

बिड दस्तावेज़ / **Bid Document**

बिड विवरण/Bid Details

बिड बंद होने की तारीख/समय / Bid End Date/Time	13-02-2026 12:00:00
बिड खुलने की तारीख/समय / Bid Opening Date/Time	13-02-2026 12:30:00
बिड पेशकश वैधता (बंद होने की तारीख से)/ Bid Offer Validity (From End Date)	30 (Days)
मंत्रालय/राज्य का नाम/ Ministry/State Name	Ministry Of Labour And Employment
विभाग का नाम/ Department Name	Employees State Insurance Corporation
संगठन का नाम/ Organisation Name	Employees State Insurance Corporation
कार्यालय का नाम/ Office Name	Esic Hospital And Medical College Joka k
कुल मात्रा/ Total Quantity	124000
वस्तु श्रेणी / Item Category	Clobazam Tablets (V2) (Q2) , Amitriptyli (Q2)
वर्षों के अनुभव के लिए एमएसई को छूट प्राप्त है / MSE Relaxation for Years Of Experience	Yes Complete
वर्षों के अनुभव के लिए स्टार्टअप को छूट प्राप्त है / Startup Relaxation for Years Of Experience	Yes Complete
विक्रेता से मांगे गए दस्तावेज़/ Document required from seller	Certificate (Requested in ATC),OEM Autl *In case any bidder is seeking exemptio supporting documents to prove his eligi evaluation by the buyer
क्या आप निविदाकारों द्वारा अपलोड किए गए दस्तावेज़ों को निविदा में भाग लेने वाले सभी निविदाकारों को दिखाना चाहते हैं? संदर्भ मेन्ू है/ Do you want to show documents uploaded by bidders to all bidders participated in bid?	Yes (Documents submitted as part of a tender/bid process will also be displaye
बिड लगाने की समय सीमा स्वतः नहीं बढ़ाने के लिए आवश्यक बिड की संख्या। / Minimum number of bids required to disable automatic bid extension	3
दिनों की संख्या, जिनके लिए बिड लगाने की समय-सीमा बढ़ाई जाएगी। / Number of days for which Bid would be auto-extended	7
ऑटो एक्सटेंशन अधिकतम कितनी बार किया जाना है। / Number of Auto Extension count	1
बिड से रिवर्स नीलामी सक्रिय किया/ Bid to RA enabled	No
बिड का प्रकार/ Type of Bid	Two Packet Bid
प्राथमिक उत्पाद श्रेणी/ Primary product category	Clobazam Tablets (V2)

बिड विवरण/Bid Details

तकनीकी मूल्यांकन के दौरान तकनीकी स्पष्टीकरण हेतु अनुमत समय /Time allowed for Technical Clarifications during technical evaluation	2 Days
निरीक्षण आवश्यक (सूचीबद्ध निरीक्षण प्राधिकरण /जेम के साथ पूर्व पंजीकृत एजेंसियों द्वारा)/Inspection Required (By Empanelled Inspection Authority / Agencies pre-registered with GeM)	No
अनुमानित बिड मूल्य /Estimated Bid Value	225560
मूल्यांकन पद्धति/Evaluation Method	Item wise evaluation
मध्यस्थता खंड/Arbitration Clause	No
सुलह खंड/Mediation Clause	No

ईएमडी विवरण/EMD Detail

आवश्यकता/Required	No
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ईपीबीजी विवरण /ePBG Detail

आवश्यकता/Required	No
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बोली विभाजन लागू नहीं किया गया/ Bid splitting not applied.

एमआईआई खरीद वरीयता / MII Purchase Preference

एमआईआई खरीद वरीयता / MII Purchase Preference	Yes
मेक इन इंडिया विक्रेताओं को खरीद में प्राथमिकता, यदि उनका मूल्य L1+X% तक की सीमा में है / Purchase Preference to MII sellers available upto price within L1+X%	20
मेक इन इंडिया खरीद में प्राथमिकता के लिए बिड की मात्रा का अधिकतम प्रतिशत / Maximum Percentage of Bid quantity for MII purchase preference	50

एमएसई खरीद वरीयता/MSE Purchase Preference

एमएसई खरीद वरीयता/MSE Purchase Preference	Yes
सूक्ष्म और लघु उद्यम मूल उपकरण निर्माताओं को खरीद में प्राथमिकता, यदि उनका मूल्य L1+X% तक की सीमा में हो / Purchase Preference to MSE OEMs available upto price within L1+X%	15
सूक्ष्म और लघु उद्यम को खरीद में प्राथमिकता के लिए बिड की मात्रा का अधिकतम प्रतिशत / Maximum Percentage of Bid quantity for MSE purchase preference	25

