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**BID NO:** GEM/2026/B/7115720

**Items:** Streptokinase Injection,Dexame...  
**Specification(S)**  
**Remaining Days :** View

**Notification(S)**  
**Bid Document** 📄  
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**Start Date:** 15-01-2026 6:09 PM  
**End Date:** 09-02-2026 7:00 PM  
**Bid Status:** Active  
**Bid Doc Hash:** View



Open Bid

Transfer of Bid/RA ⓘ

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Himanshu Nirmal Chandu

[HOME \(HTTPS://MKP.GEM.GOV.IN/DASHBOARD\)](https://mkp.gem.gov.in/dashboard) / BID FINALIZATION

BID DETAILS

TECHNICAL EVALUATION

FINANCIAL EVALUATION

EVALUATION

BID AWARDED

## 1. Bid Details

**GEM/2026/B/7115720** (/showbidDocument/8844771)**Bid Status:** Active**Quantity:** 61750**Bid Validity (From End Date):** 180 (Days)**Competent Authority Document:** View**Bid Start Date / Time:** 15-01-2026 18:09:14**Bid End Date / Time:** 09-02-2026 19:00:00**Bid Opening Date / Time:** 09-02-2026 19:30:00**Consignees / Reporting Officer / Delivery Location(S)****EMD:** Required Track EMD  
([Https://Bidplus.Gem.Gov.In/Bidding/Track/Trackepbg/8844771](https://bidplus.gem.gov.in/Bidding/Track/Trackepbg/8844771))**Average Turn Over of Last 3 Years:** 8 Lakh (s)  
**Experience with Gov. Required:** Year (s)

## Buyer Details

**Name:** Himanshu Nirmal Chandu**Address:** Himanshu Nirmal  
Chandu,Buyer143.Aiimsa.Or@Gembuyer.In,AIIMS  
BHUBANESWAR, AT-SIJUA, PATRAPADA, POST-  
DUMUDUMA,  
BHUBANESWAR,KHURDA,ODISHA,751019,India**Ministry:** Ministry Of Health And Family Welfare**Department:** Department Of Health And Family  
Welfare**Organisation:** All India Institute Of Medical  
Sciences (Aiims)**Office:** Bhubaneswar

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(<https://www.slideshare.net/GeMProcurementReimag>)

## बिड दस्तावेज़ / Bid Document

### बिड विवरण/Bid Details

बिड बंद होने की तारीख/समय /Bid End Date/Time	09-02-2026 19:00:00
बिड खुलने की तारीख/समय /Bid Opening Date/Time	09-02-2026 19:30:00
बिड पेशकश वैधता (बंद होने की तारीख से)/Bid Offer Validity (From End Date)	180 (Days)
मंत्रालय/राज्य का नाम/Ministry/State Name	Ministry Of Health And Family Welfare
विभाग का नाम/Department Name	Department Of Health And Family Welfare
संगठन का नाम/Organisation Name	All India Institute Of Medical Sciences (a
कार्यालय का नाम/Office Name	Bhubaneswar
कुल मात्रा/Total Quantity	61750
वस्तु श्रेणी /Item Category	Streptokinase Injection (Q2) , Dexameth Dicyclomine Injection (Q2) , Lactulose O
बिडर का न्यूनतम औसत वार्षिक टर्नओवर (3 वर्षों का) /Minimum Average Annual Turnover of the bidder (For 3 Years)	8 Lakh (s)
मूल उपकरण निर्माता का औसत टर्नओवर (गत 3 वर्षों का)/OEM Average Turnover (Last 3 Years)	69 Lakh (s)
उन्हीं/समान सेवा के लिए अपेक्षित विगत अनुभव के वर्ष/Years of Past Experience Required for same/similar service	3 Year (s)
वर्षों के अनुभव एवं टर्नओवर से एमएसई को छूट प्राप्त है / MSE Relaxation for Years Of Experience and Turnover	Yes   Complete
स्टार्टअप के लिए अनुभव के वर्षों और टर्नओवर से छूट प्रदान की गई है / Startup Relaxation for Years Of Experience and Turnover	Yes   Complete
विक्रेता से मांगे गए दस्तावेज़/Document required from seller	Experience Criteria,Past Performance,Bi Authorization Certificate,OEM Annual Tu ATC),Additional Doc 2 (Requested in AT Doc 4 (Requested in ATC),Compliance o *In case any bidder is seeking exemptio supporting documents to prove his eligi evaluation by the buyer
क्या आप निविदाकारों द्वारा अपलोड किए गए दस्तावेजों को निविदा में भाग लेने वाले सभी निविदाकारों को दिखाना चाहते हैं? संदर्भ मेनू 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

