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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](#)

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Himanshu Nirmal Chandu

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

## Buyer Details

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

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

## बिड दस्तावेज़ / Bid Document

| बिड विवरण/Bid Details  |   |
|--|---|
| <b>बिड बंद होने की तारीख/समय /Bid End Date/Time</b>  | 09-02-2026 19:00:00   |
| <b>बिड खुलने की तारीख/समय /Bid Opening Date/Time</b>   | 09-02-2026 19:30:00   |
| <b>बिड पेशकश वैधता (बंद होने की तारीख से)/Bid Offer Validity (From End Date)</b>   | 180 (Days)  |
| <b>मंत्रालय/राज्य का नाम/Ministry/State Name</b>   | Ministry Of Health And Family Welfare   |
| <b>विभाग का नाम/Department Name</b>  | Department Of Health And Family Welfare   |
| <b>संगठन का नाम/Organisation Name</b>  | All India Institute Of Medical Sciences (a)   |
| <b>कार्यालय का नाम/Office Name</b>   | Bhubaneswar   |
| <b>कुल मात्रा/Total Quantity</b>   | 61750   |
| <b>वस्तु श्रेणी /Item Category</b>   | Streptokinase Injection (Q2) , Dexameth Dicyclomine Injection (Q2) , Lactulose O  |
| <b>बिडर का न्यूनतम औसत वार्षिक टर्नओवर (3 वर्षों का) /Minimum Average Annual Turnover of the bidder (For 3 Years)</b>  | 8 Lakh (s)  |
| <b>मूल उपकरण निर्माता का औसत टर्नओवर (गत 3 वर्षों का)/OEM Average Turnover (Last 3 Years)</b>  | 69 Lakh (s)   |
| <b>उन्हीं/समान सेवा के लिए अपेक्षित विगत अनुभव के वर्ष/Years of Past Experience Required for same/similar service</b>  | 3 Year (s)  |
| <b>वर्षों के अनुभव एवं टर्नओवर से एमएसई को छूट प्राप्त है / MSE Relaxation for Years Of Experience and Turnover</b>  | Yes   Complete  |
| <b>स्टार्टअप के लिए अनुभव के वर्षों और टर्नओवर से छूट प्रदान की गई है / Startup Relaxation for Years Of Experience and Turnover</b>  | Yes   Complete  |
| <b>विक्रेता से मांगे गए दस्तावेज़/Document required from seller</b>  | 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 exemption supporting documents to prove his eligibility evaluation by the buyer |
| <b>क्या आप निविदाकारों द्वारा अपलोड किए गए दस्तावेज़ों 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?</b> | Yes (Documents submitted as part of a tender/bid process will also be displayed)  |
| <b>बिड लगाने की समय सीमा स्वतः नहीं बढ़ाने के लिए आवश्यक बिड की संख्या। / Minimum number of bids required to disable automatic bid extension</b>   | 3   |

### बिड विवरण/Bid Details

|  |                                   |
|--|-----------------------------------|
| दिनों की संख्या, जिनके लिए बिड लगाने की समय-सीमा बढ़ाई जाएगी। / Number of days for which Bid would be auto-extended  | 7                                 |
| ऑटो एक्सटेंशन अधिकतम कितनी बार किया जाना है। / Number of Auto Extension count  | 1                                 |
| विगत प्रदर्शन /Past Performance  | 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 केटेगरी के लिए बिड के साथ वैध समर्थित दस्तावेज प्रस्तुत करने हैं। एमएसई केटे 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 EMD

document for the relevant category as per GeM GTC with the bid. Under MSE category, only manufacturers for goods are exempted 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 force.

#### लाभार्थी /Beneficiary :

AIIMS Bhubaneswar

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

#### 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  |

- 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 "Relaxation Criteria" as defined above subject to meeting of quality and technical specifications. The bidder seeking Relaxation from the "Relaxation Criteria" shall upload the supporting documents to prove his eligibility for Relaxation.
- 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 "Relaxation Criteria" 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 the "Relaxation Criteria" shall upload the supporting documents to prove his eligibility for Relaxation.
- 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 above in the bid document. Documentary evidence in the form of certified Audited Balance Sheets of relevant period of Cost Accountant indicating the turnover details for the relevant period shall be uploaded with the bid. In case the data is less than 3-year-old, the average turnover in respect of the completed financial years after the date of constitution shall be taken into account for this criteria.