1. If the bidder is a Micro or Small Enterprise as per latest orders issued by Ministry of MSME, the bidder shall be relaxed from the "Experience Criteria" as defined above subject to meeting of quality and technical specifications. The bidder seeking Relaxation from Experience Criteria, shall upload the supporting documents to prove his eligibility for Relaxation.
2. If the bidder is a DPIIT registered Startup, the bidder shall be relaxed from the the eligibility criteria of "Experience Criteria" as defined above subject to meeting of quality and technical specifications. The bidder seeking Relaxation from Experience Criteria, shall upload the supporting documents to prove his eligibility for Relaxation.
3. Preference to Make In India products (For bids < 200 Crore):Preference shall be given to Class 1 local supplier as per Public Procurement Policy for Micro and Small Enterprises Order, 2012 (as amended from time to time and its subsequent Orders/Notifications issued by concerned Ministry), Order 2017 as amended from time to time and its subsequent Orders/Notifications issued by concerned Ministry. The minimum local content to qualify as a Class 1 local supplier is denoted in the bid document. If the bidder wants to avail purchase preference, he shall upload a certificate from the OEM regarding the percentage of the local content and the details of locations at which the product is manufactured, failing which no purchase preference shall be granted. In case the bid value is more than Rs 10 Crore, the declaration shall be certified by the statutory auditor or cost auditor, if the OEM is a company and by a practicing cost accountant or chartered accountant, if the OEM is a sole proprietorship or partnership companies as per the Public Procurement (preference to Make-in -India) order 2017 dated 04.06.2020. Only Class-1 suppliers as per MII order dated 04.06.2020 will be eligible to bid. Non - Local suppliers as per MII order dated 04.06.2020 are not eligible to participate in the bid. The buyers are advised to refer the OM No.F.1/4/2021-PPD dated 18.05.2023 [OM No.1 4 2](#) for concurrent application of Public Procurement Policy for Micro and Small Enterprises Order, 2012 and Public Procurement Policy for Micro and Small Enterprises (MSEs) Order, 2012 dated 23.03.2012 issued by Ministry of MSME.
4. Purchase preference will be given to MSEs having valid Udyam Registration and whose credentials are validated on the Public Procurement Policy for Micro and Small Enterprises (MSEs) Order, 2012 dated 23.03.2012 issued by Ministry of MSME. Traders are excluded from the purview of Public Procurement Policy for Micro and Small Enterprises Order, 2012. Products manufactured by some other OEM are not eligible for any purchase preference. In respect of bid for Service, purchase preference shall be given to the bidder offering the lowest price for the offered service. Relevant documentary evidence in this regard shall be uploaded along with the bid in respect of the eligibility for purchase preference based on documentary evidence submitted, while evaluating the bid. If L-1 is not available, the bid will be awarded for 25% (selected by Buyer) percentage of total quantity. The buyers are advised to refer the OM No.F.1/4/2021-PPD dated 18.05.2023 [OM No.1 4 2021 PPD dated 18.05.2023](#) for compliance of Concurrent application of Public Procurement Policy for Micro and Small Enterprises Order, 2012 and Public Procurement (Preference to Make in India) Order, 2017. Benefits of MSE will be allowed only if seller is validly registered and approved by Buyer after evaluation of documents submitted.
5. Estimated Bid Value indicated above is being declared solely for the purpose of guidance on EMD amount and for determining the bid opening time. It has no relevance or bearing on the price to be quoted. The buyers are advised to refer the OM No.F.1/4/2021-PPD dated 18.05.2023 [OM No.1 4 2021 PPD dated 18.05.2023](#) for impact on bid participation. Also this is not going to be used as a criteria in determining reasonableness of quoted price. The buyers are advised to refer the OM No.F.1/4/2021-PPD dated 18.05.2023 [OM No.1 4 2021 PPD dated 18.05.2023](#) based on its own assessment of reasonableness and based on competitive prices received in Bid / RA process.

मूल्यांकन विधि(मदवार मूल्यांकन विधि) / Evaluation Method (Item Wise Evaluation Method)

Contract will be awarded schedulewise and the determination of L1 will be done separately for each schedule. The details of each schedule are as under:

मूल्यांकन अनुसूचियां / Evaluation Schedules	अनुमानित मूल्य / Estimated Value	वस्तु/श्रेणी
Schedule 1	20000	Clobazan
Schedule 2	41200	Amitripty
Schedule 3	86360	Amitripty
Schedule 4	78000	Clopidogri

Clobazam Tablets (V2) (10000 tablet(s))

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 50% and 20% Local Content to be fulfilled by 2 Local Supplier respectively)

तकनीकी विशिष्टियाँ /Technical Specifications

[* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification](#)

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत
PRODUCT INFORMATION	Medicine Name	Clobazam
	Dosage Form	Tablet
	Strength	5 mg
CERTIFICATIONS & REPORTS	Availability of valid drug manufacturing license issued from the competent authority defined under Drugs and Cosmetic Act and Rules there under as amended till date	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer as per buyer requirement at the time of bid submission and along with supplies	Yes
SHELF LIFE	Shelf life in months from the date of manufacture	24, 36 Or higher (month)

परेषिती/रिपोर्टिंग अधिकारी तथा मात्रा/Consignees/Reporting Officer and Quantity

क्र.सं./S.No.	परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quar
1	ALIP RAY	700104,ESIC HOSPITAL JOKA, DIAMOND HARBOUR ROAD	10000

Amitriptyline Tablets (V2) (40000 tablet(s))

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 50% and 20% Local Conte 2 Local Supplier respectively)

तकनीकी विशिष्टियाँ /Technical Specifications

[* जेम कैटेगरी विशिष्टि के अनुसार / As per GeM Category Specification](#)

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत
PRODUCT INFORMATION	Medicine Name	Amitriptyline
	Dosage Form	Tablet
	Strength	25 mg
CERTIFICATIONS & REPORTS	Availability of valid drug manufacturing license issued from the competent authority defined under Drugs and Cosmetic Act and Rules there under as amended till date	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer as per buyer requirement at the time of bid submission and along with supplies	Yes

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत
SHELF LIFE	Shelf life in months from the date of manufacture	24, 36 Or higher (month)

परेषिती/रिपोर्टिंग अधिकारी तथा मात्रा/Consignees/Reporting Officer and Quantity

क्र.सं./S.No.	परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quar
1	ALIP RAY	700104,ESIC HOSPITAL JOKA, DIAMOND HARBOUR ROAD	40000

Amitriptyline Tablets (V2) (34000 tablet(s))

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 50% and 20% Local Conte 2 Local Supplier respectively)

तकनीकी विशिष्टियाँ /Technical Specifications

[* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification](#)

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत
PRODUCT INFORMATION	Medicine Name	Amitriptyline
	Dosage Form	Tablet
	Strength	10 mg
CERTIFICATIONS & REPORTS	Availability of valid drug manufacturing license issued from the competent authority defined under Drugs and Cosmetic Act and Rules there under as amended till date	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer as per buyer requirement at the time of bid submission and along with supplies	Yes
SHELF LIFE	Shelf life in months from the date of manufacture	24, 36 Or higher (month)

परेषिती/रिपोर्टिंग अधिकारी तथा मात्रा/Consignees/Reporting Officer and Quantity

क्र.सं./S.No.	परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quar
1	ALIP RAY	700104,ESIC HOSPITAL JOKA, DIAMOND HARBOUR ROAD	34000

Clopidogrel Tablets (V2) (40000 tablet(s))

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 50% and 20% Local Conte 2 Local Supplier respectively)

