beyond scheduled delivery date only if Procurement wing has issued PO Amendment for delivery extension.
- c. No extension of the delivery date would be granted suo motu unless the supplier specifically asks for it. However, in a few cases, it may be necessary to grant an extension of the delivery period suo motu in the interest of the administration. In such cases, the supplier should mandatorily submit clear acceptance of the extension letter.

- d. If at any time during the currency of the contract, the supplier encounters conditions hindering delivery of goods, he shall promptly inform the concerned officer in writing. The supplier/vendor should raise request for delivery time extension well in advance i.e., at least 15 days before scheduled delivery date, should mention the likely duration within which it intends to complete the supplies and request for extension of delivery schedule accordingly. On receiving the supplier's communication, CMSS shall examine the proposal and on approval from the CA, may consider issuing delivery extension with/without LD provided: -
 - i. That there are sufficient grounds for acceptance of such requests.
 - ii. That there is no falling trend in prices for this item as evidenced from the fact that, in the intervening period, neither orders have been placed at rates lower than this contract nor any tender been opened where such rates have been received even though the tender is not yet decided.
- e. In such cases, for delivery extension, PO amendment would be issued and the supplier should mandatorily supply the goods in extended time period.
- f. Vendors are strictly advised not to deliver/transport any consignment reaching beyond scheduled delivery date without proper PO amendment issued by Procurement wing of CMSS, as it would not be received by consignees. CMSS shall not process any bills of such supplies if made beyond LOA/PO delivery schedule and without any PO amendment. For such actions, vendor would be solely responsible.
- g. If the supplier again fails to deliver the balance quantity within extended time, CMSS reserves the rights/options to procure the undelivered quantity from other approved supplier available in the contract at the same rates (with no financial implication and without regular tender to save time) or from open market at the risk & cost of the defaulting supplier (which may be with financial implication) or grant further extension if deemed fit.

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

- h. After completion of complete LD period, if the supplier/vendor still fails to deliver goods (or a part of it) within extended timelines, actions against the supplier/vendor may be initiated for default in supplies as per terms & conditions stipulated in the tender including: -
 - i. CMSS reserves the rights/options to short close the delayed lot/tranche undelivered without going for purchase of balance quantity or
 - ii. Short close the delayed lot/tranche and go for procurement of the undelivered quantity from other approved supplier available in the contract at the same rates (with no financial implication) or from open market at the risk & cost of the defaulting supplier (which may be with financial implication).

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

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

19. WARRANTY

- 19.1 The supplier shall warrant that goods/items to be supplied shall be new and free from all defects and faults in material, workmanship and manufacturing and shall be of the highest grade and consistent with the established and generally accepted standards for materials of the type ordered and shall perform in full conformity with the specifications. Supplier shall warrant that goods supplied will meet and maintain the technical specification throughout specified shelf life. The supplier shall be responsible for any defects that may develop under proper storage/ use, arising because of improper quality of API, Excipients in packaging material etc. manufacturing /packaging details from faulty materials, manufacturing or workmanship or otherwise and shall remedy such defects at his own cost when called upon to do so by the purchaser who shall state in writing in what respect stores is faulty.
- 19.2 The portion of clause 16.8 (i) to (v) would also apply incase the goods/ items supplied doesn't match to shelf life.
- 19.3 Replacement under warranty clause shall be made by the Supplier within 60 days period, free of all charges at site including freight, insurance and other incidental charges.
- 19.4 If any defect is not remedied within a reasonable time the purchaser may proceed to procure such defective quantities at the Supplier's risk and cost from other tenderer or open market, but without prejudice to may other rights which the purchaser may have against the contract in respect of such defects.

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

- 20.1 If the samples do not conform to tender specifications, the Tenderer will be liable for relevant action under the existing laws and the entire stock in such batch has to be taken back by the Tenderer within a period of 30 days of the receipt of the letter from the CMSS. Such stock shall be taken back at the expense of the Tenderer. The CMSS has the right to destroy such "NOT OF STANDARD QUALITY DRUGS" if the Tenderer does not take back the goods within the stipulated time. The CMSS will arrange to destroy the "NOT OF STANDARD QUALITY DRUGS" after the expiry of 30 days mentioned above without further notice, and shall also collect demurrage charges calculated at the rate of 0.5% per week on the value of the drugs rejected till such time stipulated.
- 20.2 The CMSS will be at liberty to terminate, without assigning any reasons thereof, the contract either wholly or in part or short closed on 30 days' notice. The Tenderer will

not be entitled for any compensation whatsoever in respect of such termination besides forfeiture of Security Deposit and purchaser reserves the right to purchase balance- unsupplied item at the risk and cost of the defaulting vendor.

20.3 For infringement of the stipulations of the contract, for non-performance/ compliance of contractual terms or for other justifiable reasons, the contract may be terminated either wholly, or in part or short closed. by the CMSS and the Tenderer shall be liable to pay for all losses sustained by the CMSS in consequence of the termination which may be recovered personally from the Tenderer or from his properties, as per rules besides forfeiture of Security Deposit.

20.4 In the event of making Alternative Purchase, as specified in in Clause 13(f), Clause 14.2(a), Clause 16.8 and other clauses herein, penalty will be imposed on the supplier. The excess expenditure over and above contracted prices incurred by the CMSS, in making such purchases from any other sources or in the open market or from any other Tenderer who has quoted higher rates and other losses sustained in the process, shall be recovered from the Security Deposit or from any other money due and become due to the supplier and in the event of such amount being insufficient, the balance will be recovered personally from the supplier as per rules.

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

21.SAVINGCLAUSE

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

22. PROHIBITION OF INFLUENCING CMSS BY THEBIDDER:

- (i) No bidder shall contact or influence the CMSS or its employees on any matter relating to its bid from the time of bid opening to the time the contract is awarded.
- (ii) Any effort by a bidder to influence the CMSS in the bid evaluation, bid comparison or contract award decisions may result in rejection of the bidder's bid.
- (iii) The bidder shall not make any attempt to establish unsolicited and unauthorized contact with the Tender Accepting Authority, Tender Inviting Authority or Tender Evaluation Committee after opening of the bids and prior to the notification of award and any attempt by any bidder to bring to bear extraneous pressures on the Tender Accepting Authority, Inviting Authority or Tender Evaluation Committee, shall be sufficient reason to disqualify the bidder.
- (iv) Notwithstanding anything contained in clause (iii) above the Tender Inviting Authority or the Tender Accepting Authority, may seek bonafide clarifications from bidders relating to the bids submitted by them during the evaluation of bids.