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 Orgs indicated above in the bid document before the bid opening date. Copies of relevant contracts and delivery acceptance with bid in support of having supplied some quantity during each of the Financial year. In case of bunch bids, the cat should meet this criterion.

7. OEM Turn Over Criteria: The minimum average annual financial turnover of the OEM of the offered product during previous financial year, should be as indicated in the bid document. Documentary evidence in the form of certified A certificate from the Chartered Accountant / Cost Accountant indicating the turnover details for the relevant period of constitution / incorporation of the OEM is less than 3 year old, the average turnover in respect of the completed financial year 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 in India), Order 2017 as amended from time to time and its subsequent Orders/Notifications issued by concerned 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 it bids, 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 a companies as per the Public Procurement (preference to Make-in -India) order 2017 dated 04.06.2020. Only Class-I and II companies 4.6.2020 will be eligible to bid. Non - Local suppliers as per MII order dated 04.06.2020 are not eligible to participate and be allowed to participate .The buyers are advised to refer the OM No.F.1/4/2021-PPD dated 18.05.2023. [OM No.1\\_4](#) 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 Micro and Small Enterprises.

9. Purchase preference will be given to MSEs having valid Udyam Registration and whose credentials are validated on Public Procurement Policy for Micro and Small Enterprises (MSEs) Order, 2012 dated 23.03.2012 issued by Ministry of Micro and Small Enterprises subsequent Orders/Notifications issued by concerned Ministry. If the bidder wants to avail themselves of the Purchase preference / OEM of the offered product on GeM. Traders are excluded from the purview of Public Procurement Policy for Micro and Small Enterprises as per the 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 Over, Past Performance and Project / Past Experience etc. This has no relevance or bearing on the price to be quoted and impact on bid participation. Also this is not going to be used as a criteria in determining reasonableness of quoted price 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 at least one of the last three Financial years before the bid opening date to any Central / State Govt Organization / PSU (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 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 determination of L1 will be done separately for each schedule.

each schedule are as under:

| मूल्यांकन अनुसूचियां / Evaluation Schedules | वस्तु/श्रेणी / Item/Category |
|---|------------------------------|
| 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 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 अनुमति |
|--------------------------|--|--------------------------|
| 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 (month) |

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

| क्र.सं./S.No. | परेषिती/रिपोर्टिंग अधिकारी<br>/Consignee<br>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 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  | 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<br>/Consignee<br>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 केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

| विवरण/Specification      | विशिष्टि का नाम /Specification Name  | बिड के लिए आवश्यक अनुमति |
|--------------------------|--|--------------------------|
| 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) |

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

| क्र.सं./S.No. | परेषिती/रिपोर्टिंग अधिकारी<br>/Consignee<br>Reporting/Officer | पता/Address  | मात्रा /Quan |
|---------------|---|--|--------------|
| 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 केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

| विवरण/Specification      | विशिष्टि का नाम /Specification Name  | बिड के लिए आवश्यक अनुमति          |
|--------------------------|--|-----------------------------------|
| 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> ) |

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

| क्र.सं./S.No. | परेषिती/रिपोर्टिंग अधिकारी<br>/Consignee<br>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 Content  
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 अनुमति |
|---------------------|---|--------------------------|
| 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 अनुमति          |
|--------------------------|--|-----------------------------------|
| PACKAGING                | Type of primary packing  | Bottle                            |
|                          | <b>Primary pack size</b>   | 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<br>/Consignee<br>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 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 (so 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 \_\_\_\_\_ . (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 SUGAM portal as per the provisions 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 Act, 1940 and Rules made 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 be applicable to notifications issued by *Central Drugs Standard Control Organization (CDSCO)*, Ministry of Health & Family Welfare, 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 as per 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 to ensure that they 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 the distributor.