तकनीकी विशिष्टियाँ /Technical Specifications

* जेम कटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत
PRODUCT INFORMATION	Medicine Name	Clopidogrel
	Dosage Form	Tablet
	Strength	75 mg
CERTIFICATIONS & REPORTS	Availability of valid drug manufacturing license issued from the competent authority defined under Drugs and Cosmetic Act and Rules there under as amended till date	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer as per buyer requirement at the time of bid submission and along with supplies	Yes
SHELF LIFE	Shelf life in months from the date of manufacture	24, 36 Or higher (month)

परेषिती/रिपोर्टिंग अधिकारी तथा मात्रा/Consignees/Reporting Officer and Quantity

क्र.सं./S.No.	परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quar
1	ALIP RAY	700104,ESIC HOSPITAL JOKA, DIAMOND HARBOUR ROAD	40000

Special terms and conditions-Version:2 effective from 14-11-2025 for category Clobazam Tablets (V2)

1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the ur Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submitt regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., val drug/medicine under procurement, the license issuing authority etc. at their end.
2. The Buyer shall ask the seller to submit the "Notarized Undertaking" in the mentioned below format (sc may be verified by the buyer at their end.

UNDERTAKING

(to be on non-judicial stamp paper of Rs 10 and not)

I, _____, s/o / d/o / w/o _____, aged about _____ resident of _____ undertake that;

1. I am the partner / proprietor / director of _____ (name of entity) and duly _____ (Name of entity)
2. We are the manufacturers of the drug/medicine _____ ("Product") and intend to offer
3. We state that the license for the Product has been granted/obtained by us as per the provisions there under as amended till date.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the _____ of the Drugs and Cosmetics Rules, 1945 as amended till date. Reference no. for SUGAM portal is _____.
5. We undertake that all the information provided above is true and complete in all respect. We undertake that if any information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetic there under will be initiated.

Place:

Date:

.....

Signature, Name, Designation & Seal

on behalf of the Manufacturer

3. All Provisions of Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date will also be in compliance with all notifications issued by *Central Drugs Standard Control Organization (CDSCO)*, Ministry of Health & Family Welfare, Government of India, Ministry of Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
4. All provisions of Narcotic Drugs & Psychotropic Substances Act, 1985 as amended till date will also be in compliance with all provisions of the Act.
5. The purchase shall be made through Bidding/RA only irrespective of the value.
6. Manufacturer shall have a valid own manufacturing license issued by the competent drug licensing authority under the Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly mentioned in the License. The valid own manufacturing license shall be submitted to the buyer at the time of bid submission.

In case of authorized resellers/distributors, it will be the legal & regulatory liability of the manufacturer or resellers/distributors who are operating in compliance with all relevant laws and regulations and are properly licensed to sell the drug/medicine.

Manufacturer shall be responsible for verifying the validity and authenticity of drug license held by their resellers/distributors.

If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the copy of the revalidation certificate must be submitted with a certificate that application for renewal was made within time frame as per Drugs and Cosmetics Act that has not been deleted by drug licensing authority.

7. Bidder/Seller shall submit the valid GMP/WHO-GMP Certificate of the manufacturing site as per revised by the Concerned Drug Licensing Authority to the buyer at the time of bid submission.
8. Bidder/Seller shall submit a valid **non-Conviction** certificate for last two (2) consecutive years issued by the concerned Drug Licensing Authority to the buyer at the time of bid submission. The certificate must have been issued within 12 months from the date of bid submission.
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the concerned Drug Licensing Authority for last 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/medicine quoted should be highlighted.

This would not apply to drugs, which were introduced in India less than 2 years ago. A certificate from the Drug Licensing Authority for all new drug formulations to this effect.

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, which are manufacturing the same product, only one bidder will be allowed to submit only one offer for one product.
11. The manufacturer shall have in house testing facilities and valid Good Laboratory Practice (GLP) Certificate issued by the concerned Drug Licensing Authority under the Act and Rules made thereunder as amended up to date issued by Central / State Drug Controller / FDA.
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned drug licensing authority.

product.

13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia products shall be submitted by the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability studies) for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data shall be submitted (If manufacturer has licensed a formula from another company and such licensed formula is used for the product, it should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product by any Central or State Government's Drug procurement agencies at the time of submission of bid. Further, the bidder/seller should not have been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Partner should not participate in the bid.
16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any Central or State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intimated in writing document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Government's Drug procurement agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of the buyer.
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories should not be under any court or pending in any court of India by any department of Govt. under prevention of Corruption Act or for criminal conspiracy in the said matter at the time of submission of bid.
19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred only).

They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs/medicines as per the Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended), The Drugs and Cosmetics (Control) Act, 1950, The Indian Statistical Institute Act, 1959, GST Act.

To supply drugs of standard quality as prescribed under the provisions of Drug and Cosmetic Act, 1940 to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" as per the order of Controller of India from time to time.

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the Government of India order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Pharmaceuticals.
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date on or after 31/03/2020-Policy dated 12-9-2020.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs and Cosmetics Act, 1940.

In case pre-dispatch inspection is not applicable, the life of the drugs/medicines shall not have passed more than one sixth (1/6th) of the total shelf life of the drug/medicine at the time of delivery to the consignee.

In case of pre-dispatch inspection, at the time when the stores are offered for inspection, the life of the drug/medicine shall not have passed more than one sixth (1/6th) of the total shelf life of the drugs/medicines.

24. **Recalls**

If products are recalled because of problems with product quality or adverse reaction to the pharmaceuticals, the bidder/seller shall provide full details about the reason leading to the recall, and shall take steps to replace the product at its ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund to the buyer. The product shall not be taken off the market due to safety problems.

25. **Inspection, Testing and Quality Control**

- All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Report** from the bidder's own Quality Control Lab. The Test Report/Certificate of Analysis shall include:
 1. Generic name of the product
 2. Batch No.
 3. Pharmacopoeia Reference and/ or In-house method
 4. Batch quantity
 5. Date of manufacture
 6. Expiry date
 7. Date of test
 8. Description (clarity, color etc)
 9. All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharmacopoeia. Results and the limits for the individual tests should be given
 10. Conclusion
 11. Qualified Person's signature

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

- Buyer will embark on stringent quality checks to ensure that drugs/medicines/goods meet requirements. Buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government combination of or/ all following stages:

a) At Pre-Dispatch stage

b) At Delivery Stage: Inspection done once the drugs/medicines/goods reach at consignee local inventory.

c) Post Delivery Surveillance: The Drugs/Medicines/goods shall have the active ingredients as indicated in official compendiums or technical specifications throughout the shelf-life period of the drug may also be organized by the buyer post-delivery.