23. RESOLUTION OF DISPUTES

- (i) The CMSS and the supplier shall make every effort to resolve, amicably by direct informal negotiation any disagreement or dispute arising between the munder or in connection with the contract.
- (ii) In case of a dispute or difference arising between the CMSS and a supplier relating to any matter arising out of or connected with this agreement, such dispute or difference shall be settled in accordance with the Arbitration and Conciliation Act, 1996. The venue of arbitration shall be New Delhi.

24. JURISDICTION

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

Annexure-I**CENTRAL MEDICAL SERVICE SOCIETY****NEW DELHI-110021****Online Tender of Procurement of BUPRENORPHINE 0.4 MG****LIST OF PRODUCT & THEIR TECHNICAL SPECIFICATIONS**

Sch. No.	Item Name	Total Tentative Quantity	Unit	Detailed Technical Specifications of the Goods/Drugs	Order Distribution Criteria	Inspection Methodology (PDI/Non-PDI)	Consignee Location

Sch. No.	Item Name	Total Tentative Quantity	Unit	Detailed Technical Specifications of the Goods/Drugs	Order Distribution Criteria	Inspection Methodology (PDI/Non-PDI)	Consignee Location
II	Buprenorphine 0.4 mg	12250769	Tablet	Annexure-IA	70:30 as per clause no. 13	Non-PDI Items	CMSS Warehouses

(Please refer technical specifications attached in Annexure-IA)

Delivery Terms:

The delivery shall be on DDP (Destination basis) upto CMSS WHs.

(a) Delivery Schedule

S.No	Item	Quantity	Delivery Time
II	Buprenorphine 0.4 mg	12250769	Tranche I: 4083549 Qty. of tablets to supply within 90 days of placing LOA Tranche II: 4083549 Qty. tablets to supply within 180 days of placing LOA Tranche III: 4083549 Qty. tablets to supply within 270 days of placing LOA

Annexure 1A – Technical Specification, Packing and Artwork

Annexure 1B - CMSS Warehouses

Annexure 1 A

Technical Specifications for BUPRENORPHINE 0.4 MG

Product	Composition	Package requirement
---------	-------------	---------------------

Tablet Buprenorphine 0.4 mg	Each uncoated sublingual tablet contains Buprenorphine Hydrochloride IP equivalent to Buprenorphine 0.4 mg	Blister pack of 10 tablets and 10 blister packs per box.
-----------------------------------	--	--

- a. The shelf line should be minimum 3 years from the date of manufacture.
- b. The manufacturer/supplier shall submit an undertaking of conformance to the rules and regulations laid down in the Narcotic Drugs and Psychotropic Substances ACT 1985 and its amendments, and the Drugs and Cosmetics Act 1940 and the rules thereof. The undertaking should be accompanied with all relevant documents and certificates.
- c. The manufacturer/supplier shall submit certificate of GMP (Good Manufacturing Practice) and Market Standing Certificate.
- d. The manufacturer/supplier shall submit the proof of a valid product license congruent to the Drugs and Cosmetics Act 1940.
- e. All the schedules i.e. I, II and III above should be tasteless and odourless.
- f. Above schedule fulfill the general and/or individual drug requirements as per Indian Pharmacopoeia 2018 with addendum 2019.
- g. All blister packs of Buprenorphine sublingual tablets must indicate the dates of manufacture and expiry.
- h. All consignments must arrive at the final consignee point with a remaining shelf life or at least five-sixths (5/6ths) of the total stipulated shelf life at the time of manufacture.

Annexure "C"

Example of Tertiary level packaging (Shipper level packaging)

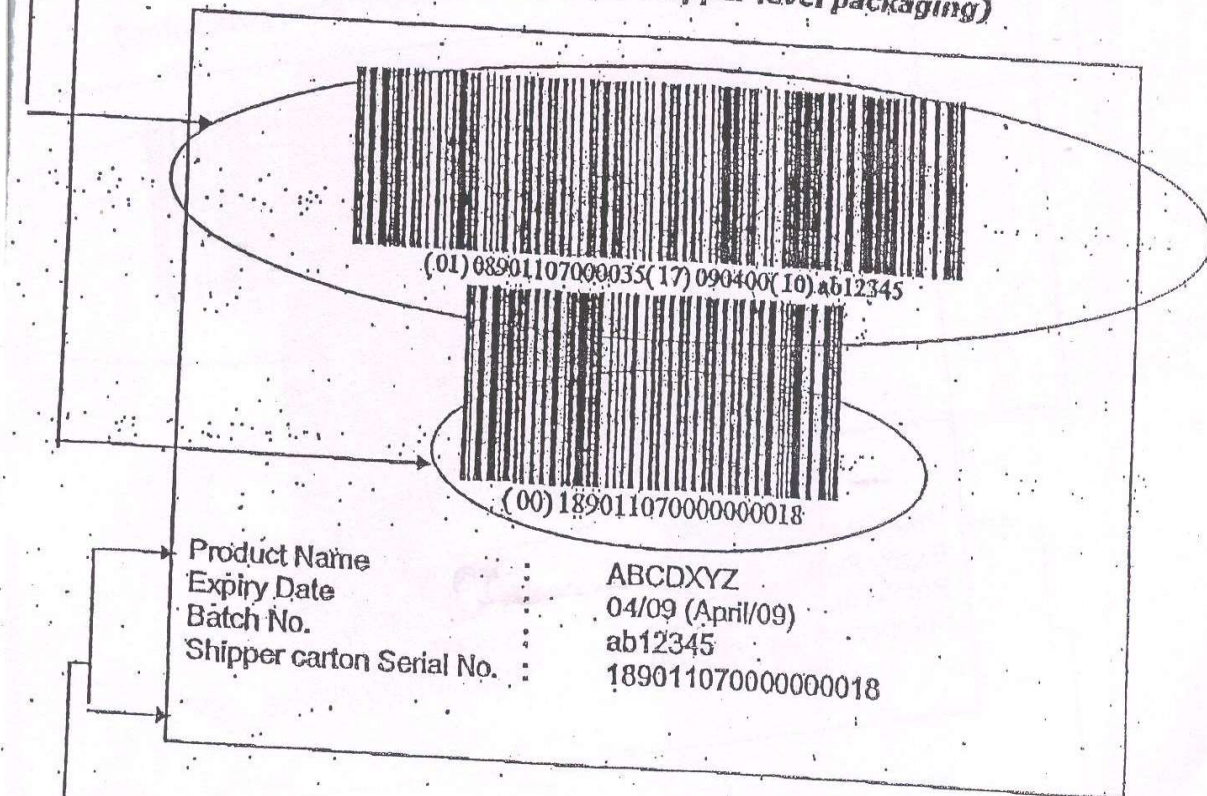
The first barcode will encode the following:

- 1) Product Identification (GTIN 14 of Shipper Pack) using application identifier (01)
- 2) Expiry Date in YYMMDD format using application identifier (17)
- 3) Batch/Lot Number using application identifier (10)

The second barcode will encode the following:

SSCC (Serial Shipping Container Code)

(Single Label for each Shipper level packaging)



Human Readable Information

Complete details on GS1 standards along with technical guidelines are available at www.gs1india.org under "downloads" section.