*If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the copy of the certificate must be submitted with a certificate that application for renewal was made within time frame as per Drug and Cosmetic Act, 1940 and Rules made there under as amended till date.*

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 Drug Licensing Authority for last two (2) consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/medicine should be highlighted.

*This would not apply to drugs, which were introduced in India less than 2 years ago. A certificate from the concerned Drug Licensing Authority shall be submitted 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 will be allowed to submit only one bid for all units but necessary document regarding separate manufacturing units shall be submitted by the bidder will be allowed to submit only one offer for one product.
11. The manufacturer shall have in house testing facilities and valid Good Laboratory Practice (GLP Certificate) issued by the concerned Drug Licensing Authority to the buyer at the time of bid submission.
12. The manufacturer shall have valid Good Manufacturing Practice (GMP) Certificate issued by the concerned Drug Licensing Authority to the buyer at the time of bid submission.
13. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned Drug Licensing Authority to the buyer at the time of bid submission.
14. Bidder/Seller shall submit complete stability data (long term stability studies and accelerated stability studies) for the drug/medicine quoted to the buyer at the time of bid submission. The stability data should be submitted 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 any Central or 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 or State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intimated to the concerned Drug Licensing Authority by the bidder/seller firm/ company within one month.

17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Govt agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of buyer.
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shall be 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 crores).

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

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

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or 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 and its Rules, 1945, as amended by the Government of India (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 before 31/02/2019/Policy dated 12-9-2020.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs and Cosmetics Act, 1940.

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

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 buyer, providing full details about the reason leading to the recall, and shall take steps to replace the products 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** or 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 pharmaceuticals. 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 or inventory.

**c) Post Delivery Surveillance:** The Drugs/Medicines/goods shall have the active ingredients and their strengths indicated in official compendiums or technical specifications throughout the shelf-life period of the drug. The surveillance of quality of the drugs/medicines/goods 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 the 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 will 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

*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 laboratories.
- If any batch/batches are declared 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/batches declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/batches will be rejected.
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in any manner, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/consignees and supply 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 required action within the stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after the expiry of 45 days.

Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suitable quality. The concerned State will also be informed by the buyer for initiating necessary action on the supplier. The cost of such action will be forfeited without any intimation.

The decision of the buyer or any officer authorized by buyer, as to the quality of the supplied drugs, will be final.

- In case any drug/medicine is found substandard either at any of testing stage or during the shelf life, the same will be accepted by the supplier/seller. If the same is disputed by the supplier, the sample will be sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final and conclusive. The supplier will be required to submit the sample within three months, from the date of communication of the disputed test report to the concerned Drug Control Authorities for getting the drugs/medicines tested, as per the instructions of the concerned Drug Control Authority.

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

- 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. 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 concerned Drug Control Authority will be responsible for the inspection, sealing or prosecution with relation to drugs/medicines under the said Act is also vested.
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amended, the concerned Drug 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 statutory 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.

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 in the 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 up to the specified shelf life from the date of delivery of the said stores to the buyer, have overages within the period 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, 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 or loss 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 option. The supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer at his option shall apply to the stores replaced from the date of the replacement thereof otherwise the period shall apply to the stores replaced from the date of the replacement thereof otherwise the period as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice this contract or otherwise".

| Sl. No. &<br>Date | Nomenclature &<br>Specification | Name & Address of<br>Manufacturing Unit | Batch No. | DOM & DOE |
|-------------------|---------------------------------|---|-----------|-----------|
|-------------------|---------------------------------|---|-----------|-----------|

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, 1940, 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 barcode standards at various packaging levels (primary and secondary) and should encode the information within the barcode as mentioned by the buyer 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 it is 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 requirements will be as per the provisions contained in the Additional Terms and Conditions (ATC) in the bid.

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 specific terms and conditions.