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laboratory. The sampling quantities shall be borne by the supplier.
- The buyer's right to inspect, test and, where necessary reject the drugs/medicines/goods after their destination shall in no way be limited or waived by reason of the goods having previously been in dispatch from the place of manufacture.
- **Inspection Methodology:** At pre-dispatch and/or delivery stage, samples of supplies in each batch shall be collected and sent to designated laboratories (NABL Accredited/Government approved laboratories).

At post-delivery surveillance - The samples will be collected from the warehouse of buyer/or designated Quality Control Labs in respect of supplied drugs/medicines/goods at any point during the shelf life.

Handling and testing charges will be borne by the buyer for the above purpose.

- In case of failure of batches during or at any stage (indicated above), the testing charges would be borne by the supplier.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the concerned State. If the supplies are found to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be rejected.

- **At any of testing stage,** Samples which do not meet quality requirement shall render the relevant batch declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/batches of drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier when the batch is found to be "Not of Standard Quality".
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in any way, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/collected fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer. The buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take the stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after the stipulated time.

Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suitable reasons. The concerned State will also be informed by the buyer for initiating necessary action on the supplier if the supplies are found to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be rejected without any intimation.

The decision of the buyer or any officer authorized by buyer, as to the quality of the supplied drugs/medicines/goods shall be final.

- In case any drug/medicine is found substandard either at any of testing stage or during the shelf life period, the batch shall be rejected. The batch shall be re-inspected by the approved laboratory shall be accepted by the supplier/seller. If the same is disputed by the supplier, the batch shall be sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final and the batch shall be submitted within three months, from the date of communication of the disputed test report to the concerned State. The supplier shall approach the concerned Drug Control Authorities for getting the drugs/medicines tested, as per the guidelines issued by the concerned State, at their own cost.

The de-registration / debarment action will be taken by the buyer against the manufacturing unit if the drugs/medicines/goods are found to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches of drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier when the batch is found to be "Not of Standard Quality".

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the drugs/medicines/goods to the buyer. In case of any complaint in the field, the B.M.R/ B.P.R for the particular batch of the product shall be submitted to the concerned State. For New drugs/medicines, complete stability data of 6 months period shall be acceptable.
- The case of admixture of drugs will be treated as a violation of terms and conditions and will not be accepted.
- Statutory provisions on manufacture, distribution, storage and quality issues of drugs/medicines/goods are up to date is vested with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Drug Control Authorities. The buyer reserves the right to initiate prosecution with relation to drugs/medicines under the said Act is also within the purview of the concerned State.
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amended.

Controller/ Drug Inspector may exercise their powers as an Inspecting Agency.

26. **Deduction, Blacklisting, and other penalties on account of Quality failure**

The suitable conditions may be added by the buyer in the bid through Additional Term & Conditions (ATC)

27. **Quality Test by Statutory Authorities:**

If any batch of any product(s) supplied by the supplier is declared "NOT OF STANDARD QUALITY", by an authority, the supplier shall inform the same immediately to the buyer so that the use of the available stock of the product with all consignee/users will be retrieved.

28. **Termination for Default**

The buyer may without prejudice to any other remedy for breach of contract, by written notice of default whole or in part If the supplier fails to promptly replace any drug/medicine/goods rejected submitted for applicable Regulatory Authority in the country of manufacture due to unacceptable quality or reports of recall.

29. **Warranty**

- Supplies must fully comply in all respect with the Technical specifications and conditions laid down in Pharmacopoeia standards.
- Each supply should be accompanied with a "Warranty Certificate" duly signed by the Bidder as under

"The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under the best workmanship and shall be strictly in accordance with the specifications and particulars mentioned in the tender. The stores would continue to conform to the description of and quality aforesaid for a period of up to the specified shelf life from the date of delivery of the said stores to the buyer, have overages within the specified limits and are not subject to recall by the applicable Regulatory Authority due to unacceptable quality. Notwithstanding the above, the fact that the said stores fail to conform to the description and quality as per the decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the stores discovered not to conform to the said description and quality. Losses due to premature deterioration of potency will be made good and supplied by the firm at its own cost at consignee's site.

On such rejection, the stores will be at the seller's risk and all provisions herein contained relating to the replacement of the stores by the supplier/Seller shall if so called upon to do so by the buyer in writing, replace the stores free of cost within forty five days or such further period as may be extended from time to time by the buyer at his cost. The provisions of the tender shall apply to the stores replaced from the date of the replacement thereof otherwise the provisions shall apply as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice the provisions of this contract or otherwise".

Sl. No. & Date	Nomenclature & Specification	Name & Address of Manufacturing Unit	Batch No.	DOM & DOE
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Signature name & designation

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may deem necessary/deemed fit by the buyer, at the suppliers' risk and expense and without prejudice against the supplier under the contract.

30. **Packaging, Labelling and Marking Requirements**

Packaging, Labelling and Marking shall be as per the provisions contained in the Drugs and Cosmetics Act, 1930 as amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buyer in the Additional Conditions (ATC) shall be complied with.

31. **Bar Coding**

All drugs/medicines supplied should incorporate GS1 barcodes standards at various packaging levels (primary, secondary and tertiary) and should encode the information within the barcodes as mentioned by the buyers in addition to other

requirements. Details of bar-coding will be given by the buyer through Additional Terms and Conditions

32. Delivery Period

- Minimum delivery period will be of 45 days from the date of issuing of the purchase
 - The supplier should maintain the recommended temperature of the drug/medicine (wherever inc found that temperature has not been maintained, supply against the said order is liable to be rej
 - The items requiring special cold storage conditions shall be supplied with cold chain transporting manufacturing unit to the warehouses/consignee location.
33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any Additional Terms and Conditions (ATC) in the bid will be applicable.
34. Any other Terms and Conditions which is not included or at variance with the conditions specified in ST Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authent quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede sp shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

Special terms and conditions-Version:2 effective from 24-05-2024 for category Amitriptyline Tablets (V:

1. 1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the ur Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submitt regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., val drug/medicine under procurement, the license issuing authority etc. at their end.
2. The Buyer shall ask the seller to submit the "Notarized Undertaking" in the mentioned below format (sc may be verified by the buyer at their end.