Annexure-1B

The details of CMSS warehouses are given below:-

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

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

Annexure-IITENDER FORWARDING LETTER

Date:

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

Sub: Acceptance of Terms & Conditions of Tender.

Tender No: CMSS/PROC/2023-24/NACO/046

Name of Tender: - Online tender for Procurement of **BUPRENORPHINE 0.4 MG** for NACO for the year 2023-24.

Dear Sir,

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

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

2.I/We here by certify that I/we have read the entire terms and conditions of the tender documents (Including all document like annexure(s), schedule(s), etc..), which form part of the contract agreement and I/we shall abide here 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 here by unconditionally and unequivocally accept the tender conditions of above-mentioned tender document(s)/ corrigendum(s) in its totality/entirety.

5.I/We do hereby declare that our Firm has not been blacklisted/debarred by any Govt. Department/Public sector undertaking for the quoted product from any procurement agency or as a whole.

6. I/We hereby declare that bid will remain valid for a period of 150 days after opening of Tender bid/packet.

7. I/We certify that all information furnished by our Firm is true & correct and in the event that the information is found to be incorrect/untrue or found violated, then your department/organization shall without giving any notice or reason therefore or summarily reject the bid or terminate the contract, without prejudice to any other rights or remedy including the forfeiture of the full said earnest money deposit absolutely.

Yours Faithfully,
(Signature of the Tenderer, with Official Seal)

Annexure-III**DETAILS OF E.M.D. SUBMITTED**

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

Sch. No.	Item Name	Quantity in Bid	UOM	Quantity Quoted	% of the Bid Quantity	Amount of EMD Payable (in INR) for 100% quantity	Amount of EMD Payable (in INR) for 50% quantity	Amount of Bid Security
II	Buprenorphine 0.4 mg	12250769	Tablet			200324.57	100162.287	

Annexure-IV**PROFORMA FOR PERFORMANCE STATEMENT
(FOR A PERIOD OF LAST 2YEARS)**

Name of Bidder with Address_____

Manufacturer with Address_____

Tender No _____

Sr. No. of the Product _____

Name of the Product _____

Sl .	Name of Product	Year 2021-22	Year 2022-23	Quantity manufactured and marketed	UOM	Name and full address of the Purchaser
1	2	3	4	5	6	7
1.					Nos.	
2.						

Note:

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

Signature of Tenderer

Name in Capitals

Date:

Seal:

Signature of Auditor/ Chartered Accountant

Name in Capitals

Date

Seal

Annexure-V**ANNUAL TURN OVER STATEMENT**

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

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

Total - Rs. _____ Lakhs.

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

Date:

Seal: Signature of Auditor/Chartered Accountant

(Name in Capital)

Annexure-VI**LIST OF ITEMS QUOTED & THEIR PRODUCTION CAPACITY**

1. Name of the firm :

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

3. Details of Endorsement for all products quoted :

Sch No	Item Code	Drug/Go ods Name	Quantity Tendered	UOM	Quantity quoted	Manufa cturing Capacity	Quantity Manufactured			Average Quantity Manufactured
							8			
							2019-20	2020-21	2021-22	
1	2	3	4	5	6	7	8A	8B	8C	9
I										

Date: Authorized Signatory:

Annexure-VII**CHECK LIST****Packet 1****Pg. No. in bid**

1. Checklist – Annexure-VII- (Clause 6.2 p)	Yes	No
2. EMD (as per Annexure-XIII) (Clause 6.2 a)	Yes	No
3. Certificate by MSME/ SSI units in support of being a MSE/ SSI unit.(Clause 6.2 a)	Yes	No
4. Tender Forwarding Letter (Annexure-II) (Clause 6.2 b)	Yes	No
5. Duly attested photocopy of Manufacturing License (valid on the date of tender opening) for the product duly approved by the Licensing Authority for each and every product quoted and ISO 13485. (Clause 6.2 c &i)	Yes	No
6. Power of Attorney duly signed & Authorization letter nominating a responsible person of the tenderer to transact the business with the Tender inviting Authority. (Clause 6.2 d)	Yes	No
7. Purchase Order Copy (Clause 6.2 e)	Yes	No
8. Market Standing Certificate (Clause 6.2 f)	Yes	No
9. Non-Conviction Certificate issued by the Drugs Controller (Clause 6.2 g)	Yes	No
10. Manufacturing Capacity Certificate (Clause 6.2 h)	Yes	No
11. Proforma for Performance Statement (Annexure-IV) (Clause 6.2 j)	Yes	No

12. Annual Turnover Statement for 3Years (Annexure-V) (Clause 6.2 k)	Yes	No
13. Copies of Annual Audit Reports including Balance Sheet & Profit & Loss Account for last three years (Clause 6.2 l)	Yes	No
14. Certificate of Incorporation in case of companies/copy of partnership deed in case of partnership firm/ Declaration in case being a proprietary firm. (Clause 6.2 m)	Yes	No
15. Long term stability data (Clause 6.2 n)	Yes	No
16. List of items quoted and their production capacity – Annexure-VI (Clause 6.2 o)	Yes	No
17. No Deviation Certificate (Annexure-XV) (Clause 6.2 s)	Yes	No
18. Near Relative Certificate (Annexure-XVI) (Clause 6.2 t)	Yes	No
19. Certificate for local content(Clause 6.2 u)	Yes	No
20. Undertaking to compliance i.r.o Ministry of Finance, Department of Expenditure, Procurement Policy Division No- 6/18/2019- PPD dated 23.07.2020 (Annexure-XIX) (Clause 6.2 v & w)	Yes	No
21. Undertaking that Firm is not being blacklisted or debarred from any Govt. Agency (Clause 6.2 x)	Yes	No
22. Para-wise compliance of technical specification of the quoted item (Clause 6.2 y)	Yes	No
23. The bidders are requested to submit an undertaking on their letterhead for compliance to the Artwork enclosed for the	Yes	No

items quoted by them. No further approval for Artwork would be provided by CMSS to any bidder. (Clause 6.2 z)

24. Annexure-XII (Mandate Form)

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

M/s _____
For Self and Firm / Company Ltd.
Signature and Seal

Annexure-VIII**NOTARISED UNDERTAKING BY MSE COMPANIES**
(In 20- Rupees stamp paper)

