

## Bid Document/ बिड दस्तावेज़

### Bid Details/बिड विवरण

<b>Bid End Date/Time/बिड बंद होने की तारीख/समय</b>	19-05-2025 13:00:00
<b>Bid Opening Date/Time/बिड खुलने की तारीख/समय</b>	19-05-2025 13:30:00
<b>Bid Offer Validity (From End Date)/बिड पेशकश वैधता (बंद होने की तारीख से)</b>	120 (Days)
<b>Ministry/State Name/मंत्रालय/राज्य का नाम</b>	Ministry Of Defence
<b>Department Name/विभाग का नाम</b>	Department Of Military Affairs
<b>Organisation Name/संगठन का नाम</b>	Indian Air Force
<b>Office Name/कार्यालय का नाम</b>	*****
<b>क्रेता ईमेल/Buyer Email</b>	medi.care.14@iaf.nic.in
<b>Total Quantity/कुल मात्रा</b>	36420
<b>Item Category/मद केटेगरी</b>	Baclofen Tablets (V2) (Q2) , Budesonide Diethylcarbamazine (DEC) Tablet (Q2) , Bromide Respules (V2) (Q2) , Amitriptyli Flunarizine Tablet (Q2) , Hydrochlorothiazide Injection (V2) (Q2) , Adrenaline Injection (V2) (Q2) , Dexamethasone Tablet (Q2) , Carbamazepine Tablets (V2) (Q2) (Q2) , Amiodarone Injection (V2) (Q2) , Lidocaine Injection (V2) (Q2) , Metoclopramide Injection (Q2) , Dicyclanil Tablet (Q2) , Bisacodyl Tablets (V2) (Q2) , Brimidine Tablets (V2) (Q2) , Fluoxetine Capsule (Q2) , Lorazepam Tablets (V2) (Q2) , Potassium Chloride Tablets (V2) (Q2) , Clindamycin Capsule (Q2) , Anti Tubercle Dexamethasone Tablet (Q2) , Clindamycin Capsule (Q2) , Acyclovir Ointment (V2) (Q2) , Betamethasone Cream (V2) (Q2) , Hyoscine Butyl Bromide Injection (Q2)
<b>Years of Past Experience Required for same/similar service/उन्हीं/समान सेवाओं के लिए अपेक्षित विगत अनुभव के वर्ष</b>	1 Year (s)
<b>MSE Exemption for Years Of Experience/अनुभव के वर्षों से एमएसई छूट/ and Turnover/टर्नओवर के लिए एमएसई को छूट प्राप्त है</b>	Yes
<b>Startup Exemption for Years Of Experience/अनुभव के वर्षों से स्टार्टअप छूट/ and Turnover/ टर्नओवर के लिए स्टार्टअप को छूट प्राप्त है</b>	Yes
<b>Document required from seller/विक्रेता से मांगे गए दस्तावेज़</b>	Experience Criteria,Past Performance,Certificate of Experience *In case any bidder is seeking exemption supporting documents to prove his eligibility for evaluation by the buyer

Bid Details/बिड विवरण	
Do you want to show documents uploaded by bidders to all bidders participated in bid?/	No
Past Performance/विगत प्रदर्शन	10 %
Bid to RA enabled/बिड से रिवर्स नीलामी सक्रिय किया	Yes
RA Qualification Rule	H1-Highest Priced Bid Elimination
Type of Bid/बिड का प्रकार	Two Packet Bid
Primary product category	Baclofen Tablets (V2)
Time allowed for Technical Clarifications during technical evaluation/तकनीकी मूल्यांकन के दौरान तकनीकी स्पष्टीकरण हेतु अनुमत समय	2 Days
Inspection Required (By Empanelled Inspection Authority / Agencies pre-registered with GeM)	No
Estimated Bid Value/अनुमानित बिड मूल्य	275918.88
Evaluation Method/मूल्यांकन पद्धति	Item wise evaluation/
Arbitration Clause	No
Mediation Clause	No

#### EMD Detail/ईएमडी विवरण

Required/आवश्यकता	No
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#### ePBG Detail/ईपीबीजी विवरण

Advisory Bank/एडवाइजरी बैंक	State Bank of India
ePBG Percentage(%) / ईपीबीजी प्रतिशत (%)	3.00
Duration of ePBG required (Months)/ईपीबीजी की अपेक्षित अवधि (महीने).	14

(a). EMD & Performance security should be in favour of Beneficiary, wherever it is applicable./ईएमडी और संपादन जमानत

#### Beneficiary/लाभार्थी :

PUBLIC FUND ACCOUNTS AFA  
14 AIR FORCE HOSPITAL, Department of Military Affairs, Indian Air Force, Ministry of Defence  
(Public Fund Accounts Afa,air Force)

#### MII Purchase Preference/एमआईआई खरीद वरीयता

MII Purchase Preference/एमआईआई खरीद वरीयता	Yes
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## MSE Purchase Preference/एमएसई खरीद वरीयता

MSE Purchase Preference/एमएसई खरीद वरीयता	Yes
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1. If the bidder is a Micro or Small Enterprise as per latest definitions under MSME rules, the bidder shall be exempted from "Experience Criteria" subject to meeting of quality and technical specifications. If the bidder is OEM of the offered product, "Average Turnover" criteria also subject to meeting of quality and technical specifications. In case any bidder is seeking exemption, the supporting documents to prove his eligibility for exemption must be uploaded for evaluation by the buyer.

2. If the bidder is a Startup, the bidder shall be exempted from the requirement of "Bidder Turnover" criteria and "Experience Criteria" subject to meeting of quality and technical specifications. If the bidder is OEM of the offered products, it would be exempted from the "OEM Average Turnover" criteria also subject to meeting of quality and technical specifications. In case any bidder is seeking exemption from Turnover / Experience Criteria, the supporting documents to prove his eligibility for exemption must be uploaded for evaluation by the buyer.

3. Experience Criteria: In respect of the filter applied for experience criteria, the Bidder or its OEM {themselves or through re-seller(s)} should have supplied same or similar Category Products to any Central / State Govt Organization / PSU for minimum one financial year before the bid opening date. Copies of relevant contracts to be submitted along with bid in support of experience criteria. In case of bunch bids, the category of primary product having highest value should meet this criterion.