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 unique Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submittal of 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 (so 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 act on behalf of \_\_\_\_\_ (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 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 SUGAM portal as per the provisions 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 Rules, 1945 as amended till date 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 applicable to notifications issued by *Central Drugs Standard Control Organization (CDSCO)*, Ministry of Health & Family Welfare, Government of India and *Department of Pharmaceuticals (DOP)*, Ministry of Chemicals & Fertilizers time to time in this regard.
4. All provisions of Narcotic Drugs & Psychotropic Substances Act, 1985 as amended till date will also be 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 as per 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 manufacturing 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 to ensure that they 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 the distributor.

*If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the copy of the certificate of revalidation must be submitted with a certificate that application for renewal was made within time frame as per Drug and Cosmetic Rules, 1945 as amended till date 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 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 manufacturing 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) 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 department.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia in 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 packing for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data (If manufacturer has licensed a formula from another company and such licensed formula is used for the product should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product / Central or 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 or State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intimated to the buyer in writing 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 or State 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 involved in any court of India by any department of Govt. under prevention of Corruption Act or for clamping down on 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).

*They will comply with all the statutes &legislation regarding manufacturing, import, sale, and supply of drugs and medicines. 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 Rules made thereunder, to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" and to regulate the sale of drugs by the Controller of India from time to time.*

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or the bidder/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 and Rules made thereunder.
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date before 31/06/2019/Policy dated 12-9-2020.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs and Cosmetics Act, 1940.

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

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 inform the buyer, providing full details about the reason leading to the recall, and shall take steps to replace the products with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund if the products have 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** and own Quality Control Lab. The Test Report/Certificate of Analysis shall include:

1. Generic name of the product
2. Batch No.
3. Pharmacopoeia Reference and/ or In-house method
4. Batch quantity
5. Date of manufacture
6. Expiry date
7. Date of test
8. Description (clarity, color etc)
9. All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharmacopoeia results and the limits for the individual tests should be given
10. Conclusion
11. Qualified Person's signature

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

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

**a) At Pre-Dispatch stage**

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

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

*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 buyer.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the supplier.

*"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 will be rejected. 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 manner, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/consignees and supply 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 action within the 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 suitable quality. The concerned State will also be informed by the buyer for initiating necessary action on the supplier. The cost of such action will 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, will be final.

- In case any drug/medicine is found substandard either any of testing stage or during the shelf life, the buyer will send the sample to an approved laboratory for testing. The sample sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final and conclusive. The buyer will submit the report within three months, from the date of communication of the disputed test report to the concerned Drug Control Authorities for getting the drugs/medicines tested, as per the instructions of the concerned Drug Control Authorities.

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 buyer. 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 Control Authority, sealing or prosecution with relation to drugs/medicines under the said Act is also valid.
- 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 (A1)

**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, whole or in part if the supplier fails to promptly replace any drug/medicine/goods rejected submitted to the 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 in the 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 up to 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 in 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 charge within forty five days or such further period as may be extended from time to time by the buyer at his option. The supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer at any time shall apply to the stores replaced from the date of the replacement thereof otherwise the risk 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 |
|----------------|------------------------------|--------------------------------------|-----------|-----------|
|----------------|------------------------------|--------------------------------------|-----------|-----------|

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 indicated) 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 manufacturing unit to the warehouses/consignee location.

33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any other requirements mentioned in the 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 ST 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 unique number assigned to them. 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 (so 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 \_\_\_\_\_ (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 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 SUGAM portal as per the provisions 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 Rules, 1945 as amended till date 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 be notifications issued by *Central Drugs Standard Control Organization (CDSCO)*, Ministry of Health & Family 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 authority 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly mentioned on 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 that 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 of the certificate must be submitted with a certificate that application for renewal was made within time frame as per Drug Control Act, 1940 and the drug license is valid.*

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 two (2) consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/medicine quoted should be highlighted.