बिड विवरण/Bid Details	
दिनों की संख्या, जिनके लिए बिड लगाने की समय-सीमा बढ़ाई जाएगी। / <b>Number of days for which Bid would be auto-extended</b>	7
ऑटो एक्सटेंशन अधिकतम कितनी बार किया जाना है। / <b>Number of Auto Extension count</b>	1
विगत प्रदर्शन / <b>Past Performance</b>	80 %
बिड से रिवर्स नीलामी सक्रिय किया/Bid to RA enabled	Yes
रिवर्स नीलामी योग्यता नियम/RA Qualification Rule	H1-Highest Priced Bid Elimination
बिड का प्रकार/Type of Bid	Two Packet Bid
प्राथमिक उत्पाद श्रेणी/Primary product category	Streptokinase Injection
तकनीकी मूल्यांकन के दौरान तकनीकी स्पष्टीकरण हेतु अनुमत समय /Time allowed for Technical Clarifications during technical evaluation	3 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
मूल्यांकन पद्धति/Evaluation Method	Item wise evaluation
मध्यस्थता खंड/Arbitration Clause	No
सुलह खंड/Mediation Clause	No

#### ईएमडी विवरण/EMD Detail

एडवाइजरी बैंक/Advisory Bank	Bank of India
Schedule 1 ईएमडी राशि/EMD Amount (In INR)	8437
Schedule 2 ईएमडी राशि/EMD Amount (In INR)	15000
Schedule 3 ईएमडी राशि/EMD Amount (In INR)	1470
Schedule 4 ईएमडी राशि/EMD Amount (In INR)	12
Schedule 5 ईएमडी राशि/EMD Amount (In INR)	27000

#### ईपीबीजी विवरण /ePBG Detail

एडवाइजरी बैंक/Advisory Bank	Bank of India
ईपीबीजी प्रतिशत (%) /ePBG Percentage(%)	5.00
ईपीबीजी की आवश्यक अवधि (माह) /Duration of ePBG required (Months).	26

(a). जेम की शर्तों के अनुसार ईएमडी छूट के इच्छुक बिडर को संबंधित कैटेगरी के लिए बिड के साथ वैध समर्थित दस्तावेज प्रस्तुत करने हैं। एमएसई केटेगरी के लिए सेवा प्रदाता ईएमडी से छूट के पात्र हैं। व्यापारियों को इस नीति के दायरे से बाहर रखा गया है।/EMD EXEMPTION: The bidder seeking EMI

document for the relevant category as per GeM GTC with the bid. Under MSE category, only manufacturers for goods are eligible for exemption from EMD. Traders are excluded from the purview of this Policy.

(b). The EMD Amount will be applicable for each schedule/group selected during Bid creation.

(c). ईएमडी और संपादन जमानत राशि, जहां यह लागू होती है, लाभार्थी के पक्ष में होनी चाहिए। / EMD & Performance security should be in favor of the beneficiary.

#### लाभार्थी /Beneficiary :

AIIMS Bhubaneswar  
Bhubaneswar, Department of Health and Family Welfare, All India Institute of Medical Sciences (AIIMS), Ministry of Health and Family Welfare (Aiiims Bhubaneswar)

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
सार्वजनिक खरीद (मेक-इन-इंडिया को प्राथमिकता) आदेश 2017 के अनुसार केवल क्लास 1/क्लास 2 के स्थानीय आपूर्तिकर्ताओं को ही भागीदारी की अनुमति है दिनांक 16.09.2020 (समय-समय पर संशोधित एवं लागू) / Allow participation only from Class 1/Class 2 local suppliers as per the Public procurement(Preference to Make-in-india) order 2017 date 16.09.2020(as amended and applicable time to time)	Yes, in compliance with the MII ORDER : (time to time)

#### 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 Micro or Small Enterprise (MSE) as per latest orders issued by Ministry of MSME, the bidder shall be relaxed from the "Turnover" as defined above subject to meeting of quality and technical specifications. If the bidder itself is MSE OEM, the "OEM Average Turnover" criteria also subject to meeting of quality and technical specifications. The bidder seeking Relaxation from Turnover Criteria, shall upload the supporting documents to prove his eligibility for Relaxation.