4. Preference to Make In India products (For bids < 200 Crore): Preference shall be given to Class 1 local supplier as per the Public Procurement (Preference to Make in India) Order, 2017 as amended from time to time and its subsequent Orders/Notifications issued by concerned Ministry. Minimum local content to qualify as a Class 1 local supplier is denoted in the bid document. If the bidder wants to avail purchase preference, it should upload a certificate from the OEM regarding the percentage of the local content and the details of locations at which the product is manufactured, failing which no purchase preference shall be granted. In case the bid value is more than Rs 10 Crore, the declaration should be certified by the statutory auditor or cost auditor, if the OEM is a company and by a practicing cost accountant or Chartered Accountant for companies as per the Public Procurement (Preference to Make in India) Order, 2017 dated 04.06.2020. Only Class-I suppliers as per MII order dated 04.06.2020 will be eligible to bid. Non - Local suppliers as per MII order dated 04.06.2020 are not eligible to participate. The buyers are advised to refer the OM No.F.1/4/2021-PPD dated 18.05.2023 [OM No.1 4 2021 PPD dated 18.05.2023](#) for concurrent application of Public Procurement Policy for Micro and Small Enterprises Order, 2012 and Public Procurement Policy for Micro and Small Enterprises (MSEs) Order, 2012 dated 23.03.2012 issued by Ministry of Commerce and Industries.

5. Purchase preference will be given to MSEs having valid Udyam Registration and whose credentials are validated on the GeM portal. Traders are excluded from the purview of Public Procurement Policy for Micro and Small Enterprises (MSEs) Order, 2012 dated 23.03.2012 issued by Ministry of Commerce and Industries. If the bidder wants to avail themselves of the Purchase Preference, they should upload a certificate from the OEM of the offered product on GeM. Traders are excluded from the purview of Public Procurement Policy for Micro and Small Enterprises (MSEs) Order, 2012 dated 23.03.2012 issued by Ministry of Commerce and Industries. Products manufactured by some other OEM are not eligible for any purchase preference. In respect of bid for Service, the bidder should upload a certificate from the OEM of the offered Service. Relevant documentary evidence in this regard shall be uploaded along with the bid in respect of the eligibility for purchase preference based on documentary evidence submitted, while evaluating the bid. If L-1 is not available, the bid will be awarded for 25% (selected by Buyer) of margin of purchase preference / price band defined in relevant policy, such that the price and contract will be awarded for 25% (selected by Buyer) percentage of total quantity. The buyers are advised to refer the OM No.F.1/4/2021-PPD dated 18.05.2023 [OM No.1 4 2021 PPD dated 18.05.2023](#) for compliance of Concurrent application of Public Procurement Policy for Micro and Small Enterprises Order, 2012 and Public Procurement (Preference to Make in India) Order, 2017. Benefits of MSE will be allowed only if seller is valid and approved by Buyer after evaluation of documents submitted.

6. Estimated Bid Value indicated above is being declared solely for the purpose of guidance on EMD amount and for determining the bid participation. This has no relevance or bearing on the price to be quoted. The bidder should quote the price based on its own assessment of reasonableness and based on competitive prices received in Bid / RA process.

7. Past Performance: The Bidder or its OEM {themselves or through re-seller(s)} should have supplied same or similar products to any Central / State Govt Organization / PSU for minimum one financial year 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.

8. Reverse Auction would be conducted amongst all the technically qualified bidders except the Highest quoting bidder. However, H-1 will also be allowed to participate in RA in following cases:

- If number of technically qualified bidders are only 2 or 3.
- If Buyer has chosen to split the bid amongst N sellers, and H1 bid is coming within N.
- In case Primary product of only one OEM is left in contention for participation in RA on elimination of H-1.
- 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.
- 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.

## Evaluation Method ( Item Wise Evaluation Method )

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

Evaluation Schedules	Estimated Value	Item/Category
Schedule 1	4680	Baclofen Tablets (v2)
Schedule 2	28200	Budesonide Respirator Solution For Use In Nebulizer
Schedule 3	2400	Diethylcarbamazine (dec) Tablet
Schedule 4	14040	Azathioprine Tablets (v2)
Schedule 5	1344	Ipratropium Bromide Respules (v2)
Schedule 6	1620	Amitriptyline Tablets (v2)
Schedule 7	2160	Levetiracetam Tablet
Schedule 8	456	Flunarizine Tablet
Schedule 9	6600	Hydrochlorothiazide Tablet
Schedule 10	2956.8	Bupivacaine Injection (v2)
Schedule 11	2112	Adrenaline Injection (v2)
Schedule 12	3858	Dexamethasone Injection
Schedule 13	6840	Levetiracetam Injection
Schedule 14	3369.6	Carbamazepine Tablets (v2)
Schedule 15	11232	Donepezil Tablet
Schedule 16	1764	Hydroxyurea Capsule
Schedule 17	5376	Amiodarone Injection (v2)
Schedule 18	1080	Digoxin Tablet
Schedule 19	430.08	Labetalol Injection
Schedule 20	1176	Metoclopramide Injection
Schedule 21	2394	Dicyclomine Injection
Schedule 22	3000	Sodium Phosphate Enema
Schedule 23	1320	Bisacodyl Tablets (v2)
Schedule 24	12960	Brimonidine Drops (v2)
Schedule 25	8139.6	Ondansetron Oral Liquid
Schedule 26	2880	Fluoxetine Capsule
Schedule 27	3168	Lorazepam Tablet
Schedule 28	43200	Budesonide + Formoterol Fumarate Respules
Schedule 29	1824	Potassium Chloride Injection
Schedule 30	34060.8	Cefuroxime Oral Liquid
Schedule 31	6600	Clindamycin Capsule
Schedule 32	14400	Anti Tb Drugs - Levofloxacin 500 Mg Tablets
Schedule 33	11040	Dexamethasone Tablet

Schedule 34	10386	Clindamycin Injection
Schedule 35	912	Metoprolol Injection
Schedule 36	5925.6	Acyclovir Ointment (v2)
Schedule 37	690	Betamethasone Injection (v2)
Schedule 38	974.4	Dobutamine Injection
Schedule 39	10350	Hyoscine Butyl Bromide Injection