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

2. Whereas, CMSS (Tender Inviting Authority) has invited Tender for supply of Drugs and medicines, goods for the year 2023-24 and in pursuant to the conditions in the tender documents. M/s _____ (Proprietary Concern/ Firm / Company Ltd.), having its Office at _____ is exempted from payment of Earnest Money Deposit as indicated in the Clause 9.2 of tender document.
3. And whereas, in pursuant to the conditions in Clause Nos. 9.2, 9.3 & 9.4 of the tender, the Earnest Money Deposit can be forfeited by the Tender Inviting Authority in case of violation of any of the conditions and for non-performance of the obligation under tender document.
4. In consideration of exempting M/s. _____ (Proprietary Concern/ Firm / Company Ltd.) from payment of Earnest Money Deposit as indicated in the clause 9.2 of tender document, I undertake to pay the said sum without any demur on receipt of demand issued by the tender inviting authority.

M/s _____

For Self and Firm / Company Ltd.

Signature and Seal

Witness: -

(1)

(2)

Annexure-IX**Central Medical Services Society**

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

21410906

Email: gmproc.cmss@gmail.com

LETTER OF ACCEPTANCE

No: CMSS/PROC/2023-24/NACO/046 Date _____

To,

M/s _____

Address: _____

Attn: _____

Phone: _____

Email _____

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

Sub: Acceptance of Tender for supply to CMSS

Ref: 1) CMSS Tender No. **CMSS/PROC/2023-24/NACO/046** opened on _____

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

Dear Sir,

I am pleased to inform you that your offer in response to above mentioned tender for supply of **BUPRENORPHINE 0.4 MG** has been accepted for following items:

Sch No.	Items Description	Quantity	Unit	Ex-Works per Unit (Rs.)	GST (%)	GST (Rs)	Transport & any other charges (Rs.)	Total unit price (all incl.) (Rs.)	Grand Total (Rs.)
1	BUPRENORPHINE 0.4 MG	12250769	Nos		0	0	0		

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

3. Please convey your acceptance to this LOA within 03 days of issue, else it will be presumed that you are not keen to accept the LOA and CMSS may proceed for allocation of quantity to other bidder and with other actions stipulated in referred Tender document.
4. All other terms and conditions will be applicable as per Tender document no. CMSS/PROC/2023-24/NACO/046 and subsequent amendments to it.

Anjana
GM/Procurement

Annexure A to LOA No:

Supplier: M/s _____

Annexure-A

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

Annexure-X

LONG TERM AGREEMENT (LTA) NO.: CMSS/PROC/2023-24/NACO/046/LTA/

E- STAMP CERTIFICATE NO.:

LTA Validity: From _____ to _____

TERMS OF AGREEMENT

THIS AGREEMENT made the..... day of, year between **Central Medical Services Society, 2nd Floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Marg, Opposite Police Station Chanakaya Puri, New Delhi-110021** (here in after "the Purchaser") of the one part and (Name of Supplier) of..... (Address and Country of Supplier) (Here in after called "the Supplier") of the other part:

WHEREAS the Purchaser is desirous that certain Goods and ancillary services viz; **Procurement of, BUPRENORPHINE 0.4 MG** in the Tender Reference No. **CMSS/PROC/2023-24/NACO/046, Dt _____** (Brief Description of Goods and Services) and has accepted a bid by the Supplier for the supply of those goods and services for the sum of..... (Contract Price in Words and Figures) (Hereinafter called "the Contract Price").

WHEREAS the Supplier confirms that it is qualified, ready, willing and able to supply/services the **Procurement of BUPRENORPHINE 0.4** in accordance with the terms and conditions of this Agreement.

1. DEFINITIONS

Commencement Date means _____

Expiry Date means _____

Products, in singular form Product, means the item(s), as described and detailed above, provided by the Supplier to CMSS from time to time pursuant to this agreement.

Tender means Tender No. Tender No: **CMSS/PROC/2023-24/NACO/046** from CMSS to the Supplier, to quote for the cost of supply of the Products to CMSS.

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

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

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:

1. LTA DOCUMENTS:

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

- (a) This LTA
- (b) The Notice Inviting Tender
- (c) Terms and Conditions of Tender Document as given in Tender No: **CMSS/PROC/2023-24/NACO/046** dt. _____
- (d) The Minutes of Pre-Bid meeting and corrigendum issued.
- (e) Schedule of Requirement.
- (f) The Technical Specification
- (g) The Supplier's Offer including Enclosures, Annexure etc.
- (h) Any other document listed in the supplier's bid and replies to queries, clarifications issued by the purchaser, such confirmations given by the tenderer which are acceptable to the purchaser and the entire Addendum issued as forming part of the contract.
- (i) The Letter of Acceptance issued by the purchaser.

2. PURPOSE OF LTA:

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

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

Sc h No.	Items Descript ion	Quantity	Unit	Ex- Works per Unit (Rs.)	GST (%)	GST (Rs)	Transport & any other charges (Rs.)	Total unit price (all incl.) (Rs.)	Grand Total (Rs.)
1	BUPRENO RPHINE 0.4 MG	12250769	Nos		0	0	0		

2.3 The supplier agrees that his supplies are subject to terms and conditions details contained in LTA documents mentioned above. The supplier appreciates that the supplies are meant for public health system in the country and hence will

agree to supply the goods of good quality as per standards in a timely manner as specified as per tender terms and conditions. The supplier has already given its no deviation (clause-by-clause compliance) for the subject terms and conditions.

3. Manufacturing License and Site

License and Site Address: As per Annexure A.

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

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

Signature
Name
Address

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

Signature
Name
Address

Annexure A to LTA No:
Supplier: M/s

Annexure-A

Annexure A to LTA No:
Supplier: M/s

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

Annexure-XI**CENTRAL MEDICAL SERVICES SOCIETY**

Ministry of Health & Family Welfare

(Government of India)

2nd Floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Marg,
Opposite Police Station Chankaya Puri, New Delhi-110021, India

PURCHASE ORDER**PO No: CMSS/PROC/2023-24/NACO/046 Dated: _____**

To,

M/s _____

Address: _____

Attn: _____

Phone: _____

Email _____

Subject: Purchase Order for supply of BUPRENORPHINE 0.4

Ref : Long Term Agreement No: CMSS/PROC/2023-24/NACO/046/LTA/.....
dated _____

Dear Sir,

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

Sr. No.	Item Code	Item Description	Quantity Accepted by the Purchaser	Unit	Ex Works Price per Unit (Rs)	GST (%)	GST (Rs)	Transportation Charges (Rs)	Rate Per Unit (Landed Price)(Rs)	Total Value (Rs)	Destination
1		BUPRENORPHINE 0.4 MG									As per Annex 1

1. All the Terms & Conditions of the Agreement signed by you on acceptance of your tender are applicable.
2. Delivery Period: As per Annexure A of the tender document
3. Manufacturing license as per Annexure A and site address as per Annexure B.
4. Payment Terms: Within 75 days of supplies in respect of items requiring sterility tests and within 60 days of supplies for other items.