3. 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.

Relaxation.

4. If the bidder is a DPIIT registered Startup, the bidder shall be relaxed from the the eligibility criteria of "Bidder Turnover and technical specifications. If the bidder is DPIIT Registered OEM of the offered products, it would be relaxed subject to meeting of quality and technical specifications. The bidder seeking Relaxation from Turnover shall upload Relaxation.

5. The minimum average annual financial turnover of the bidder during the last three years, ending on 31st March of the year above in the bid document. Documentary evidence in the form of certified Audited Balance Sheets of relevant period or Cost Accountant indicating the turnover details for the relevant period shall be uploaded with the bid. In case the bidder is less than 3-year-old, the average turnover in respect of the completed financial years after the date of constitution shall be considered.

6. Experience Criteria: In respect of the filter applied for experience criteria, the Bidder or its OEM of the product offered should have regularly, manufactured and supplied same or similar Category Products to any Central / State Govt Org. as indicated above in the bid document before the bid opening date. Copies of relevant contracts and delivery acceptance certificates with bid in support of having supplied some quantity during each of the Financial year. In case of bunch bids, the category should meet this criterion.

7. OEM Turn Over Criteria: The minimum average annual financial turnover of the OEM of the offered product during the previous financial year, should be as indicated in the bid document. Documentary evidence in the form of certified Audited certificate from the Chartered Accountant / Cost Accountant indicating the turnover details for the relevant period shall be uploaded. If the constitution / incorporation of the OEM is less than 3 year old, the average turnover in respect of the completed financial years shall be taken into account for this criteria.

8. Preference to Make In India products (For bids < 200 Crore): Preference shall be given to Class 1 local supplier as per the Public Procurement (preference to Make-in -India) order 2017 as amended from time to time and its subsequent Orders/Notifications issued by concerned Ministry. No minimum local content to qualify as a Class 1 local supplier is denoted in the bid document. If the bidder wants to avail, 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 for companies as per the Public Procurement (preference to Make-in -India) order 2017 dated 04.06.2020. Only Class-I suppliers as per the 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 2021 PPD dated 18.05.2023](#) 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 Commerce and Industries.

9. Purchase preference will be given to MSEs having valid Udyam Registration and whose credentials are validated or verified in Public Procurement Policy for Micro and Small Enterprises (MSEs) Order, 2012 dated 23.03.2012 issued by Ministry of Commerce and Industries. If the bidder wants to avail themselves of the Purchase preference, they should declare the same in the bid. Traders are excluded from the purview of Public Procurement Policy for Micro and Small Enterprises. Products manufactured by some other OEM are not eligible for any purchase preference. In respect of bid for 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 within L-1+ 15% (Selected by Buyer) of margin of purchase preference /price band defined in relevant policy, such 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 valid and approved by Buyer after evaluation of documents submitted.

10. Estimated Bid Value indicated above is being declared solely for the purpose of guidance on EMD amount and for qualification of bidder. It has no relevance or bearing on the price to be quoted. It will not have any impact on bid participation. Also this is not going to be used as a criteria in determining reasonableness of quoted price. The bidder should be based on its own assessment of reasonableness and based on competitive prices received in Bid / RA process.

11. Past Performance: The Bidder or its OEM {themselves or through re-seller(s)} should have supplied same or similar products to any Central / State Govt Organization / PSU (minimum cumulative order quantity in any one financial year) to be submitted along with bid in support of quantity supplied in the category related to primary product having highest bid value should meet this criterion.