### Baclofen Tablets (V2) ( 1200 tablet(s) )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively)  
(के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

#### Technical Specifications/तकनीकी विशिष्टियाँ

\* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Strength	10 mg

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्ट िंग अधिकारी	Address/पता	Delivery Schedule/contract start date
1	*****	*****Rangareddi	Quantity/मात्रा
			300
			300
			300
			300

### Budesonide Respirator Solution For Use In Nebulizer ( 1200 pieces )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively)  
(के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

#### Technical Specifications/तकनीकी विशिष्टियाँ

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Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Strength	1 mg

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्ट िंग अधिकारी	Address/पता	Delivery Scl contract sta
1	*****	*****Rangareddi	Quantity/मात्रा
			300
			300
			300
			300

### Diethylcarbamazine (DEC) Tablet ( 2400 tablet(s) )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier resp के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

### Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Strength	50 mg

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Scl contract sta
1	*****	*****Rangareddi	<div>Quantity/मात्रा</div> <div>600</div> <div>600</div> <div>600</div> <div>600</div>

### Azathioprine Tablets (V2) ( 3600 tablet(s) )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively in the form of tender for the purpose of supply)

#### Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Strength	50 mg

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Scl contract sta
1	*****	*****Rangareddi	<div>Quantity/मात्रा</div> <div>900</div> <div>900</div> <div>900</div> <div>900</div>

### Ipratropium Bromide Respules (V2) ( 240 pieces )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively in the form of tender to be submitted for the purpose)

#### Technical Specifications/तकनीकी विशिष्टियाँ

\* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
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#### Consignees/Reporting Officer/परेषिती/रिपोर्टिंग अधिकारी and/ तथा Quantity/मात्रा

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Schedule/contract start date
1	*****	*****Rangareddi	<div>Quantity/मात्रा</div> <div>60</div> <div>60</div> <div>60</div> <div>60</div>

#### Amitriptyline Tablets (V2) ( 720 tablet(s) )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively in the form of tender to be submitted for the purpose)

#### Technical Specifications/तकनीकी विशिष्टियाँ

\* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Strength	10 mg

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



S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Scl contract sta
1	*****	*****Rangareddi	<div>Quantity/मात्रा</div> <div>180</div> <div>180</div> <div>180</div> <div>180</div>

### Levetiracetam Tablet ( 1440 tablet(s) )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively in the form of tender for the purpose of procurement)

### Technical Specifications/तकनीकी विशिष्टियाँ

\* जेम कैटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Strength	250 mg

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Scl contract sta
1	*****	*****Rangareddi	<div>Quantity/मात्रा</div> <div>360</div> <div>360</div> <div>360</div> <div>360</div>

### Flunarizine Tablet ( 240 tablet(s) )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively in the form of a declaration to be submitted by the bidder)

#### Technical Specifications/तकनीकी विशिष्टियाँ

\* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Strength	5 mg

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्ट िंग अधिकारी	Address/पता	Delivery Schedule contract start date
1	*****	*****Rangareddi	Quantity/मात्रा
			60
			60
			60
			60

#### Hydrochlorothiazide Tablet ( 6000 tablet(s) )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively in the form of a declaration to be submitted by the bidder)

#### Technical Specifications/तकनीकी विशिष्टियाँ

\* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Strength	12.5 mg

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Scl contract sta
1	*****	*****Rangareddi	<div>Quantity/मात्रा</div> <div>1500</div> <div>1500</div> <div>1500</div> <div>1500</div>

### Bupivacaine Injection (V2) ( 60 pieces )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively in the form of tender to be submitted for the purpose)

### Technical Specifications/तकनीकी विशिष्टियाँ

\* जेम कैटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Strength	0.5%
PACKAGING	Primary pack size	20 ml

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Scl contract sta
1	*****	*****Rangareddi	<div>Quantity/मात्रा</div> <div>15</div> <div>15</div> <div>15</div> <div>15</div>

**Adrenaline Injection (V2) ( 480 pieces )**

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively in the form of tender to be submitted for the purpose)

**Technical Specifications/तकनीकी विशिष्टियाँ**

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
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**Consignees/Reporting Officer/परेषिती/रिपोर्टिंग अधिकारी and/ तथा Quantity/मात्रा**

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Schedule/contract start date
1	*****	*****Rangareddi	Quantity/मात्रा: 120 120 120 120

**Dexamethasone Injection ( 300 pieces )**

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively in the form of tender to be submitted for the purpose)

**Technical Specifications/तकनीकी विशिष्टियाँ**

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PACKAGING	Primary pack size	2 ml

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Scl contract sta
1	*****	*****Rangareddi	<div>Quantity/मात्रा</div> <div>75</div> <div>75</div> <div>75</div> <div>75</div>

### Levetiracetam Injection ( 60 pieces )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively in the form of tender to be submitted for the purpose)

### Technical Specifications/तकनीकी विशिष्टियाँ

\* जेम कैटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
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### Consignees/Reporting Officer/परेषिती/रिपोर्टिंग अधिकारी and/ तथा Quantity/मात्रा

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Scl contract sta
1	*****	*****Rangareddi	<div>Quantity/मात्रा</div> <div>15</div> <div>15</div> <div>15</div> <div>15</div>

### Carbamazepine Tablets (V2) ( 2160 tablet(s) )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively in the form of tender to be submitted for the purpose)

**Technical Specifications/तकनीकी विशिष्टियाँ**

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Strength	200 mg

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Schedule/contract start date
1	*****	*****Rangareddi	Quantity/मात्रा
			540
			540
			540
			540

**Donepezil Tablet ( 2880 tablet(s) )**

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively in the form of a declaration to be submitted along with the bid)  
के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

**Technical Specifications/तकनीकी विशिष्टियाँ**

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Strength	5 mg

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्ट िंग अधिकारी	Address/पता	Delivery Scl contract sta
1	*****	*****Rangareddi	<div>Quantity/मात्रा</div> <div>720</div> <div>720</div> <div>720</div> <div>720</div>

### Hydroxyurea Capsule ( 360 capsule(s) )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively in the form of tender for the purpose of procurement)

#### Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Strength	500 mg

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्ट िंग अधिकारी	Address/पता	Delivery Scl contract sta
1	*****	*****Rangareddi	<div>Quantity/मात्रा</div> <div>90</div> <div>90</div> <div>90</div> <div>90</div>

### Amiodarone Injection (V2) ( 120 pieces )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier resp  
के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

#### Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PACKAGING	Primary pack size	3 ml

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्ट िंग अधिकारी	Address/पता	Delivery Sch contract sta
1	*****	*****Rangareddi	Quantity/मात्रा
			30
			30
			30
			30

#### Digoxin Tablet ( 1080 tablet(s) )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier resp  
के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

#### Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
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#### Consignees/Reporting Officer/परेषिती/रिपोर्टिंग अधिकारी and/ तथा Quantity/मात्रा



S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्ट िंग अधिकारी	Address/पता	Delivery Scl contract sta
1	*****	*****Rangareddi	<div>Quantity/मात्रा</div> <div>270</div> <div>270</div> <div>270</div> <div>270</div>

### Labetalol Injection ( 24 pieces )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively in the form of tender to be submitted for the purpose)

### Technical Specifications/तकनीकी विशिष्टियाँ

\* जेम कैटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PACKAGING	Primary pack size	4 ml

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्ट िंग अधिकारी	Address/पता	Delivery Scl contract sta
1	*****	*****Rangareddi	<div>Quantity/मात्रा</div> <div>6</div> <div>6</div> <div>6</div> <div>6</div>

### Metoclopramide Injection ( 240 pieces )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively in the form of tender to be submitted for the purpose)

**Technical Specifications/तकनीकी विशिष्टियाँ**

\* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PACKAGING	Primary pack size	2 ml

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्ट िंग अधिकारी	Address/पता	Delivery Schedule/contract start date
1	*****	*****Rangareddi	Quantity/मात्रा
			60
			60
			60
			60

**Dicyclomine Injection ( 600 pieces )**

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively in the form of tender to be submitted for the purpose)

**Technical Specifications/तकनीकी विशिष्टियाँ**

\* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PACKAGING	Primary pack size	2 ml

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्ट िंग अधिकारी	Address/पता	Delivery Scl contract sta
1	*****	*****Rangareddi	<div>Quantity/मात्रा</div> <div>150</div> <div>150</div> <div>150</div> <div>150</div>

### Sodium Phosphate Enema ( 120 pieces )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively in the form of tender to be submitted for the purpose)

#### Technical Specifications/तकनीकी विशिष्टियाँ

\* जेम कैटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
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#### Consignees/Reporting Officer/परेषिती/रिपोर्टिंग अधिकारी and/ तथा Quantity/मात्रा

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्ट िंग अधिकारी	Address/पता	Delivery Scl contract sta
1	*****	*****Rangareddi	<div>Quantity/मात्रा</div> <div>30</div> <div>30</div> <div>30</div> <div>30</div>

### Bisacodyl Tablets (V2) ( 1200 tablet(s) )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively in the form of tender to be submitted for the purpose)

**Technical Specifications/तकनीकी विशिष्टियाँ**

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
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**Consignees/Reporting Officer/परेषिती/रिपोर्टिंग अधिकारी and/ तथा Quantity/मात्रा**

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्ट िंग अधिकारी	Address/पता	Delivery Sch contract sta
1	*****	*****Rangareddi	Quantity/मा
			300
			300
			300
			300

**Brimonidine Drops (V2) ( 60 pieces )**

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier resp के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

**Technical Specifications/तकनीकी विशिष्टियाँ**

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PACKAGING	Primary pack size	5 ml

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्ट िंग अधिकारी	Address/पता	Delivery Scl contract sta
1	*****	*****Rangareddi	<div>Quantity/मात्रा</div> <div>15</div> <div>15</div> <div>15</div> <div>15</div>

### Ondansetron Oral Liquid ( 420 pieces )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier resp  
के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

#### Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
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### Consignees/Reporting Officer/परेषिती/रिपोर्टिंग अधिकारी and/ तथा Quantity/मात्रा

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्ट िंग अधिकारी	Address/पता	Delivery Scl contract sta
1	*****	*****Rangareddi	<div>Quantity/मात्रा</div> <div>105</div> <div>105</div> <div>105</div> <div>105</div>

### Fluoxetine Capsule ( 1440 capsule(s) )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier resp  
के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

**Technical Specifications/तकनीकी विशिष्टियाँ**

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Strength	20 mg

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Schedule/contract start date
1	*****	*****Rangareddi	Quantity/मात्रा
			360
			360
			360
			360

**Lorazepam Tablet ( 1440 tablet(s) )**

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively in the form of a declaration to be submitted along with the bid.)

**Technical Specifications/तकनीकी विशिष्टियाँ**

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Strength	1 mg

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्ट िंग अधिकारी	Address/पता	Delivery Scl contract sta
1	*****	*****Rangareddi	<div>Quantity/मात्रा</div> <div>360</div> <div>360</div> <div>360</div> <div>360</div>

### Budesonide + Formoterol Fumarate Respules (V2) ( 1080 pieces )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier resp  
के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

#### Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Strength	0.5 mg + 20 mcg

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्ट िंग अधिकारी	Address/पता	Delivery Scl contract sta
1	*****	*****Rangareddi	<div>Quantity/मात्रा</div> <div>270</div> <div>270</div> <div>270</div> <div>270</div>

### Potassium Chloride Injection ( 96 pieces )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively)  
 के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

**Technical Specifications/तकनीकी विशिष्टियाँ**

\* जेम कैटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Strength	150 mg/mL (15% w/v)

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्ट िंग अधिकारी	Address/पता	Delivery Sch contract sta
1	*****	*****Rangareddi	Quantity/मा
			24
			24
			24
			24

**Cefuroxime Oral Liquid ( 240 pieces )**

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively)  
 के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

**Technical Specifications/तकनीकी विशिष्टियाँ**

\* जेम कैटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PACKAGING	Primary pack size	30 ml

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



S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्ट िंग अधिकारी	Address/पता	Delivery Scl contract sta
1	*****	*****Rangareddi	<div>Quantity/मात्रा</div> <div>60</div> <div>60</div> <div>60</div> <div>60</div>