(Anjana)

General Manager (Procurement)

Copy to :

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

Annexure-A

Annexure A to PO No:

Supplier: M/s

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

Annexure-B

Annexure B to PO No:

Supplier: M/s

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

Annexure-XII**MANDATE FORM**

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

Date:

Company Seal

Signature

Place:

(Name of the person signing & designation)

Mandate Form contd..

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

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

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

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

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

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

Annexure-XIII**Bank Guarantee for EMD (Format)
(if applicable)**

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

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

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

Date: _____

BIDGUARANTEE No.: _____

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

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

At the request of the Tenderer, we *[insert **name of Bank**]* hereby irrevocably under take to pay you any sum or sums not exceeding in total an amount of *[insert **amount in figures** (**insert amount inwards**)]* 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 Tenderers.
- (c) does not accept the correction of the Bid Price
- (d) This guarantee will expire: (a) if the Tenderer is the successful tenderer, upon our receipt to copies of the contract signed by the Tenderer and the performance security issued to you upon the instruction of the Tenderer; or (b) if the Tenderer is not the successful tenderer, upon the earlier of (i) our receipt of a copy of your notification to the Tenderer of the name of the successful tenderer; or (ii) Twenty Eight days after the expiration of the Tenderer's Bid.

Consequently, any demand for payment under this guarantee must be received by us at the office on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No. 758.

[signature(s)]

Annexure-XIV**Security Bank Guarantee (Format)**

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

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

Date: _____

PERFORMANCE GUARANTEE No.: _____

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

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

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

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

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

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

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

Annexure-XV**No Deviation Certificate**

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

Signature (with Stamp)

Annexure-XVI**Near Relative Certificate**

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

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

The near relatives for this purpose are defined as:

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

Signature/Signatures (with Stamp)

Annexure-XVII**Format of Local Content Declaration**

Tender Reference No:

Date:

I _____, S/o, D/o, W/o _____,

Resident of _____ do hereby solemnly affirm and declare as under: -

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

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

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

(Name of Firm/ Entity)

Authorized Signatory/ Statutory Auditor/ Chartered Accountant

(With Company Seal/Stamp)

(Refer Clause 3 of DPIIT Order dtd. 30.12.2020)

Annexure-XVIII**UNDERTAKING****(On Company's Letter Head)**

We,..... (name of bidder), having office sat

..... are participating in Bid No.

..... Dated.....

We equivocally and irrevocably undertake that,

- i) Compliance of DOE, MOF order No. 6/18/2019 - PPD dated: - 23.07.2020 and No.F.7/10/2021-PPD (1), dated 23.02.2023 or any other subsequent revised order in said matter.
- ii) Compliance of Public Procurement Order 2017- revision, issued vide No. P-45021/2017-PP (BE-II) Dated: - 16/9/2020 or any other subsequent revised order in said matter.

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

M/s _____

Witness For Self and Firm/Company Limited

1.

Signature & Seal of company

Annexure-XIXCONSIGNEE RECEIPT CERTIFICATE**(To be given by consignee's authorized representative)**

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

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

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

Annexure-XX

FORMAT OF PRICE BID - Packet 2

Validate

Print

Help

BoQ

Tender Inviting Authority: DG & CEO, CMSS

Name of Work: Procurement of Buprenorphine 0.4 mg

Tender No: CMSS/PROC/2023-24/NTEP/046

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	NUMBER	TEXT	TEXT	NUMBER	NUMBER	NUMBER	NUMBER
Sl. No.	Name of the Item	Quantity in Tender	Units	Quantity Offered	EX Works price per unit in Rs.	GST (In Rs.)	Transportation and any Other Charges in Rs. (Till Consignee Locations) on DDP basis, All Inclusive and firm & fixed	Total Unit Price With GST(In Rs.) (Col 6+ Col 7+Col 8)
1	2	3	4	5	6	7	8	9
1.01	Buprenorphine 0.4 mg	12,250,769	Tablets					₹ 0.0000
Total in Figures								₹ 0.0000

Annexure B

रजिस्ट्री सं० डी० एल०-33004/99

REGD. NO. D. L.-33004/99



भारत का राजपत्र

The Gazette of India

असाधारण

EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (i)

PART II—Section 3—Sub-section (i)

प्राधिकार से प्रकाशित

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स्वास्थ्य और परिवार कल्याण मंत्रालय

(स्वास्थ्य एवं परिवार कल्याण विभाग)

अधिसूचना

नई दिल्ली, 30 अगस्त, 2013

सा.का.नि. 588(अ).—ओषधि और प्रसाधन सामग्री नियम, 1945 का और संशोधन करने के लिए कतिपय प्रारूप नियम, ओषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 12 और धारा 33 द्वारा अपेक्षित ओषधि तकनीकी सलाहकार बोर्ड से परामर्श किए बिना भारत सरकार के स्वास्थ्य और परिवार कल्याण मंत्रालय (स्वास्थ्य एवं परिवार कल्याण विभाग) की अधिसूचना संख्यांक सा.का.नि. 588(अ) तारीख 20 मार्च, 2012 द्वारा भारत के राजपत्र असाधारण, भाग 2, खण्ड 3, उपखण्ड (i) तारीख 20 मार्च, 2012 को, उन सभी व्यक्तियों से, जिनका उससे प्रभावित होना संभाव्य है, उस तारीख के, जिसको उक्त अधिसूचना वाले राजपत्र की प्रतियां जनता को उपलब्ध करवाई गई थी, पैंतालिस दिन की अवधि के समाप्ति से पूर्व आक्षेप और सुझाव और आमंत्रित करने के लिए प्रकाशित किए गए थे; और राजपत्र के प्रतियां जिसमें उक्त अधिसूचना प्रकाशित की गई थी, तारीख 20 मार्च, 2012 को जनता को उपलब्ध करवा दी गई थी; और ओषधि तकनीकी सलाहकार बोर्ड से उक्त विषय में परामर्श कर लिया गया है; और ओषधि तकनीकी सलाहकार बोर्ड से उक्त विषय में परामर्श कर लिया गया है; और केन्द्रीय सरकार द्वारा उक्त प्रारूप नियमों की बाबत प्राप्त आक्षेपों और सुझावों पर विचार कर लिया गया है; अतः, अब, केन्द्रीय सरकार, ओषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 12 और धारा 33 द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए ओषधि तकनीकी सलाहकार बोर्ड से परामर्श करने के पश्चात् ओषधि और सामग्री नियम, 1945 का और संशोधन करने के लिए निम्नलिखित नियम बनाती है, अर्थात् :