12. Reverse Auction would be conducted amongst all the technically qualified bidders except the Highest quoting bidder. The Highest quoting bidder will not be allowed to participate in RA. However, H-1 will also be allowed to participate in RA in following cases:

- i. If number of technically qualified bidders are only 2 or 3.
- ii. If Buyer has chosen to split the bid amongst N sellers, and H1 bid is coming within N.
- iii. In case Primary product of only one OEM is left in contention for participation in RA on elimination of H-1.
- iv. If L-1 is non-MSE and H-1 is eligible MSE and H-1 price is coming within price band of 15% of Non-MSE L-1.
- v. If L-1 is non-MII and H-1 is eligible MII and H-1 price is coming within price band of 20% of Non-MII L-1.

#### **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 d



each schedule are as under:

मूल्यांकन अनुसूचियां / <b>Evaluation Schedules</b>	वस्तु/श्रेणी / <b>Item/Category</b>
Schedule 1	Streptokinase Injection
Schedule 2	Dexamethasone Injection
Schedule 3	Haloperidol Injection
Schedule 4	Dicyclomine Injection
Schedule 5	Lactulose Oral Liquid

### Streptokinase Injection ( 150 pieces )

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 80% and 51% Local Content 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	Streptokinase
	Dosage Form	Injection
	<b>Strength</b>	1500000 IU
	Compliance to uploaded Special Terms and Conditions	Yes
PACKAGING	Type of primary packing	Vial
	Primary pack size	Single Vial
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 <b>(month)</b>

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

क्र.सं./S.No.	परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quar
1	GAGAN BIHARI NAIK	751019,AIIMS BHUBANESWAR, AT-SIJUA, PATRAPADA, POST-DUMUDUMA, BHUBANESWAR	150

### Dexamethasone Injection ( 50000 pieces )

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 80% and 51% Local Content 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	Dexamethasone
	Dosage Form	Injection
	Strength	4 mg/mL
	Compliance to uploaded Special Terms and Conditions	Yes
PACKAGING	Type of primary packing	Vial
	Primary pack size	2 ml
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	GAGAN BIHARI NAIK	751019,AIIMS BHUBANESWAR, AT-SIJUA, PATRAPADA, POST-DUMUDUMA, BHUBANESWAR	50000

### Haloperidol Injection ( 7000 pieces )

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 80% and 51% Local Content 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	Haloperidol
	Dosage Form	Injection
	Strength	5 mg/mL
	Compliance to uploaded Special Terms and Conditions	Yes
PACKAGING	Type of primary packing	Ampoule
	Primary pack size	1 ml
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)

#### प्रेषिती/रिपोर्टिंग अधिकारी तथा मात्रा/Consignees/Reporting Officer and Quantity

क्र.सं./S.No.	प्रेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quar
1	GAGAN BIHARI NAIK	751019,AIIMS BHUBANESWAR, AT-SIJUA, PATRAPADA, POST-DUMUDUMA, BHUBANESWAR	7000

#### Dicyclomine Injection ( 100 pieces )

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 80% and 51% Local Content 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	Dicyclomine
	Dosage Form	Injection
	Strength	10 mg/ mL
	Compliance to uploaded Special Terms and Conditions	Yes
PACKAGING	Type of primary packing	Ampoule
	<b>Primary pack size</b>	2 ml
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 <b>(month)</b>

**परिषिती/रिपोर्टिंग अधिकारी तथा मात्रा/Consignees/Reporting Officer and Quantity**

क्र.सं./S.No.	परिषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quar
1	GAGAN BIHARI NAIK	751019,AIIMS BHUBANESWAR, AT-SIJUA, PATRAPADA, POST-DUMUDUMA, BHUBANESWAR	100

**Lactulose Oral Liquid ( 4500 pieces )**

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 80% and 51% 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	Lactulose
	Dosage Form	Oral Liquid
	Strength	10 g/15 mL
	Compliance to uploaded Special Terms and Conditions	Yes

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत
PACKAGING	Type of primary packing	Bottle
	Primary pack size	200 ml
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 <b>(month)</b>

**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	GAGAN BIHARI NAIK	751019,AIIMS BHUBANESWAR, AT-SIJUA, PATRAPADA, POST-DUMUDUMA, BHUBANESWAR	4500

**Special terms and conditions-Version:1 effective from 14-11-2025 for category Streptokinase Injection**

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 no legal action/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 include notifications issued by *Central Drugs Standard Control Organization (CDSCO)*, Ministry of Health & Family Welfare (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 applicable to these 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 authority under 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly marked with 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 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 authorized resellers/distributors.