UNDERTAKING

(to be on non-judicial stamp paper of Rs 10 and not

I, _____, s/o / d/o / w/o _____, aged about ____ resident of _____ undertake that;

1. I am the partner / proprietor / director of _____ (name of entity) and duly _____ (Name of entity)
2. We are the manufacturers of the drug/medicine _____ ("Product") and intend to offer
3. We state that the license for the Product has been granted/obtained by us as per the provisions there under as amended till date.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the of the Drugs and Cosmetics Rules, 1945 as amended till date. Reference no. for SUGAM portal is
5. We undertake that all the information provided above is true and complete in all respect. We un information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetic there under will be initiated.

Place:

Date:

.....

Signature, Name, Designation & Seal

on behalf of the Manufacturer

3. All Provisions of Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date will a notifications issued by *Central Drugs Standard Control Organization (CDSCO)*, Ministry of Health & Fam Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
4. All provisions of Narcotic Drugs & Psychotropic Substances Act, 1985 as amended till date will also be a Substances.
5. The purchase shall be made through Bidding/RA only irrespective of the value.
6. Manufacturer shall have a valid own manufacturing license issued by the competent drug licensing autl 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly m License. The valid own manufacturing license shall be submitted to the buyer at the time of bid submis

In case of authorized resellers/distributors, it will be the legal & regulatory liability of the manufacturer are operating in compliance with all relevant laws and regulations and are properly licensed to sell the

Manufacturer shall be responsible for verifying the validity and authenticity of drug license held by the

If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the copy must be submitted with a certificate that application for renewal was made within time frame as per DR that has not been deleted by drug licensing authority.

7. Bidder/Seller shall submit the valid GMP/WHO-GMP Certificate of the manufacturing site as per revised by the Concerned Drug Licensing Authority to the buyer at the time of bid submission.
8. Bidder/Seller shall submit a valid **non-Conviction** certificate for last two (2) consecutive years issued to the buyer at the time of bid submission. The certificate must have been issued within 12 months from the date of bid submission.
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the concerned authority for last 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/medicine name shall be highlighted.

This would not apply to drugs, which were introduced in India less than 2 years ago. A certificate from the concerned authority for all new drug formulations to this effect.

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, which shall be allowed to submit only one bid for all units but necessary document regarding separate manufacturing units shall be submitted. Only one bidder will be allowed to submit only one offer for one product.
11. The manufacturer shall have in house testing facilities and valid Good Laboratory Practice (GLP) Certificate issued by the concerned authority. The Act and Rules made thereunder as amended up to date issued by Central / State Drug Controller / FDA.
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned drug controller for the product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia shall be submitted by the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability studies) for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data shall be submitted (If manufacturer has licensed a formula from another company and such licensed formula is used for the product, the license should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product by any Central / State Government's Drug procurement agencies at the time of submission of bid. Further, the bidder/seller should not have been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Partner should not participate in the bid.
16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any Central / State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intimated to the buyer by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Government's Drug procurement agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of the buyer.
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories should not be blacklisted or pending in any court of India by any department of Govt. under prevention of Corruption Act or for misappropriation of Government fund or any criminal conspiracy in the said matter at the time of submission of bid.
19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred only) in the following format.

They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs/medicines as per the Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended up to date), The Drugs (Prices Control) Act, 1950, The Indian Statistical Institute Act, 1959, GST Act.

To supply drugs of standard quality as prescribed under the provisions of Drug and Cosmetic Act, 1940 and to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" as per the order of the Controller of India from time to time.

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the Drugs (Prices Control) Act, 1950 (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in India shall be applicable.
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date of more than 31026/1/2019-Policy dated 12-9-2020.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs and Cosmetics Act, 1940.

In case pre-dispatch inspection is not applicable, the life of the drugs/medicines shall not have passed the shelf life of the drug/medicine at the time of delivery to the consignee.

Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suital concerned State will also be informed by the buyer for initiating necessary action on the supplier be forfeited without any intimation.

The decision of the buyer or any officer authorized by buyer, as to the quality of the supplied dru

- In case any drug/medicine is found substandard either any of testing stage or during the shelf lif approved laboratory shall be accepted by the supplier/seller. If the same is disputed by the supp sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final anc submitted within three months, from the date of communication of the disputed test report to th approach the concerned Drug Control Authorities for getting the drugs/medicines tested, as per own cost.

The de-registration / debarment action will be taken by the buyer against the manufacturing unit category-A and category-B defects as per guidelines issued by the Ministry of Health & Family W communicated to GeM.

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning t buyer. In case of any complaint in the field, the B.M.R/ B.P.R for the particular batch of the produ For New drugs/medicines, complete stability data of 6 months period shall be acceptable.
- The case of admixture of drugs will be treated as a violation of terms and conditions and will not
- Statutory provisions on manufacture, distribution, storage and quality issues of drugs/medicines up to date is vested with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Dr confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also wi
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amend Controller/ Drug Inspector may exercise their powers as an Inspecting Agency.

26. **Deduction, Blacklisting, and other penalties on account of Quality failure**

The suitable conditions may be added by the buyer in the bid through Additional Term & Conditions (AT

27. **Quality Test by Statutory Authorities:**

If any batch of any product(s) supplied by the supplier is declared "NOT OF STANDARD QUALITY", by ar authority, the supplier shall inform the same immediately to the buyer so that the use of the available : the available stock of the product with all consignee/users will be retrieved.

28. **Termination for Default**

The buyer may without prejudice to any other remedy for breach of contract, by written notice of defau whole or in part If the supplier fails to promptly replace any drug/medicine/goods rejected submitted fo applicable Regulatory Authority in the country of manufacture due to unacceptable quality or reports o of the recall.

29. **Warranty**

- Supplies must fully comply in all respect with the Technical specifications and conditions laid dow Pharmacopoeia standards.
- Each supply should be accompanied with a "Warranty Certificate" duly signed by the Bidder as u

"The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under th workmanship and shall be strictly in accordance with the specifications and particulars mentione the stores would continue to conform to the description of and quality aforesaid for a period of u specified shelf life from the date of delivery of the said stores to the buyer, have overages withir and are not subject to recall by the applicable Regulatory Authority due to unacceptable quality Notwithstanding the above, the fact that the said stores fail to conform to the description and qu decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the discovered not to conform to the said description and quality. Losses due to premature deteriora potency will be made good and supplied by the firm at its own cost at consignee's site.