### Clindamycin Capsule ( 600 capsule(s) )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively in order to be eligible for award of contract)  
(कम से कम 50% और 20% स्थानीय सामग्री की आवश्यकता है कि क्वालिफाइंग के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

### Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Strength	300 mg

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्ट िंग अधिकारी	Address/पता	Delivery Scl contract sta
1	*****	*****Rangareddi	<div>Quantity/मात्रा</div> <div>150</div> <div>150</div> <div>150</div> <div>150</div>

### Anti TB Drugs - Levofloxacin 500 Mg Tablets ( 360 strip )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively)  
 के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

#### Technical Specifications/तकनीकी विशिष्टियाँ

\* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Conformity to technical specifications including labeling, packaging, storage, logos etc	As per detailed technical specification

#### Additional Specification Documents/अतिरिक्त विशिष्टि दस्तावेज़

Applicable Specification Document	<a href="#">View</a>
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#### Consignees/Reporting Officer/परेषिती/रिपोर्टिंग अधिकारी and/ तथा Quantity/मात्रा

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Schedule/contract start date
1	*****	*****Rangareddi	<div>Quantity/मात्रा:</div> <div>90</div> <div>90</div> <div>90</div> <div>90</div>

#### Dexamethasone Tablet ( 2400 tablet(s) )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively)  
 के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

#### Technical Specifications/तकनीकी विशिष्टियाँ

\* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Strength	4 mg

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Scl contract sta
1	*****	*****Rangareddi	<div>Quantity/मात्रा</div> <div>600</div> <div>600</div> <div>600</div> <div>600</div>

Clindamycin Injection ( 360 pieces )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier resp के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
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Consignees/Reporting Officer/परेषिती/रिपोर्टिंग अधिकारी and/ तथा Quantity/मात्रा

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Scl contract sta
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S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Scl contract sta
1	*****	*****Rangareddi	<div>Quantity/मात्रा</div> <div>90</div> <div>90</div> <div>90</div> <div>90</div>

### Metoprolol Injection ( 60 pieces )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively)  
(कम से कम 50% और 20% स्थानीय सामग्री के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

### Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PACKAGING	Primary pack size	5 ml

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Scl contract sta
1	*****	*****Rangareddi	<div>Quantity/मात्रा</div> <div>15</div> <div>15</div> <div>15</div> <div>15</div>

### Acyclovir Ointment (V2) ( 60 pieces )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively in the form of tender to be submitted for the purpose)

#### Technical Specifications/तकनीकी विशिष्टियाँ

\* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PACKAGING	Primary pack size	10 gm

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्ट िंग अधिकारी	Address/पता	Delivery Sch contract sta
1	*****	*****Rangareddi	Quantity/मा
			15
			15
			15
			15

#### Betamethasone Injection (V2) ( 150 pieces )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively in the form of tender to be submitted for the purpose)

#### Technical Specifications/तकनीकी विशिष्टियाँ

\* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PACKAGING	Primary pack size	1 ml

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Schedule/contract start date
1	*****	*****Rangareddi	<div>Quantity/मात्रा</div> <div>38</div> <div>37</div> <div>37</div> <div>38</div>

### Dobutamine Injection ( 30 pieces )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively in the form of tender to be submitted for the purpose)

### Technical Specifications/तकनीकी विशिष्टियाँ

\* जेम कैटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
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### Consignees/Reporting Officer/परेषिती/रिपोर्टिंग अधिकारी and/ तथा Quantity/मात्रा

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Schedule/contract start date
1	*****	*****Rangareddi	<div>Quantity/मात्रा</div> <div>7</div> <div>7</div> <div>7</div> <div>9</div>

### Hyoscine Butyl Bromide Injection ( 900 pieces )

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively in the form of tender to be submitted for the purpose)

**Technical Specifications/तकनीकी विशिष्टियाँ**

\* जेम कैटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
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**Consignees/Reporting Officer/परेषिती/रिपोर्टिंग अधिकारी and/ तथा Quantity/मात्रा**

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Schedule/contract start date
1	*****	*****Rangareddi	Quantity/मात्रा: 225 225 225 225

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

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 submit regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., valid drug/medicine under procurement, the license issuing authority etc. at their end.
2. The Buyer shall ask the seller to submit the "Notarized Undertaking" in the mentioned below format (seller's name 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 of \_\_\_\_\_ there under as amended till date.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the portal of the Drugs and Cosmetics Rules, 1945 as amended till date. Reference no. for SUGAM portal is \_\_\_\_\_.
5. We undertake that all the information provided above is true and complete in all respect. We undertake that no legal action/information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetic Rules there under will be initiated.

Place:

Date:

.....

*Signature, Name, Designation & Seal*

*on behalf of the Manufacturer*

3. All Provisions of Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date will also be subject to notifications issued by *Central Drugs Standard Control Organization (CDSCO)*, Ministry of Health & Family Welfare, Government of India and 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 subject to notifications issued by the Government of India.
5. The purchase shall be made through Bidding/RA only irrespective of the value.
6. Manufacturer shall have a valid own manufacturing license issued by the competent drug licensing authority under the Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly marked with the license number. The valid own manufacturing license shall be submitted to the buyer at the time of bid submission.

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

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

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

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

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

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, which are licensed by the concerned Drug Licensing Authority, only one bidder will be allowed to submit only one offer for one product.
11. The manufacturer shall have in house testing facilities and valid Good Laboratory Practice (GLP Certificate) issued by the Central / State Drug Controller / FDA.
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned drug licensing authority.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia (USP, BP, IP) shall be submitted by the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability studies) for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data shall be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product by any Central or State Government's Drug procurement agencies at the time of submission of bid. Further, the bidder/seller should not have been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Partner 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 blacklisted or pending in any court of India by any department of Govt. under prevention of Corruption Act or for criminal offenses.