*If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the copy of the application must be submitted with a certificate that application for renewal was made within time frame as per Drug 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 requirements issued 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 court to the buyer at the time of bid submission. The certificate must have been issued within 12 months from the date of submission to the buyer.
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 to 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 are licensed by the concerned Drug Licensing Authority, only one bid for all units but necessary document regarding separate manufacturing units shall be submitted. 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 Central / State Drug Controller / FDA.
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned drug licensing authority for the product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia (USP, BP, IP) 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 along with licensing agreement. (If manufacturer has licensed a formula from another company and such licensed formula is used for the product, the stability data 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 the Central / State Government's Drug procurement agencies at the time of submission of bid. Further, if the bidder/seller has been blacklisted or testing by any State Government / Central Government / its Drug procurement agencies at the time of submission of bid, he/she should have been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Partner shall not be allowed to 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 intimated to the buyer by a 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 I
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories sho or pending in any court of India by any department of Govt. under prevention of Corruption Act or for cl 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 o

*They will comply with all the statues & legislation regarding manufacturing, import, sale, and supply of i Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as ar (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" 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 | seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisio India) order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Ph
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry da 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 a

In case pre-dispatch inspection is not applicable, the life of the drugs/medicines shall not have passed i 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 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 pharmace buyer, providing full details about the reason leading to the recall, and shall take steps to replace the p ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refun been 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 Repoi** 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 pharma 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 requir 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 locat inventory.

**c) Post Delivery Surveillance:** The Drugs/Medicines/goods shall have the active ingredients an 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 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 batch is 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 test, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/consignees 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 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 debarring/blacklisting against the supplier for suitable concerned State will also be informed by the buyer for initiating necessary action on the supplier if the batch is 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 test, the batch 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 supplier shall submit the same within three months, from the date of communication of the disputed test report to the buyer. The supplier shall approach the concerned Drug Control Authorities for getting the drugs/medicines tested, at his own cost.

The de-registration / debarment action will be taken by the buyer against the manufacturing unit if the batch is found to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be rejected as per guidelines issued by the Ministry of Health & Family Welfare, Government of India.

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the product 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 buyer. 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 up to date is vested with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Drug Control Authorities. The power of confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also vested with the DCGI (CDSCO)/ MoH& FW.
- 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 inspection.



applicable Regulatory Authority in the country of manufacture due to unacceptable quality or reports of the 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 under

"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 at the end of 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 the 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. The 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) and 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 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 the

shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

**Special terms and conditions-Version:1 effective from 14-11-2025 for category Dexamethasone Injection**

1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submit regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., valid 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 notary)**

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 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 who are operating in compliance with all relevant laws and regulations and are properly licensed to sell the product.

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

*If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the copy of the application 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 court 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.

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, which 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 i 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 intil 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 l
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories sho or pending in any court of India by any department of Govt. under prevention of Corruption Act or for cl 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 o

*They will comply with all the statues & legislation regarding manufacturing, import, sale, and supply of i Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as ar (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" 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 | seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisio India) order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Ph
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry da 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 a

In case pre-dispatch inspection is not applicable, the life of the drugs/medicines shall not have passed i 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 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 pharmace buyer, providing full details about the reason leading to the recall, and shall take steps to replace the p ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refun been 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 Repor** 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 approved laboratory. 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 location 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. This 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. 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 the possession of the supplier or dispatched 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 laboratory).

**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 laboratory.

If the batch is 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 of the tests, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/colony 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 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 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 batch is found to be "Not of Standard Quality" or spurious or adulterated or misbranded.

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, the batch shall be rejected. The batch shall be accepted by the supplier/seller. If the same is disputed by the supplier, it shall be sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final and submitted within three months, from the date of communication of the disputed test report to the buyer. The supplier shall approach the concerned Drug Control Authorities for getting the drugs/medicines tested, as per the guidelines. The cost of testing shall be borne by the supplier.