1. (1) इन नियमों का संक्षिप्त नाम ओषधि और प्रसाधन सामग्री (चौथा संशोधन) नियम, 2013 है।
- (2) ये राजपत्र में इनके प्रकाशन के छः मास पश्चात् प्रवृत्त होंगे।
2. ओषधि और प्रसाधन सामग्री नियम, 1945 (जिन्हें इसमें इसके पश्चात् उक्त नियम कहा गया है) में,—
- (i) नियम 65 में,
- (क) शर्त (3) के खंड (1) में,—

(अ) उपखंड (च) में और उपखंड (छ) के तीसरे परंतुक की मद (ii) में "अनुसूची ज" शब्द और अक्षर के स्थान पर क्रमशः "अनुसूची ज और अनुसूची ज।" शब्द, अक्षर और अंक रखे जायेंगे;

(आ) खंड (छ) और उसके परंतुकों के पश्चात् निम्नलिखित अंतःस्थापित किया जाएगा, अर्थात्—

"(ज) अनुसूची ज। में विनिर्दिष्ट ओषधि के प्रदाय को उसका प्रदाय किए जाने के समय नुस्खा लेखक का नाम और पता, रोगी का नाम, ओषधि का नाम और प्रदाय की गई मात्रा का विवरण देते हुए एक पृथक् रजिस्टर में अभिलिखित किया जाएगा और ऐसे अभिलेख तीन वर्ष के लिए रखे जायेंगे और निरीक्षण के लिए खुले रहेंगे।"

07/01/2013

(1)



(ख) शर्त (9) के खंड (क) और खंड (ख) में, "अनुसूची ज" शब्द और अक्षर के स्थान पर "अनुसूची ज और अनुसूची ज1" शब्द, अक्षर और अंक रखे जाएंगे;

(ग) शर्त (11) में, "अनुसूची ज" शब्द और अक्षर के स्थान पर "अनुसूची ज और अनुसूची ज1" शब्द, अक्षर और अंक रखे जाएंगे;

(घ) शर्त (11 क) में, "अनुसूची ज" शब्द और अक्षर के स्थान पर "अनुसूची ज और अनुसूची ज1" शब्द, अक्षर और अंक रखे जाएंगे ;

(iii) नियम 97 के उप नियम (1) में खंड (घ) के पश्चात् निम्नलिखित खंड अंतःस्थापित किया जाएगा अर्थात्:-

'(इ) यदि इसमें अनुसूची ज1 में विनिर्दिष्ट औषधि पदार्थ अंतर्विष्ट हैं तो औषधि विनिर्मित के लेबल पर Rx चिन्ह का लेबल लाल रंग में सहज दृश्य रूप से लेबल ऊपरी बाएं कोने पर लगाया जाएगा और पर एक बॉक्स में लाल रंग के बॉर्डर के भीतर निम्नलिखित शब्दों से युक्त लेबल भी लगाया जायेगा :

"अनुसूची ज1 औषधि-चेतावनी :
- सिवाय चिकित्सा परामर्श से इस निर्मित का सेवन खतरनाक है।
-पंजीकृत चिकित्सा के परामर्श के बिना फुटकर आधार पर विक्रय नहीं किया जाना है।" ;

3. उक्त नियमों की अनुसूची ज में निम्नलिखित प्रवृष्टियों का लोप किया जायगा, अर्थात् :-

1. अल्प्रैजोलम
2. सेफडीनीर
3. सेफेपाइम हाइड्रोक्लोराइड
4. सेफेटामेट पिवोक्सिल
5. सेफपाइरोम
6. सेफपडोक्साइम पोक्सेटिल
7. सेफडाजीडाइम पेंटाहाइड्रेट
8. सेफटीजोडाइम सोडियम
9. क्लोरडाईजेपोक्साइड
10. क्लोफेजीमाइन
11. कोडीन
12. डाइजापाम
13. डिफेनोजाइलेट और इसके लवण
14. इथामबूटोल हाइड्रोक्लोराइड
15. एथियोनामाइड
16. लेवोफ्लोक्सासीन
17. मेरोपेनाम
18. मीडाजोलम



भाग II—खण्ड 3(i)]

भारत का राजपत्र : असाधारण

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19. मोक्सीफ्लोक्सासीन
 20. बाइट्राजापाम
 21. पैटाजोसाइन
 22. पायरजाइनामाइड
 23. स्परफ्लोक्सासीन
 24. थियासेटाजोन
 25. ट्रमाडोल हाइड्रोक्लोराइड
 26. जोल्फीडेम "
4. उक्त नियमों की अनुसूची ज के पश्चात् निम्नलिखित अनुसूची अंतःस्थापित की जाएगी, अर्थात् :-
"अनुसूची ज1
(नियम 65 और नियम 97 देखिए)

1. अल्प्रैजोलम
2. बालोफ्लोक्सासीन
3. बुप्रेनोर्फिन
4. कैप्रैओमाइसिन
5. सेफाडीनीर
6. सेफडीटोरन
7. सेफेनाइम
8. सेफेतामेट
9. सेफीजाइम
10. सेफोपेराजोन
11. सेफोटैक्सिम
12. सेफपीरोम
13. सेफपोडोजाइम
14. सेफटाजिडीम
15. सेफ्टीबुटेन
16. सेफटीजोजाइम
17. सेफटीयाजोन
18. क्लोरडाइजेपोक्साइड
19. क्लोफैजिमाइन
20. कोडीन
21. साइक्लोसेराइन
22. डाइजपाम
23. डीफेनोक्सीलेट
24. डोरिपेनेम
25. एरटापेनेम
26. इथामबुटोल हाइड्रोक्लोराइड
27. एथियोनामाइड
28. फेरोपेनेम
29. जेमीफ्लोक्सासीन
30. इमीपेनेम
31. इसोनियजिड



32. लेवोफ्लोक्सासीन
33. मेरापेनाम
34. मीडाजोलाम
35. मोक्सीफ्लोक्सासीन
36. निद्राजेपाम
37. पेंटाजोसीन
38. पुलीफ्लोक्सासीन
39. पाइराजीनामाइड
40. रिफाबुटीन
41. रिफाम्पिसिन
42. सोडियम पैरा-अमिनोसालिसाइलेट
43. स्परफ्लोक्सासीन
44. थायसीटाजोन
45. टारामाडोल
46. जोलपीडेम