- Government fund or any criminal conspiracy in the said matter at the time of submission of bid.
19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred and 00/-) in the following format:
- They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs and cosmetics as per the provisions of the Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended), The Indian Statistical Institute Act, 1959, GST Act.*
- To supply drugs of standard quality as prescribed under the provisions of Drug and Cosmetic Act, 1940 to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" as per the order of 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, The Drugs and Cosmetics Rules, 1945 (as amended), The Indian Statistical Institute Act, 1959, GST Act, and the PPO 2017-revision as amended to date, related to procurement of Goods & Services in Pharmacy.
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date on or after 31/03/2020.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs and Cosmetics Act, 1940.
- In case pre-dispatch inspection is not applicable, the life of the drugs/medicines shall not have passed more than one sixth (1/6th) of the total shelf life of the drugs/medicines at the time of delivery to the consignee.
- In case of pre-dispatch inspection, at the time when the stores are offered for inspection, the life of the drugs/medicines shall not have passed more than one sixth (1/6th) of the total shelf life of the drugs/medicines.
24. **Recalls**
- If products are recalled because of problems with product quality or adverse reaction to the pharmaceuticals, the bidder/seller shall provide 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 to the consignee.
25. **Inspection, Testing and Quality Control**
- All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Report** from the bidder's own Quality Control Lab. The Test Report/Certificate of Analysis shall include:
    1. Generic name of the product
    2. Batch No.
    3. Pharmacopoeia Reference and/ or In-house method
    4. Batch quantity
    5. Date of manufacture
    6. Expiry date
    7. Date of test
    8. Description (clarity, color etc)
    9. All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharmaceuticals 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 required quality standards. Buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government Laboratory or any combination of or/ all following stages:
    - a) **At Pre-Dispatch stage**
    - b) **At Delivery Stage:** Inspection done once the drugs/medicines/goods reach at consignee local inventory.
    - c) **Post Delivery Surveillance:** The Drugs/Medicines/goods shall have the active ingredients and strength as indicated in official compendiums or technical specifications throughout the shelf-life period of the drug and the inspection may also be organized by the buyer post-delivery.
  - The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laboratory for the purpose of inspection. The sampling quantities shall be borne by the supplier.
  - The buyer's right to inspect, test and, where necessary reject the drugs/medicines/goods after their delivery to the destination shall in no way be limited or waived by reason of the goods having previously been inspected or tested.

dispatch from the place of manufacture.

- **Inspection Methodology:** At pre-dispatch and/or delivery stage, samples of supplies in each batch shall be collected and sent to designated laboratories (NABL Accredited/Government approved laboratories).

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

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would be borne by the supplier.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the concerned State.

“Not of Standard Quality” or spurious or adulterated or misbranded, such batch/ batches will be rejected.

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

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

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

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

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

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the 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. Any violation of the said Act is also liable for confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also liable for prosecution.
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amended, the Controller/ Drug Inspector may exercise their powers as an Inspecting Agency.

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

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

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

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

## 28. **Termination for Default**

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

## 29. **Warranty**

- Supplies must fully comply in all respect with the Technical specifications and conditions laid down in the 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 guarantee of workmanship and shall be strictly in accordance with the specifications and particulars mentioned in the tender. The stores would continue to conform to the description of and quality aforesaid for a period of the specified shelf life from the date of delivery of the said stores to the buyer, have overages within the tolerance 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 of potency will be made good and supplied by the firm at its own cost at consignee's site.

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

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

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

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

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

### 31. **Bar Coding**

All drugs/medicines supplied should incorporate GS1 barcodes standards at various packaging levels (primary, secondary and tertiary) and should encode the information within the barcodes as mentioned by the buyers in addition to other requirements. Details of bar-coding will be given by the buyer through Additional Terms and Conditions (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) and if found that temperature has not been maintained, supply against the said order is liable to be rejected.
- The items requiring special cold storage conditions shall be supplied with cold chain transporting from the manufacturing unit to the warehouses/consignee location.

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

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

**Special terms and conditions-Version:1 effective from 23-03-2024 for category Budesonide Respirator 500mcg/200mcg**

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

### UNDERTAKING

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

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

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

Place:

Date:

.....

*Signature, Name, Designation & Seal*

*on behalf of the Manufacturer*

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

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

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

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

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

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

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, which 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 drug product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia (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 (If manufacturer has licensed a formula from another company and such licensed formula is used for the 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 house testing or testing by any State Government / Central Government / its Drug procurement agencies been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Partner 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 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
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories should or pending in any court of India by any department of Govt. under prevention of Corruption Act or for Central Government fund or any criminal conspiracy in the said matter at the time of submission of bid.
19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred and

*They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs & Cosmetics Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended) (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" to 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 India) order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Pharmaceuticals.
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date 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

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

In case of pre-dispatch inspection, at the time when the stores are offered for inspection, the life of the drug shall be 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 at their ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund to the consumer. If 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** from the buyer's own Quality Control Lab. The Test Report/Certificate of Analysis shall include:
  1. Generic name of the product
  2. Batch No.
  3. Pharmacopoeia Reference and/ or In-house method
  4. Batch quantity
  5. Date of manufacture
  6. Expiry date

7. Date of test
8. Description (clarity, color etc)
9. All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharma results and the limits for the individual tests should be given
10. Conclusion
11. Qualified Person's signature

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

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

**a) At Pre-Dispatch stage**

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

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

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

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

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would be borne by the buyer.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the buyer.
- If the batch is found "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be rejected and the cost of the batch shall be borne by the supplier.
- **At any of testing stage,** Samples which do not meet quality requirement shall render the relevant batch declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/batches of drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier when the batch is found substandard.
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in inspection, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/colony and replace with fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer. The buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take back the rejected goods within stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after the expiry of the stipulated time.

Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suitable reasons. The concerned State will also be informed by the buyer for initiating necessary action on the supplier if the batch is found substandard without any intimation.

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

- In case any drug/medicine is found substandard either any of testing stage or during the shelf life, the batch shall be rejected and the cost of the batch shall be recovered from the supplier. If the same is disputed by the supplier, the batch shall be sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final and the cost of the batch shall be recovered from the supplier. The report shall be submitted within three months, from the date of communication of the disputed test report to the buyer. The buyer has the right to approach the concerned Drug Control Authorities for getting the drugs/medicines tested, as per the guidelines issued by the Ministry of Health & Family Welfare, Government of West Bengal, at their own cost.

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

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the drugs/medicines/goods.