*This would not apply to drugs, which were introduced in India less than 2 years ago. A certificate from the concerned authority shall be submitted 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 will be allowed to submit only one bid for all units but necessary document regarding separate manufacturing units shall be submitted by the bidder will be allowed to submit only one offer for one product.
11. The manufacturer shall have in house testing facilities and valid Good Laboratory Practice (GLP Certificate) issued by the concerned Drug Licensing Authority to the buyer at the time of bid submission.
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned authority to the buyer at the time of bid submission.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia drugs should 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 (If manufacturer has licensed a formula from another company and such licensed formula is used for the product) should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product by any Central or State Government's Drug procurement agencies at the time of submission of bid. Further, 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 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 pending in any court of India by any department of Govt. under prevention of Corruption Act or for cladding 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).

*They will comply with all the statutes &legislation regarding manufacturing, import, sale, and supply of drugs and medicines. They will also comply with all the provisions of the following Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended), The Narcotic Drugs and Psychotropic Substances Act, 1985, The Narcotic Drugs and Psychotropic Substances Rules, 1986, 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 Rules made there under. The buyer shall not supply drugs which are "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 Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the central government's policy (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 before 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 Cosmetic Act, 1940.

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 the 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** 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 product. 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 requirement. 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.

**c) Post Delivery Surveillance:** The Drugs/Medicines/goods shall have the active ingredients and 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 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 the 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 box 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

*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 recovered from the supplier.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the supplier.
- "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/ batches declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/batches/drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier when the supplier fails to conform to the specifications or fails in any way.
- 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/consignees and supply 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 required action within the stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after the expiry of 45 days.

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

The decision of the buyer or any officer authorized by buyer, as to the quality of the supplied drugs, will be final.

- In case any drug/medicine is found substandard either any of testing stage or during the shelf life, the same shall be accepted by the supplier/seller. If the same is disputed by the supplier, the sample shall be sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final and conclusive. The supplier shall submit the sample within three months, from the date of communication of the disputed test report to the concerned Drug Control Authorities for getting the drugs/medicines tested, as per the instructions of the concerned Drug Control Authorities.

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

- 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 acceptable. 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 concerned Drug Control Authorities will have the power of inspection, confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also vested.
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amended, the Drug 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 (A1).

## 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 statutory 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, wholly or in part. If the supplier fails to promptly replace any drug/medicine/goods rejected submitted to the concerned 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 in the 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 up to the specified shelf life from the date of delivery of the said stores to the buyer, have overages within the 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 in 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 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 supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer at his discretion shall apply to the stores replaced from the date of the replacement thereof otherwise the period 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 |
|----------------|------------------------------|--------------------------------------|-----------|-----------|
|----------------|------------------------------|--------------------------------------|-----------|-----------|

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, 1940, as amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buyer. Additional Terms and Conditions (ATC) shall be complied with.

### **31. Bar Coding**

All drugs/medicines supplied should incorporate GS1 barcode standards at various packaging levels (pouches, cartons, boxes) 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 it is 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 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 requirements mentioned in the 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 STC, Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authentic and quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede 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 Dicyclomine Injection**

1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the unique identification number assigned to them. 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 (so 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 registered \_\_\_\_\_.
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 of the Drugs and Cosmetics Rules, 1945 as amended till date. Reference no. for SUGAM portal is \_\_\_\_\_.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the SUGAM portal as per the provisions 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 Rules, 1945 as amended till date 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 be followed by the manufacturer. The manufacturer shall be responsible for ensuring that all notifications issued by Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare, Government of India and the Director of Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
4. All provisions of Narcotic Drugs & Psychotropic Substances Act, 1985 as amended till date will also be followed by the manufacturer.
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 as per the provisions of 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 manufacturing 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 that they 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 the manufacturer.

*If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the copy of the certificate of revalidation must be submitted with a certificate that application for renewal was made within time frame as per Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date 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 Drug Licensing Authority for the drug/medicine quoted to the buyer at the time of bid submission. The drug/medicine quoted should be highlighted.