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 Welfare communicated to GeM.

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the product. In case of any complaint in the field, the B.M.R/ B.P.R for the particular batch of the product. 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 acceptable.
- 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 Drug Inspector, confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also within the purview of the said Act.
- 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, reject the whole or in part. If the supplier fails to promptly replace any drug/medicine/goods rejected submitted for approval by 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 in the Bill of Materials (BOM) and 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 warranty shall be strictly in accordance with the specifications and particulars mentioned in the Bill of Materials (BOM). 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 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 specified in the Bill of Materials (BOM) or 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 replacement. 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 discretion. The warranty shall apply to the stores replaced from the date of the replacement thereof otherwise the warranty shall be void. 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 Rules, 1945 as 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 (primary, secondary, 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 (ATC).

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 facility from 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 ST-1 shall be given by the buyer through 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 Special Terms and Conditions (STC), which shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

**Special terms and conditions-Version:1 effective from 14-11-2025 for category Haloperidol Injection**

1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the valid Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submitted regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., valid 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 (which may be verified by the buyer at their end).

**UNDERTAKING**

**(to be on non-judicial stamp paper of Rs 10 and notarized)**

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 authorized to sign on behalf of \_\_\_\_\_ (Name of entity)
2. We are the manufacturers of the drug/medicine \_\_\_\_\_ ("Product") and intend to offer the same for sale.
3. We state that the license for the Product has been granted/obtained by us as per the provisions of the Drugs and Cosmetics Rules, 1945 as amended till date.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the website 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 no legal action/claim will be initiated against us.

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 include notifications issued by *Central Drugs Standard Control Organization (CDSCO)*, Ministry of Health & Family Welfare (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 applicable to the 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 authority under the 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly marked with 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 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 authorized resellers/distributors.

*If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the copy of the application must be submitted with a certificate that application for renewal was made within time frame as per Drug 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 requirements issued 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 authority to the buyer at the time of bid submission. The certificate must have been issued within 12 months from the date of submission to the buyer.
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 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 are licensed by the concerned Drug Licensing Authority, only one bid 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 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 for the 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 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, if the bidder/seller has been blacklisted or testing by any State Government / Central Government / its Drug procurement agencies at the time of submission of bid, such bidder/seller or their Partner shall not be allowed to 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 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 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) that they will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs/medicines.

*They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs/medicines. Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended), The Drugs (Price 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"*

*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 seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provision (India) order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Ph
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date 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 &

In case pre-dispatch inspection is not applicable, the life of the drugs/medicines shall not have passed 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 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 pharmaceutical buyer, providing 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 if the product has been 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 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 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 approved 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 location inventory.

**c) Post Delivery Surveillance:** The Drugs/Medicines/goods shall have the active ingredients and specifications indicated in official compendiums or technical specifications throughout the shelf-life period of the drug. This 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 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 delivery to the destination shall in no way be limited or waived by reason of the goods having previously been inspected at the time of 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
  - The supplies will be deemed to be completed only upon receipt of the quality certificates from the
- “Not of Standard Quality” or spurious or adulterated or misbranded, such batch/ batches will be
- **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 substandard.
  - 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/colleges and 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 back the rejected stock within stipulated time. The buyer will arrange to destroy the “NOT OF STANDARD QUALITY ITEMS” after

Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suitable period. The concerned State will also be informed by the buyer for initiating necessary action on the supplier if the supplier 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.

- 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 batch shall be sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final and binding. The supplier shall submit the report of CDL within three months, from the date of communication of the disputed test report to the buyer. The supplier shall approach the concerned Drug Control Authorities for getting the drugs/medicines tested, as per the guidelines issued by the Government of India.

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

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the drugs/medicines/goods supplied 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 buyer. 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. Any violation of the provisions of the Act is also a violation of the provisions of the Act.
- 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 in the tender and 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 tender are of good 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 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 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 replacement. 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 period shall apply to the stores replaced from the date of the replacement thereof otherwise the liability shall be as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice the rights of the buyer under 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. The 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 (ATC).

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 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 source and quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede special terms and conditions, which shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

**Special terms and conditions-Version:1 effective from 14-11-2025 for category Dicyclomine Injection**

1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the valid Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submitting regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., valid 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 (which may be verified by the buyer at their end).