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
- 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 Controller, sealing or prosecution with relation to drugs/medicines under the said Act is also with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Drug Controller.
- 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 (ATC).

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

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

28. **Termination for Default**

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

29. **Warranty**

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

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

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

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

Signature name & designation

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may, if necessary, deem fit by the buyer, at the suppliers' risk and expense and without prejudice to the contract 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 barcodes standards at various packaging levels (p and should encode the information within the barcodes as mentioned by the buyers in addition to other requirements. Details of bar-coding will be given by the buyer through Additional Terms and Conditions

32. **Delivery Period**

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

**Special terms and conditions-Version:2 effective from 09-05-2024 for category Azathioprine Tablets (V2**

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

**UNDERTAKING**

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

I, \_\_\_\_\_, s/o / d/o / w/o \_\_\_\_\_, aged about \_\_\_\_resident of \_\_\_\_\_  
undertake that;

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

Place:

Date:

.....

*Signature, Name, Designation & Seal*

*on behalf of the Manufacturer*

3. All Provisions of Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date will a notifications issued by *Central Drugs Standard Control Organization (CDSCO)*, Ministry of Health & Fam Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
4. All provisions of Narcotic Drugs & Psychotropic Substances Act, 1985 as amended till date will also be a



Substances.

5. The purchase shall be made through Bidding/RA only irrespective of the value.
6. Manufacturer shall have a valid own manufacturing license issued by the competent drug licensing authority under the Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly marked with the license number. The valid own manufacturing license shall be submitted to the buyer at the time of bid submission.

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

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

*If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the copy of the application must be submitted with a certificate that application for renewal was made within time frame as per Drugs and Cosmetics Rules 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 bidder/seller by the buyer at the time of bid submission. The certificate must have been issued within 12 months from the date of submission.
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the concerned Drug Licensing Authority for last 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/medicine shall be highlighted.

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

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

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

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

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the Drugs and Cosmetics Act, 1940 (India) order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Pharmaceuticals.

22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date 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, 1930.

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

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

24. **Recalls**

If products are recalled because of problems with product quality or adverse reaction to the pharmaceuticals, the manufacturer 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 to the buyer. The product shall not be taken off the market due to safety problems.

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

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

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

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

**a) At Pre-Dispatch stage**

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

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

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laboratory for post-delivery surveillance. 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 dispatch shall in no way be limited or waived by reason of the goods having previously been inspected or tested at the place of manufacture.
- **Inspection Methodology:** At pre-dispatch and/or delivery stage, samples of supplies in each batch shall be collected and sent to designated laboratories (NABL Accredited/Government approved laboratories).

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

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would be borne by the supplier.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the supplier. If the supplies are found to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be rejected and the supplier shall be liable for the replacement of the supplies.
- **At any of testing stage,** Samples which do not meet quality requirement shall render the relevant batch/ batches as "Not of Standard Quality".

declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/b drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier whe

- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/co fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after

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

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

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

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

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

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

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

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

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

28. **Termination for Default**

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

29. **Warranty**

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

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

On such rejection, the stores will be at the seller's risk and all provisions herein contained relatin

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

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

Signature name & designation

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

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

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

31. **Bar Coding**

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

32. **Delivery Period**

- Minimum delivery period will be of 45 days from the date of issuing of the purchase order.
  - The supplier should maintain the recommended temperature of the drug/medicine (wherever indicated). If found that temperature has not been maintained, supply against the said order is liable to be rejected.
  - The items requiring special cold storage conditions shall be supplied with cold chain transporting facility from manufacturing unit to the warehouses/consignee location.
33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any other particulars shall be given by the buyer through Additional Terms and Conditions (ATC) in the bid will be applicable.
34. Any other Terms and Conditions which is not included or at variance with the conditions specified in STC shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

**Special terms and conditions-Version:1 effective from 06-07-2023 for category Ipratropium Bromide Re**

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 submit regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., valid drug/medicine under procurement, the license issuing authority etc. at their end.
2. The Buyer shall ask the seller to submit the "Notarized Undertaking" in the mentioned below format (which may be verified by the buyer at their end).

**UNDERTAKING**

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

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

1. I am the partner / proprietor / director of \_\_\_\_\_ (name of entity) and duly

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

Place:

Date:

.....

*Signature, Name, Designation & Seal*

*on behalf of the Manufacturer*

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

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

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

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

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

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

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, which are manufacturing the same product, only one bidder will be allowed to submit only one offer for one product.
11. The manufacturer shall have in house testing facilities and valid Good Laboratory Practice (GLP Certificate) issued by the Central / State Drug Controller / FDA.
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned drug licensing authority for the product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia (USP, BP, IP) shall be submitted by the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability studies) for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data shall be submitted along with the licensing agreement.
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product by the Central or State Government's Drug procurement agencies at the time of submission of bid. Further, the bidder/seller should not be under any legal proceedings.

house testing or testing by any State Government / Central Government / its Drug procurement agencies / been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Partner 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 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 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 should not be under any legal proceedings or pending in any court of India by any department of Govt. under prevention of Corruption Act or for cheating in Government fund or any criminal conspiracy in the said matter at the time of submission of bid.
19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred only) that they will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs and cosmetics.

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

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

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

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

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

#### 24. **Recalls**

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

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

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

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

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

##### **a) At Pre-Dispatch stage**

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

inventory.

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

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

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

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would be borne by the supplier.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the concerned State.
- **At any of testing stage,** Samples which do not meet quality requirement shall render the relevant batch declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/batches of drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier when the batch is found substandard.
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in any of the tests, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/colleges and fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer. The buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take the same within stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after the expiry of the stipulated time.

Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suitable concerned State will also be informed by the buyer for initiating necessary action on the supplier if the batch is found substandard without any intimation.

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

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

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

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

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 in whole or in part If the supplier fails to promptly replace any drug/medicine/goods rejected submitted for approval by the applicable Regulatory Authority in the country of manufacture due to unacceptable quality or reports of recall.