टिप्पण : पूर्वोक्त औषधि पदार्थों और उनके लवणों को अंतर्विष्ट करने वाली निर्मितियां, जिनमें वे शामिल नहीं हैं, जो सीमित या बाह्य प्रयोग (ऑख, और कान/नाक विनिर्मितियों के सिवाय) के लिए आशयित हैं, जिनमें पूर्वोक्त पदार्थ अंतर्विष्ट हैं, भी उक्त सूचि के अधीन आती हैं।

[फा. सं. एक्स-11014/6/2010-डीएफक्यूसी]

अरुण के. पण्डा, संयुक्त सचिव

पाद टिप्पण : मूल नियम राजपत्र में अधिसूचना सं. एफ.28-10/45-एच(1), तारीख 21 दिसंबर, 1945 द्वारा प्रकाशित किए गए थे और इनमें अंतिम संशोधन अधिसूचना सं. सा.का.नि. तारीख द्वारा किया गया।

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 30th August, 2013

G.S.R. 588(E).— Whereas certain draft rules further to amend the Drugs and Cosmetics Rules, 1945, were published, as required by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), without consulting the Drugs Technical Advisory Board vide notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare), number G.S.R. 228(E), dated the 20th March, 2012, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), dated the 20th March, 2012, inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas the copies of the Gazette in which the said notification was published were made available to the public on the 20th March, 2012;

And whereas, the Drugs Technical Advisory Board has been consulted in the matter;

And whereas, objections and suggestions received in respect of the said draft rules, have been considered by the Central Government;



[भाग II - खण्ड 3(i)]

भारत का राजपत्र : असाधारण

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Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

1. (1) These rules may be called the Drugs and Cosmetics (**Fourth Amendment**) Rules, 2013.
- (2) They shall come into force after six months of their publication in the Official Gazette.
2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as said rules),-
 - (i) in rule 65,-
 - (a) in condition (3), in clause (1),-
 - (A) in sub-clause (f) and in item (ii) of the third proviso to sub-clause (g), for the words and letter 'Schedule H', the words and letters "Schedule H and Schedule H1" shall respectively be substituted;
 - (B) after clause (g) and the provisos thereof, the following shall be inserted, namely:-

"(h) the supply of a drug specified in Schedule H1 shall be recorded in a separate register at the time of the supply giving the name and address of the prescriber, the name of the patient, the name of the drug and the quantity supplied and such records shall be maintained for three years and be open for inspection.
 - (b) in condition (9), in clauses (a) and (b), for the words and letter 'Schedule H', the words and letters "Schedule H and Schedule H1" shall respectively be substituted;
 - (c) in condition (11), for the words and letter 'Schedule H', the words and letters "Schedule H and Schedule H1" shall be substituted;
 - (d) in condition (11A), for the words and letter 'Schedule H', the words and letters "Schedule H and Schedule H1" shall be substituted;
 - (ii) in rule 97, in sub rule (1), after clause (d), the following shall be inserted, namely,-
 - (e) if it contains a drug substance specified in Schedule H1, the drug formulation shall be labelled with the symbol Rx which shall be in red and conspicuously displayed on the left top corner of the label, and shall also be labelled with the following words in a box with a red border:

3767 4713-2



"SCHEDULE H1 DRUG – WARNING:

-It is dangerous to take this preparation except in accordance with the medical advice.

-Not to be sold by retail without the prescription of a Registered Medical Practitioner." ;

3. In the said rules, in Schedule H, the following entries shall be omitted, namely:-

1. Alprazolam
2. Cefdinir
3. Cefepime Hydrochloride
4. Cefetamet Pivoxil
5. Cefpirome
6. Cefpodoxime Poxetil
7. Ceftazidime Pentahydrate
8. Ceftizoxime Sodium
9. Chlordiazepoxide
10. Clofazimine
11. Codeine
12. Diazepam
13. Diphenoxylate and its salts
14. Ethambutol Hydrochloride
15. Ethionamide
16. Levofloxacin
17. Meropenam
18. Midazolam
19. Moxifloxacin
20. Nitrazepam
21. Pentazocine
22. Pyrazinamide
23. Sparfloxacin
24. Thiacetazone
25. Tramadol hydrochloride
26. Zolpidem";



[अनुसूची II—खण्ड 3(i)]

भारत का राजपत्र : असाधारण

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4. In the said rules, after Schedule H, the following Schedule shall be inserted, namely:-

"Schedule H1

(See rules 65 and 97)

1. Alprazolam
2. Balofloxacin
3. Buprenorphine
4. Capreomycin
5. Cefdinir
6. Cefditoren
7. Cefepime
8. Cefetamet
9. Cefixime
10. Cefoperazone
11. Cefotaxime
12. Cefpirome
13. Cefpodoxime
14. Ceftazidime
15. Ceftibuten
16. Ceftizoxime
17. Ceftriaxone
18. Chlordiazepoxide
19. Clofazimine
20. Codeine
21. Cycloserine
22. Diazepam
23. Diphenoxylate
24. Doripenem
25. Ertapenem
26. Ethambutol Hydrochloride
27. Ethionamide
28. Feropenem
29. Gemifloxacin



30. Imipenem
31. Isoniazid
32. Levofloxacin
33. Meropenem
34. Midazolam
35. Moxifloxacin
36. Nitrazepam
37. Pentazocine
38. Prulifloxacin
39. Pyrazinamide
40. Rifabutin
41. Rifampicin
42. Sodium Para-aminosalicylate
43. Sparfloxacin
44. Thiacetazone
45. Tramadol
46. Zolpidem

Note.- Preparations containing the above drug substances and their salts excluding those intended for topical or external use (except ophthalmic and ear or nose preparations) containing above substances are also covered by this Schedule."

[F. No. X-11014/6/2010-DFQC]

ARUN K. PANDA, Jt. Secy.