On such rejection, the stores will be at the seller's risk and all provisions herein contained relatn supplier/Seller shall if so called upon to do so by the buyer in writing, replace the stores free of c forty five days or such further period as may be extended from time to time by the buyer at his c supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer ar period shall apply to the stores replaced from the date of the replacement thereof otherwise the as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice this contract or otherwise".

- Sl. No. & Date

- Nomenclature & Specification
- Name & Address of Manufacturing Unit
- Batch No.
- DOM & DOE
- Qty. of each batch
- Remarks

Signature name & designati

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without prejudice against the supplier under the contract.

30. Packaging, Labelling and Marking Requirements

Packaging, Labelling and Marking shall be as per the provisions contained in the Drugs and Cosmetics / amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buyer. Conditions (ATC) shall be complied with.

31. Bar Coding

All drugs/medicines supplied should incorporate GS1 barcodes standards at various packaging levels (p and should encode the information within the barcodes as mentioned by the buyers in addition to other requirements. Details of bar-coding will be given by the buyer through Additional Terms and Conditions

32. Delivery Period

- Minimum delivery period will be of 45 days from the date of issuing of the purchase
- The supplier should maintain the recommended temperature of the drug/medicine (wherever inc found that temperature has not been maintained, supply against the said order is liable to be rej
- The items requiring special cold storage conditions shall be supplied with cold chain transporting manufacturing unit to the warehouses/consignee location.

33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any Additional Terms and Conditions (ATC) in the bid will be applicable.

34. Any other Terms and Conditions which is not included or at variance with the conditions specified in ST Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authent quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede sp shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

Special terms and conditions-Version:1 effective from 06-07-2023 for category Clopidogrel Tablets (V2)

1. 1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the ur Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submitt regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., val drug/medicine under procurement, the license issuing authority etc. at their end.
2. The Buyer shall ask the seller to submit the "Notarized Undertaking" in the mentioned below format (sc may be verified by the buyer at their end.

UNDERTAKING

(to be on non-judicial stamp paper of Rs 10 and not:

I, _____, s/o / d/o / w/o _____, aged about ____ resident of _____ undertake that;

1. I am the partner / proprietor / director of _____ (name of entity) and duly _____ (Name of entity)
2. We are the manufacturers of the drug/medicine _____ ("Product") and intend to offer
3. We state that the license for the Product has been granted/obtained by us as per the provisions there under as amended till date.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the of the Drugs and Cosmetics Rules, 1945 as amended till date. Reference no. for SUGAM portal is
5. We undertake that all the information provided above is true and complete in all respect. We uni information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetic

there under will be initiated.

Place:

Date:

.....

Signature, Name, Designation & Seal

on behalf of the Manufacturer

3. All Provisions of Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date will a notifications issued by *Central Drugs Standard Control Organization (CDSCO)*, Ministry of Health & Fam Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
4. All provisions of Narcotic Drugs & Psychotropic Substances Act, 1985 as amended till date will also be a Substances.
5. The purchase shall be made through Bidding/RA only irrespective of the value.
6. Manufacturer shall have a valid own manufacturing license issued by the competent drug licensing autl 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly m License. The valid own manufacturing license shall be submitted to the buyer at the time of bid submis

In case of authorized resellers/distributors, it will be the legal & regulatory liability of the manufacturer are operating in compliance with all relevant laws and regulations and are properly licensed to sell the

Manufacturer shall be responsible for verifying the validity and authenticity of drug license held by thei

If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the copy must be submitted with a certificate that application for renewal was made within time frame as per Dr that has not been deleted by drug licensing authority.

7. Bidder/Seller shall submit the valid GMP/WHO-GMP Certificate of the manufacturing site as per revised by the Concerned Drug Licensing Authority to the buyer at the time of bid submission.
8. Bidder/Seller shall submit a valid **non-Conviction** certificate for last two (2) consecutive years issued t buyer at the time of bid submission. The certificate must have been issued within 12 months from the c
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the co 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/ highlighted.

This would not apply to drugs, which were introduced in India less than 2 years ago. A certificate from t for all new drug formulations to this effect.

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, whic be allowed to submit only one bid for all units but necessary document regarding separate manufacturi one bidder will be allowed to submit only one offer for one product.
11. The manufacturer shall have in house testing facilities and valid Good Laboratory Practice (GLP Certific Act and Rules made thereunder as amended up to date issued by Central / State Drug Controller / FDA
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned d product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia t the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stabil packing for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete sta (If manufacturer has licensed a formula from another company and such licensed formula is used for th should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted produ / Central or State Government's Drug procurement agencies at the time of submission of bid. Further, c house testing or testing by any State Government / Central Government / its Drug procurement agenci been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Par participate in the bid.
16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any : State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be inti document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Gov agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of t

18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories should not be involved in any court of India by any department of Govt. under prevention of Corruption Act or for cheating Government fund or any criminal conspiracy in the said matter at the time of submission of bid.
19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred and no paise).

They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs/medicines as per the Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended), The Drugs (Control) Act, 1950, The Indian Statistical Institute Act, 1959, GST Act.

To supply drugs of standard quality as prescribed under the provisions of Drug and Cosmetic Act, 1940 and to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" as per the order of Controller of India from time to time.

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the Government of India order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Pharmaceuticals.
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date on or after 31026/1/2019-Policy dated 12-9-2020.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs and Cosmetics Act, 1940.

In case pre-dispatch inspection is not applicable, the life of the drugs/medicines shall not have passed more than one sixth (1/6th) of the total shelf life of the drug/medicine at the time of delivery to the consignee.

In case of pre-dispatch inspection, at the time when the stores are offered for inspection, the life of the drugs/medicines shall not exceed one sixth (1/6th) of the total shelf life of the drugs/medicines.