**UNDERTAKING**

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 no legal 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, 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 reseller 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 authorized resellers/distributors.

*If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the copy of the application 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 requirements issued 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 competent 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 authority for last 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/medicine 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 are registered with the concerned Drug Licensing Authority, only one bid 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 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 for the product.

13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia and 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 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 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 blacklisted or pending in any court of India by any department of Govt. under prevention of Corruption Act or for criminal offence 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 only) in the following format.

*They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs and cosmetics 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 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 drugs/medicines 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 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 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 bidder/seller 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 and 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. 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 location inventory.

**c) Post Delivery Surveillance:** The Drugs/Medicines/goods shall have the active ingredients and specifications 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 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 arrival at destination shall in no way be limited or waived by reason of the goods having previously been in transit or 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.

“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 of the tests, 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 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 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 batch 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 at any of testing stage or during the shelf life period, the batch shall be rejected. The batch 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 binding if submitted within three months, from the date of communication of the disputed test report to the buyer. The supplier shall approach the concerned Drug Control Authorities for getting the drugs/medicines tested, at his/her own cost.

The de-registration / debarment action will be taken by the buyer against the manufacturing unit found defective in category-A and category-B defects as per guidelines issued by the Ministry of Health & Family Welfare, Government of India.

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the drugs/medicines/goods. In case of any complaint in the field, the B.M.R/ B.P.R for the particular batch of the product shall be furnished. 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 acceptable.
- 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 purview of the concerned authorities.
- 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. 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 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 decided by 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 replacement. 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 option. The provisions of the contract shall apply to the stores replaced from the date of the replacement thereof otherwise the provisions shall apply to the stores 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, if necessary/deemed fit by the buyer, at the suppliers' risk and expense and without prejudice to the contract, reject the stores 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 and its amendments up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buyer in the Additional Terms & 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 information.

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 authentic 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 09-06-2025 for category Lactulose Oral Liquid

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 noti**

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 Drug License 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 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 the last 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/medicine 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 for each unit 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 Central / State Drug Controller / FDA.
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned drug licensing authority 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, if the bidder/seller has been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Partner shall 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 cheating or 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) that they will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs/medicines.

*They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs/medicines. 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 to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" as per order of the Drug 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 and Cosmetics Act, 1940 (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 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.



In case of pre-dispatch inspection, at the time when the stores are offered for inspection, the life of the 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 pharmacist/buyer, providing 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 if the product has been 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 supplier'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 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 approved laboratory or 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 location inventory.

**c) Post Delivery Surveillance:** The Drugs/Medicines/goods shall have the active ingredients and strength 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 inspection and testing. 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 receipt at the destination shall in no way be limited or waived by reason of the goods having previously been in receipt at the destination 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 laboratory).

**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 supplier.

If the batch is 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 of the tests, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/consignees and replace with 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 back the rejected goods within stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after the rejection.

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 and 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 dov 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 relatir 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
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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 / 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 authentic 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.

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

1. Experience Certificate for the supply of the same to any Govt/ PSU/ any renowned private organisation along
2. If the agency is registered under MSME or NSIC, then EMD exemption certificate needs to be enclosed.
3. Make in india specific authorisation certificate needs to be enclosed.

4. **Generic**

**Bidder financial standing:** The bidder should not be under liquidation, court receivership or similar proceed undertaking to this effect with bid.

5. **Generic**

Experience Criteria: The Bidder or its OEM {themselves or through reseller(s)} should have regularly, manufa Products to any Central / State Govt Organization / PSU for 3 years before the bid opening date. Copies of relk support of having supplied some quantity during each of the year. In case of bunch bids, the primary product

6. **Generic**

OPTION CLAUSE: The Purchaser reserves the right to increase or decrease the quantity to be ordered up to 50 of contract. The purchaser also reserves the right to increase the ordered quantity up to 50% of the contracte 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 delive

$(\text{Increased quantity} \div \text{Original quantity}) \times \text{Original delivery period (in days)}$ , subject to minimum of 30 days. If the additional time equals the original delivery period. The Purchaser may extend this calculated delivery duration by exercising the option clause. Bidders must comply with these terms.