*This would not apply to drugs, which were introduced in India less than 2 years ago. A certificate from the concerned Drug Licensing Authority shall be submitted 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 located in different states, then the manufacturer shall be allowed to submit 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 concerned Drug Licensing Authority as per the provisions of the Drugs and Cosmetics 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 drug/medicine quoted to the buyer at the time of bid submission.

13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia or 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 packing for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data (If manufacturer has licensed a formula from another company and such licensed formula is used for the product, then the bidder/seller should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product or by Central or 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 State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intimated to the bidder/seller in the 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 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 pending in any court of India by any department of Govt. under prevention of Corruption Act or for defrauding 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).

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

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

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or the bidder/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 policy (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 before 31/02/2019/Policy dated 12-9-2020.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs and Cosmetics Act, 1940.

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

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 inform the buyer, providing full details about the reason leading to the recall, and shall take steps to replace the product 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** or 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. 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 excipients indicated in official compendiums or technical specifications throughout the shelf-life period of the drug. Sampling 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 arrival at the destination shall in no way be limited or waived by reason of the goods having previously been in transit 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 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 delivery.

*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 buyer.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the supplier.

"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 will be rejected. The cost of entire batch paid will be recovered from the supplier who supplied the batch.
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in any manner, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/consignees and supply 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 action within the stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after 45 days.

Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suitable quality. The concerned State will also be informed by the buyer for initiating necessary action on the supplier. The cost of testing will 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 at any of testing stage or during the shelf life, the sample shall be accepted by the supplier/seller. If the same is disputed by the supplier, the sample shall be sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final and binding. The supplier shall submit the report within three months, from the date of communication of the disputed test report to the buyer. The buyer may approach the concerned Drug Control Authorities for getting the drugs/medicines tested, as per the guidelines issued by the concerned Drug Control Authority.

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

- 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. 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. Confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also within the jurisdiction of the concerned Drug Control 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 (A1

**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 or in part if the supplier fails to promptly replace any drug/medicine/goods rejected submitted to the 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 in the 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 up to 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 discovered not to conform to the said description and quality. Losses due to premature deterioration or 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 charge within forty five days or such further period as may be extended from time to time by the buyer at his option. The supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer at any time shall apply to the stores replaced from the date of the replacement thereof otherwise the same 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 |
|----------------|------------------------------|--------------------------------------|-----------|-----------|
|----------------|------------------------------|--------------------------------------|-----------|-----------|

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, 1940, 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 barcode standards at various packaging levels (primary and secondary) 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.

### **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 unique 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., 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 (so 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 \_\_\_\_\_. (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 be notifications issued by Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare, 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 authority 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 are operating in compliance with all relevant laws and regulations and are properly licensed to sell the Manufacturer shall be responsible for verifying the validity and authenticity of drug license held by thei

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

7. Bidder/Seller shall submit the valid GMP/WHO-GMP Certificate of the manufacturing site as per revised by the Concerned Drug Licensing Authority to the buyer at the time of bid submission.
8. Bidder/Seller shall submit a valid **non-Conviction** certificate for last two (2) consecutive years issued to 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 drug/medicine quoted to the buyer at the time of bid submission. The drug/medicine highlighted.

*This would not apply to drugs, which were introduced in India less than 2 years ago. A certificate from the concerned authority is not required 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 manufacturing units by one bidder will be allowed to submit only one offer for one product.
11. The manufacturer shall have in house testing facilities and valid Good Laboratory Practice (GLP Certificate) issued by the concerned authority 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 department of the concerned authority for the product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia quoted to 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 the quoted product for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data (If manufacturer has licensed a formula from another company and such licensed formula is used for the product, the licensed formula should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product by any Central or State Government's Drug procurement agencies at the time of submission of bid. Further, if the bidder/seller has 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 Central or State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intimated to the concerned authority 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 pending in any court of India by any department of Govt. under prevention of Corruption Act or for criminal conspiracy in the said matter at the time of submission of bid.
19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred only).

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

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

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or 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 and its Rules, 1945 (as amended) issued by the concerned authority (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 before 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 expiry date 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 pharmaceutical buyer, providing full details about the reason leading to the recall, and shall take steps to replace the product with an 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** or 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 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 or inventory.