Foot note : The principal rules were published in the Official Gazette vide notification No. F.28-10/45-H (1), dated 21st December, 1945 and last amended vide notification number **G.S.R. 72 (E), dated the 8th February, 2013.**



Annexure C

रजिस्ट्री सं० डी० एल०-33004/99

REGD. NO. D. L.-33004/99

भारत का राजपत्र The Gazette of India

असाधारण

EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (ii)

PART II—Section 3—Sub-section (ii)

प्राधिकार से प्रकाशित

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NEW DELHI, TUESDAY, MAY 5, 2015/VAISAKHA 15, 1937

वित्त मंत्रालय

(राजस्व विभाग)

अधिसूचना

नई दिल्ली, 5 मई, 2015

का.आ.1181(अ).—स्वापक औषधि और मनःप्रभावी पदार्थ अधिनियम, 1985 (1985 का 61) की धारा 2 के खण्ड (viii) के तहत प्रदत्त शक्तियों का प्रयोग करते हुए केन्द्र सरकार, एतद्वारा, औषधिक और वैज्ञानिक प्रयोग के लिए निम्नलिखित स्वापक औषधियों को आवश्यक स्वापक औषधि के रूप में अधिसूचित करती है, यथा:-

- (1) मेथाइल मार्फीन (सामान्यतया जिसे 'कोडीन' के नाम से जाना जाता है) और इथाइल मार्फीन और उनके लवण (डायोनाइन समेत), सभी तनु (डाइल्यूशन्स) और उत्पाद, उनको छोड़कर जिसमें एक या एक से अधिक अन्य अवयवों का संयोग है और जिनमें प्रति खुराक में यह औषधि 100 मिलीग्राम से अधिक न हो और अप्रथक उत्पाद में 2.5 प्रतिशत से अधिक सांद्रता न हो और जिनका चिकित्सा कार्य में प्रयोग हो रहा हो;
- (2) 1-फैनथाईल-4-एन- प्रोपियोनाइलानीलिनो-पाइपरीडाइन (जिसका इंटरनेशनल-नान- प्रोपाइटी नाम फेन्टानाइल है) और इसके लवण तथा उत्पाद, मिश्रण, निष्कर्ष और अन्य पदार्थ जिसमें यह औषधि मिली हुई हो;
- (3) डाईहाइड्रोकोडीनोन (जिसे सामान्यतया हाइड्रोकोडोन के नाम से जाना जाता है), इसके लवण (जैसे कि डाइकोडाइड, कोडीनोवो, डाइकोनोन, हाइकोडोन, मल्टाकोडीन, नायोडाइड, वाईडोर्ड, और इसी तरह के) तथा लवण इसके ईस्टर और ईस्टरों के लवण और उत्पाद, मिश्रण, निष्कर्ष और अन्य पदार्थ जिनमें इनमें से कोई भी औषधि मौजूद हो;
- (4) 4:4 - डाइफेनाइल-6- डाईमेथाइल अमीनों - हेप्टानोन -3(अन्यथा जिसे 6-डाईमिथाइल एमिनो 4:4 डाईफेनाइल -3- हेप्टानोन और मेथाडोन के नाम से जाना जाता है) इसके लवण जैसे कि (एडनान, एल्गोलीसिन, एमीडोन, एमडोसन, बूटाल्जिन, डेप्रीडोल, डायमिनान, डायनान, डोलाफिन, डोलामिड, डोल्पाइन, डोरिक्साल, हेप्टाडाल, हैलानाल, होएस्ट, 10820, डेटाल्जिन, मेकोडीन, मिपेक्शन, मेफेनान, मियाडोन, मोह्प्टोन, फीजेप्टोन, सीसोपेप्टोन, पोलामिडोन, सीमोरान, टूनानोन, और इसी तरह के) तथा इसके उत्पाद, निष्कर्ष और अन्य पदार्थ जिनमें इनमें से कोई भी औषधि मौजूद हो;
- (5) मार्फीन और इसके लवण और ऐसे सभी उत्पाद जिसमें मार्फीन 0.2 प्रतिशत से अधिक हो;

1991 GI/2015

(1)



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THE GAZETTE OF INDIA : EXTRAORDINARY

[PART II—SEC. 3(ii)]

- (6) डिहाइड्राक्सी कोडीनोन (जिसे सामान्यतया आक्सीकोडोन और डिहाइड्राक्सीकोडीनोन के नाम से जाना जाता है), इसके लवण (जैसे कि यूकोडाल, बोंकोडाल, डीनार्कान हाइड्रोलाडीन, न्यूकोडान, पकोडान, स्कोफेडाल, टीबोडाल, और इसी तरह के) इसके ईस्टर और इसके ईस्टरों के लवण और उत्पाद, मिश्रण, निष्कर्ष तथा अन्य पदार्थ जिसमें यह औषधि मौजूद हो।

[फा.सं. एन-11011/1/2014-एनसी-II (2)]

सत्य नारायण दास, अवर सचिव

MINISTRY OF FINANCE

(Department of Revenue)

NOTIFICATION

New Delhi, the 5th May, 2015

S.O.1181(E).—In exercise of the powers conferred by clause (viii) of Section 2 of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985), the Central Government hereby notifies for medical and scientific use, the following narcotic drugs to be essential narcotic drugs, namely:-

- (1) Methyl morphine (commonly known as 'Codeine') and Ethyl morphine and their salts (including Dionine), all dilutions and preparations except those which are compounded with one or more other ingredients and containing not more than 100 milligrammes of the drug per dosage unit and with a concentration of not more than 2.5 % in undivided preparations and which have been established in therapeutic practice;
- (2) 1-phenethyl-4-N - propionylaniline-piperidine (the international-non-proprietary name of which is Fentanyl) and its salts and preparations, admixtures, extracts or other substances containing any of these drugs;
- (3) Dihydrocodeinone (commonly known as Hydrocodone), its salts (such as Dicode, Codinovo, Diconone, Hycodan, Multacodin, Nyodide, Ydroced and the like) and its esters and salts of its esters, and preparations, admixtures, extracts or other substances containing any of these drugs;
- (4) 4,4-diphenyl-6-dimethylamino-heptanone-3 (otherwise known as 6-dimethyl amino 4 : 4-diphenyl-3-heptanone and as Methadone) and its salts such as (Adanon, Algolysin, Amidone, Amdosan, Butalgin, Depridol, Diaminon, Dianone, Dolafin, Dolamid, Dolphine, Doriexol, Heptadol, Heptanal, Hoechst, 10820, Detalgine, Mecodin, Mepection, Mephenon, Miadone, Moheptal, Physeptone, Psysopeptone, Polamidon, Simoron, Turnanon and the like) and preparations, admixtures, extracts or other substances containing any of these drugs;
- (5) Morphine and its salts and all preparations containing more than 0.2 per cent. of Morphine;
- (6) Dihydroxy Codeinone (commonly known as 'Oxy-codone and Dihydroxycodone'), its salts (such as Eucodal, Boncodal, Dinarcon, Hydrolaudin, Nucodan, Percodan, Scophedal, Tebodol and the like), its esters and the salts of its esters and preparations, admixtures, extracts or other substances containing any of these drugs.

[F. No. N-11011/1/2014-NC-II (2)]

SATYA NARAYANA DASH, Under Secy.



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