#### 7. **Generic**

Without prejudice to Buyer's right to price adjustment by way of discount or any other right or remedy available any part thereof by a written notice to the Seller, if:

- i) The Seller fails to comply with any material term of the Contract.
- ii) The Seller informs Buyer of its inability to deliver the Material(s) or any part thereof within the stipulated Delivery Period and/or to the Buyer's satisfaction.
- iii) The Seller fails to deliver the Material(s) or any part thereof within the stipulated Delivery Period and/or to the Buyer's satisfaction.
- iv) The Seller becomes bankrupt or goes into liquidation.
- v) The Seller makes a general assignment for the benefit of creditors.
- vi) A receiver is appointed for any substantial property owned by the Seller.
- vii) The Seller has misrepresented to Buyer, acting on which misrepresentation Buyer has placed the Purchase Order.

#### 8. **Generic**

**Manufacturer Authorization:** Wherever Authorised Distributors/service providers are submitting the bid, All Service Provider details such as name, designation, address, e-mail Id and Phone No. required to be furnished.

#### 9. **Generic**

Bidders are advised to check applicable GST on their own before quoting. Buyer will not take any responsibility for actuals or as per applicable rates (whichever is lower), subject to the maximum of quoted GST %.

#### 10. **Scope of Supply**

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

#### 11. **Turnover**

**Bidder Turn Over Criteria:** The minimum average annual financial turnover of the bidder during the last three financial years, should be as indicated in the bid document. Documentary evidence in the form of certified Audited financial statement from the Chartered Accountant / Cost Accountant indicating the turnover details for the relevant period. If the date of constitution / incorporation of the bidder is less than 3 years old, the average turnover in respect of the bidder shall be taken into account for this criteria.

#### 12. **Turnover**

**OEM Turn Over Criteria:** The minimum average annual financial turnover of the OEM of the offered product during the previous financial year, should be as indicated in the bid document. Documentary evidence in the form of Audited financial statement or a certificate from the Chartered Accountant / Cost Accountant indicating the turnover details for the relevant period. If the date of constitution / incorporation of the OEM is less than 3 years old, the average turnover in respect of the OEM shall be taken into account for this criteria. In case of bunch bids, the OEM of CATEGORY RELATED to the bid should meet this criterion.

#### 13. **Forms of EMD and PBG**

Bidders can also submit the EMD with Fixed Deposit Receipt made out or pledged in the name of A/C

AIIMS BHUBANESWAR

The bank should certify on it that the deposit can be withdrawn only on the demand or with the sanction of the bank. The released amount should be in the favour of the bidder by the Buyer after making endorsement on the back of the FDR duly signed by the Buyer. The bidder has to upload scanned copy/ proof of the FDR along with bid and has to ensure delivery of hardcopy to the Buyer.

#### 14. **Forms of EMD and PBG**

Successful Bidder can submit the Performance Security in the form of Fixed Deposit Receipt also (besides PBG) made out or pledged in the name of

AIIMS BHUBANESWAR

A/C (Name of the Seller). The bank should certify on it that the deposit can be withdrawn only on the demand Security Deposit, the FDR will be released in favour of bidder by the Buyer after making endorsement on the covering letter. Successful Bidder has to upload scanned copy of the FDR document in place of PBG and has to Buyer within 15 days of award of contract.

## अस्वीकरण/Disclaimer

The additional terms and conditions have been incorporated by the Buyer after approval of the Competent Authority 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 are incorporated by the Buyer regarding following, the bid and resultant contracts shall be treated as null and void at 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 extant policy.
3. Publishing Custom / BOQ bids for items for which regular GeM categories are available without any Category restriction.
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 EMD Detail, ePBG Detail and MII and MSE Purchase Preference sections of the bid, unless otherwise allowed by the Buyer.
16. In a category based bid, adding additional items, through buyer added additional scope of work/ additional terms 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 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, 2020; Working Conditions Code, 2020; and the Code on Social Security, 2020 as and when notified and brought into force.**

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

**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 to be 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 Conditions of the GeM.](#)

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 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 and undertake 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 law.

**---धन्यवाद/Thank You---**