24. **Recalls**

If products are recalled because of problems with product quality or adverse reaction to the pharmaceuticals, the seller/bidder shall immediately inform the buyer, providing full details about the reason leading to the recall, and shall take steps to replace the products at their ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund to the buyer. The products shall not be taken off the market due to safety problems.

25. **Inspection, Testing and Quality Control**

- All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Report** from the seller's own Quality Control Lab. The Test Report/Certificate of Analysis shall include:
 1. Generic name of the product
 2. Batch No.
 3. Pharmacopoeia Reference and/ or In-house method
 4. Batch quantity
 5. Date of manufacture
 6. Expiry date
 7. Date of test
 8. Description (clarity, color etc)
 9. All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharmaceutical standards. The results and the limits for the individual tests should be given
 10. Conclusion
 11. Qualified Person's signature

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

- Buyer will embark on stringent quality checks to ensure that drugs/medicines/goods meet requirements. The buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government Laboratory. The combination of or/ all following stages:

a) At Pre-Dispatch stage

b) At Delivery Stage: Inspection done once the drugs/medicines/goods reach at consignee local inventory.

c) Post Delivery Surveillance: The Drugs/Medicines/goods shall have the active ingredients and their concentrations as indicated in official compendiums or technical specifications throughout the shelf-life period of the drug. The surveillance may also be organized by the buyer post-delivery.

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laboratory for the purpose of Quality Control. The sampling quantities shall be borne by the supplier.

- The buyer's right to inspect, test and, where necessary reject the drugs/medicines/goods after their destination shall in no way be limited or waived by reason of the goods having previously been in dispatch from the place of manufacture.
- **Inspection Methodology:** At pre-dispatch and/or delivery stage, samples of supplies in each batch shall be collected and sent to designated laboratories (NABL Accredited/Government approved laboratories).

At post-delivery surveillance - The samples will be collected from the warehouse of buyer/or designated Quality Control Labs in respect of supplied drugs/medicines/goods at any point during the contract period.

Handling and testing charges will be borne by the buyer for the above purpose.

- In case of failure of batches during or at any stage (indicated above), the testing charges would be borne by the supplier.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the concerned State Government. If the supplies are found to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be rejected.

- **At any of testing stage,** Samples which do not meet quality requirement shall render the relevant batch declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/batches of drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier when the batch is rejected.
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in any other way, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/collected fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer. The buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take the same back within stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after the expiry of the stipulated time.

Action may also be initiated by the buyer for debarment/blacklisting against the supplier for suits/claims concerned State will also be informed by the buyer for initiating necessary action on the supplier if the same is found to be forfeited without any intimation.

The decision of the buyer or any officer authorized by buyer, as to the quality of the supplied drugs/medicines/goods shall be final.

- In case any drug/medicine is found substandard either any of testing stage or during the shelf life, the batch shall be accepted by the supplier/seller. If the same is disputed by the supplier, the sample shall be sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final and the supplier shall approach the concerned Drug Control Authorities for getting the drugs/medicines tested, as per guidelines issued by the Government of West Bengal at their own cost.

The de-registration / debarment action will be taken by the buyer against the manufacturing unit if found to be category-A and category-B defects as per guidelines issued by the Ministry of Health & Family Welfare, Government of West Bengal communicated to GeM.

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the drugs/medicines/goods to the buyer. In case of any complaint in the field, the B.M.R/ B.P.R for the particular batch of the product shall be submitted to the concerned Drug Control Authorities. For New drugs/medicines, complete stability data of 6 months period shall be acceptable.
- The case of admixture of drugs will be treated as a violation of terms and conditions and will not be accepted.
- Statutory provisions on manufacture, distribution, storage and quality issues of drugs/medicines/goods up to date is vested with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Drug Control Authorities. Confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also within the powers of the concerned authorities.
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amended, the Controller/ Drug Inspector may exercise their powers as an Inspecting Agency.

26. **Deduction, Blacklisting, and other penalties on account of Quality failure**

The suitable conditions may be added by the buyer in the bid through Additional Term & Conditions (ATC).

27. **Quality Test by Statutory Authorities:**

If any batch of any product(s) supplied by the supplier is declared "NOT OF STANDARD QUALITY", by any authority, the supplier shall inform the same immediately to the buyer so that the use of the available stock of the product with all consignee/users will be retrieved.

28. **Termination for Default**

The buyer may without prejudice to any other remedy for breach of contract, by written notice of default terminate the contract in whole or in part if the supplier fails to promptly replace any drug/medicine/goods rejected submitted for testing to the applicable Regulatory Authority in the country of manufacture due to unacceptable quality or reports of recall.

29. **Warranty**

- Supplies must fully comply in all respect with the Technical specifications and conditions laid down Pharmacopoeia standards.
- Each supply should be accompanied with a "Warranty Certificate" duly signed by the Bidder as u

"The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under the workmanship and shall be strictly in accordance with the specifications and particulars mentioned. The stores would continue to conform to the description of and quality aforesaid for a period of the specified shelf life from the date of delivery of the said stores to the buyer, have overages within and are not subject to recall by the applicable Regulatory Authority due to unacceptable quality. Notwithstanding the above, the fact that the said stores fail to conform to the description and quality decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the stores discovered not to conform to the said description and quality. Losses due to premature deterioration of potency will be made good and supplied by the firm at its own cost at consignee's site.

On such rejection, the stores will be at the seller's risk and all provisions herein contained relating to the supplier/Seller shall if so called upon to do so by the buyer in writing, replace the stores free of cost within forty five days or such further period as may be extended from time to time by the buyer at his cost. The supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer within the period shall apply to the stores replaced from the date of the replacement thereof otherwise the liability as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice this contract or otherwise".

Sl. No. & Date	Nomenclature & Specification	Name & Address of Manufacturing Unit	Batch No.	DOM & DOE
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Signature name & designation

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without prejudice against the supplier under the contract.

30. **Packaging, Labelling and Marking Requirements**

Packaging, Labelling and Marking shall be as per the provisions contained in the Drugs and Cosmetics Act, 1930 as amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buyer. Additional Terms and Conditions (ATC) shall be complied with.

31. **Bar Coding**

All drugs/medicines supplied should incorporate GS1 barcodes standards at various packaging levels (primary, secondary and tertiary) and should encode the information within the barcodes as mentioned by the buyers in addition to other requirements. Details of bar-coding will be given by the buyer through Additional Terms and Conditions.