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

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laboratory or 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 the arrival at the destination shall in no way be limited or waived by reason of the goods having previously been in transit 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 laboratories).

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

*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 buyer.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the supplier.

"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 or drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier when the supplier fails to conform to the specifications or fails in any manner.
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in any manner, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/consignees and supply 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 required action within the stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after the expiry of 45 days.

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 be forfeited without any intimation.

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

- In case any drug/medicine is found substandard either any of testing stage or during the shelf life approved laboratory shall be accepted by the supplier/seller. If the same is disputed by the supplier 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 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 for 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 buyer. 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 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. Confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also within the jurisdiction of the concerned Drug Control Authorities.
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amended, the Controller/ Drug Inspector may exercise their powers as an Inspecting Agency.

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

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

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

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

## 28. **Termination for Default**

The buyer may without prejudice to any other remedy for breach of contract, by written notice of default, whole or in part. If the supplier fails to promptly replace any drug/medicine/goods rejected submitted to the 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 in the 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 up to 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 in 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 option. The supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer at any period shall apply to the stores replaced from the date of the replacement thereof otherwise the same 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 |
|----------------|------------------------------|--------------------------------------|-----------|-----------|
|----------------|------------------------------|--------------------------------------|-----------|-----------|

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 indicated) 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 manufacturing unit to the warehouses/consignee location.

33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any other requirements mentioned in the 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 ST and shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

## **केता 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 with the bid.
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 proceedings or undertaking to this effect with bid.

### 5. **Generic**

**Experience Criteria:** The Bidder or its OEM {themselves or through reseller(s)} should have regularly, manufactured Products to any Central / State Govt Organization / PSU for 3 years before the bid opening date. Copies of relevant 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 contracted rates. The delivery period of quantity shall commence from the last date of original delivery or during the extended delivery period the additional time shall commence from the last date of extended delivery.

(Increased quantity ÷ Original quantity) × Original delivery period (in days), subject to minimum of 30 days. If the additional time equals the original delivery period. The Purchaser may extend this calculated delivery duration 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.
- iii) The Seller fails to deliver the Material(s) or any part thereof within the stipulated delivery period and/or to the Material(s) promptly.
- 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 Purchaser

## 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 Audit certificate from the Chartered Accountant / Cost Accountant indicating the turnover details for the relevant period. In case the date of constitution / incorporation of the bidder is less than 3 years old, the average turnover in respect of the date of constitution 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 certified Audit certificate from the Chartered Accountant / Cost Accountant indicating the turnover details for the relevant period. In case the date of constitution / incorporation of the OEM is less than 3 years old, the average turnover in respect of the date of constitution shall be taken into account for this criteria. In case of bunch bids, the OEM of CATEGORY RELATED 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 released in the favour of the bidder by the Buyer after making endorsement on the back of the FDR duly signed. 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 consequence arising in the bidding process due to these ATCs and due to modification of technical specifications and / or terms and conditions 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 Order / Office Memorandum issued.
3. Publishing Custom / BOQ bids for items for which regular GeM categories are available without any Category item.
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 the same.
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 like EMD Detail, ePBG Detail and MII and MSE Purchase Preference sections of the bid, unless otherwise allowed by the system.
16. In a category based bid, adding additional items, through buyer added additional scope of work/ additional terms and conditions along with the main item, the same must be added through bunching category based item in the 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; the Working Conditions Code, 2020; and the Code on Social Security, 2020 as and when notified and brought into operation.**

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

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 इस नियिदा में बिड देने के लिए तभी पात्र होगा जब वह बिड देने वाला सक्षम प्राधिकारी के पास पंजीकृत हो। बिड में भाग लेते समय बिडर को जाने व इसका अनुपालन न करने पर अनुबंध को तत्काल समाप्त करने और कानून के अनुसार आगे की कानूनी कार्रवाई का आधार होगा।/In term 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 to 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 of the country.

---धन्यवाद/Thank You---