32. **Delivery Period**

- Minimum delivery period will be of 45 days from the date of issuing of the purchase order.
- The supplier should maintain the recommended temperature of the drug/medicine (wherever indicated). If found that temperature has not been maintained, supply against the said order is liable to be rejected.
- The items requiring special cold storage conditions shall be supplied with cold chain transporting facilities from the manufacturing unit to the warehouses/consignee location.

33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any other particulars shall be given by the buyer through Additional Terms and Conditions (ATC) in the bid will be applicable.

34. Any other Terms and Conditions which is not included or at variance with the conditions specified in the Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authentic quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede specific terms and conditions, which shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

क्रेता द्वारा जोड़ी गई बिड की विशेष शर्तें/**Buyer Added Bid Specific Terms and Conditions**

1. **Generic**

OPTION CLAUSE: The Purchaser reserves the right to increase or decrease the quantity to be ordered up to 25% of contract. The purchaser also reserves the right to increase the ordered quantity up to 25% of the contracted rates. The delivery period of quantity shall commence from the last date of original delivery or during the extended delivery period the additional time shall commence from the last date of extended delivery. (Increased quantity ÷ Original quantity) × Original delivery period (in days), subject to minimum of 30 days. If the additional time equals the original delivery period. The Purchaser may extend this calculated delivery duration exercising the option clause. Bidders must comply with these terms.

2. **Scope of Supply**

Scope of supply (Bid price to include all cost components) : Only supply of Goods

3. **Certificates**

Material Test Certificate Should Be Sent Along with The Supply. The Material Will Be Checked by Buyer's Lab for Acceptance of the Item.

अस्वीकरण/**Disclaimer**

The additional terms and conditions have been incorporated by the Buyer after approval of the Competent Authority. The organization is solely responsible for the impact of these clauses on the bidding process, its outcome, and consequences arising in the bidding process due to these ATCs and due to modification of technical specifications and / or terms and conditions are incorporated by the Buyer regarding following, the bid and resultant contracts shall be treated as null and void at any stage of bidding process without any notice:-

1. Definition of Class I and Class II suppliers in the bid not in line with the extant Order / Office Memorandum issued.
2. Seeking EMD submission from bidder(s), including via Additional Terms & Conditions, in contravention to existing terms and conditions.
3. Publishing Custom / BOQ bids for items for which regular GeM categories are available without any Category based bid.
4. Creating BoQ bid for single item.
5. Mentioning specific Brand or Make or Model or Manufacturer or Dealer name.
6. Mandating submission of documents in physical form as a pre-requisite to qualify bidders.
7. Floating / creation of work contracts as Custom Bids in Services.
8. Seeking sample with bid or approval of samples during bid evaluation process. (However, in bids for [attached](#) procurement policy of the buyer nodal Ministries)
9. Mandating foreign / international certifications even in case of existence of Indian Standards without specifying.
10. Seeking experience from specific organization / department / institute only or from foreign / export experience.
11. Creating bid for items from irrelevant categories.
12. Incorporating any clause against the MSME policy and Preference to Make in India Policy.
13. Reference of conditions published on any external site or reference to external documents/clauses.
14. Asking for any Tender fee / Bid Participation fee / Auction fee in case of Bids / Forward Auction, as the case may be.
15. Buyer added ATC Clauses which are in contravention of clauses defined by buyer in system generated bid terms and conditions, EMD Detail, ePBG Detail and MII and MSE Purchase Preference sections of the bid, unless otherwise allowed by the system.
16. In a category based bid, adding additional items, through buyer added additional scope of work/ additional terms and conditions, needs more items along with the main item, the same must be added through bunching category based item BoQ with the main category based item, the same must not be done through ATC or Scope of Work.

Further, if any seller has any objection/grievance against these additional clauses or otherwise on any aspect of this same by using the Representation window provided in the bid details field in Seller dashboard after logging in as a seller, he is duty bound to reply to all such representations and would not be allowed to open bids if he fails to reply to such representations.

All GeM Sellers/Service Providers shall ensure full compliance with all applicable labour laws, including guidelines under the four Labour Codes i.e. the Code on Wages, 2019; the Industrial Relations Code, 20
Working Conditions Code, 2020; and the Code on Social Security, 2020 as and when notified and brought

For all provisions of the Labour Codes that are pending operationalisation through rules, schemes or notifications, and the pre-existing labour enactments (such as The Minimum Wages Act, 1948, The Payment of Wages Act, 1947, The Equal Remuneration Act, 1976, The Payment of Gratuity Act, 1972, etc. and relevant State Rules) shall

The Seller/ Service Providers shall, therefore, be responsible for ensuring compliance under:

- **All notified and enforceable provisions of the new Labour Codes as mentioned hereinabove; and**
- **All operative provisions of the erstwhile Labour Laws until their complete substitution.**

All obligations relating to wages, social security, safety, working conditions, industrial relations etc. are strictly met by the Seller/ Service Provider. Any non-compliance shall constitute a breach of the contract and appropriate action in accordance with the contract and applicable law.

[यह बिड सामान्य शर्तों के अंतर्गत भी शासित है /This Bid is also governed by the General Terms and](#)

जेम की सामान्य शर्तों के खंड 26 के संदर्भ में भारत के साथ भूमि सीमा साझा करने वाले देश के बिडर से खरीद पर प्रतिबंध के संबंध में भाग लेने वाले देशों के बिडर को इस निविदा में बिड देने के लिए तभी पात्र होगा जब वह बिड देने वाला सक्षम प्राधिकारी के पास पंजीकृत हो। बिड में भाग लेते समय बिडर को जानने व इसका अनुपालन न करने पर अनुबंध को तत्काल समाप्त करने और कानून के अनुसार आगे की कानूनी कार्रवाई का आधार होगा।/In terms of a country which shares a land border with India, any bidder from a country which shares a land border with India will be eligible to bid in this tender only if the bidder is registered with the competent authority. Bidding from such countries shall be subject to the bidder's compliance with the applicable laws and regulations. Any non-compliance of this and any false declaration and non-compliance of this would be a ground for immediate termination of the contract and further legal action in accordance with the contract and applicable law.

---धन्यवाद/Thank You---