**29. Warranty**

- Supplies must fully comply in all respect with the Technical specifications and conditions laid down in the 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 guarantee of workmanship and shall be strictly in accordance with the specifications and particulars mentioned in the contract. The stores would continue to conform to the description of and quality aforesaid for a period of the specified shelf life from the date of delivery of the said stores to the buyer, have overages within the tolerance and are not subject to recall by the applicable Regulatory Authority due to unacceptable quality. Notwithstanding the above, the fact that the said stores fail to conform to the description and quality as per the decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the stores discovered not to conform to the said description and quality. Losses due to premature deterioration of potency will be made good and supplied by the firm at its own cost at consignee's site.

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

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

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

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

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

**31. Bar Coding**

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

**32. Delivery Period**

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



- 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:2 effective from 24-05-2024 for category Amitriptyline Tablets (V**

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

**UNDERTAKING**

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

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

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

Place:

Date:

.....

*Signature, Name, Designation & Seal*

*on behalf of the Manufacturer*

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

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

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

*If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the 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 the buyer at the time of bid submission. The certificate must have been issued within 12 months from the date of bid submission.
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the concerned authority for the last 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/medicine shall be highlighted.

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

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

*They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs/medicines 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 Drug Controller of India from time to time.*

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

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

In case of pre-dispatch inspection, at the time when the stores are offered for inspection, the life of the drugs/medicines shall be 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 at the ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund.

been taken off the market due to safety problems.

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

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

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

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

**a) At Pre-Dispatch stage**

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

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

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

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

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would be borne by the supplier.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the supplier.
- **At any of testing stage,** Samples which do not meet quality requirement shall render the relevant batch declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/batches of drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier when the batch is found to be "Not of Standard Quality".
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in any of the tests, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/consignees and replace with fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer. The buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take the same within stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after the expiry of the shelf life.

Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suitable reasons. The concerned State will also be informed by the buyer for initiating necessary action on the supplier if the quality of the supplied drugs/medicines/goods is found to be substandard.

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

- In case any drug/medicine is found substandard either at any of testing stage or during the shelf life, the batch shall be rejected and the cost of the batch shall be recovered from the supplier.

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

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

### 27. Quality Test by Statutory Authorities:

## 28. Termination for Default

## 29. Warranty

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

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

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

Packaging, Labelling and Marking shall be as per the provisions contained in the Drugs and Cosmetics Rules, 1955 as amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buyer. The Additional Terms and Conditions (ATC) shall be complied with.

31. **Bar Coding**

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

32. **Delivery Period**

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

**Special terms and conditions-Version:1 effective from 06-07-2023 for category Bupivacaine Injection (V)**

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 submit regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., valid drug/medicine under procurement, the license issuing authority etc. at their end.
2. The Buyer shall ask the seller to submit the "Notarized Undertaking" in the mentioned below format (seller's signature may be verified by the buyer at their end).

**UNDERTAKING**

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

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

1. I am the partner / proprietor / director of \_\_\_\_\_ (name of entity) and duly authorized to sign this undertaking. (Name of entity)
2. We are the manufacturers of the drug/medicine \_\_\_\_\_ ("Product") and intend to offer the same for sale.
3. We state that the license for the Product has been granted/obtained by us as per the provisions of the Drugs and Cosmetics Rules, 1955 as amended till date.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the website of the Drugs and Cosmetics Rules, 1955 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 understand that if any false information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetics Rules, 1955 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 & notifications issued by *Central Drugs Standard Control Organization (CDSCO)*, Ministry of Health & Family Welfare, Government of India, Ministry of Chemicals & Fertilizers time to time in this regard.
4. All provisions of Narcotic Drugs & Psychotropic Substances Act, 1985 as amended till date will also be applicable to 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 under the Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly mentioned in the bid. The valid own manufacturing license shall be submitted to the buyer at the time of bid submission.

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

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

*If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the copy of the application must be submitted with a certificate that application for renewal was made within time frame as per Drugs and Cosmetics Rules, 1945 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 bidder/seller by the buyer at the time of bid submission. The certificate must have been issued within 12 months from the date of submission of the bid.
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the concerned Drug Licensing Authority for 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/medicine shall be highlighted.

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

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, which are licensed by the concerned Drug Licensing Authority, only one bidder will be allowed to submit only one offer for one product.
11. The manufacturer shall have in house testing facilities and valid Good Laboratory Practice (GLP Certificate) issued by the Central / State Drug Controller / FDA under the Drugs and Cosmetics Act and Rules made thereunder as amended up to date.
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned drug licensing authority for the product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia (USP, BP, IP) shall be submitted by the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability studies) for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data shall be submitted along with licensing agreement.
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product by the 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 blacklisted or pending in any court of India by any department of Govt. under prevention of Corruption Act or for disclosure 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) to the buyer.

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

(Control) Act, 1950, The Indian Statistical Institute Act, 1959, GST Act.

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

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

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

In case of pre-dispatch inspection, at the time when the stores are offered for inspection, the life of the one sixth (1/6th) of the total shelf life of the drugs/medicines.

24. **Recalls**

If products are recalled because of problems with product quality or adverse reaction to the pharmaceutical buyer, providing full details about the reason leading to the recall, and shall take steps to replace the product at its ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund if the product has been taken off the market due to safety problems.

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

- All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Report** from own Quality Control Lab. The Test Report/Certificate of Analysis shall include:
  1. Generic name of the product
  2. Batch No.
  3. Pharmacopoeia Reference and/ or In-house method
  4. Batch quantity
  5. Date of manufacture
  6. Expiry date
  7. Date of test
  8. Description (clarity, color etc)
  9. All identity, potency, purity, sterility, pyrogen and all other test required by the specified 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. The buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government approved or combination of or/ all following stages:

**a) At Pre-Dispatch stage**

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

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

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laboratory for Quality Control. The sampling quantities shall be borne by the supplier.
- The buyer's right to inspect, test and, where necessary reject the drugs/medicines/goods after their release at destination shall in no way be limited or waived by reason of the goods having previously been inspected 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 contract period.

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would
  - The supplies will be deemed to be completed only upon receipt of the quality certificates from the
- “Not of Standard Quality” or spurious or adulterated or misbranded, such batch/ batches will be
- **At any of testing stage**, Samples which do not meet quality requirement shall render the relevant drugs/medicines/goods declared to be “Not of Standard Quality” or spurious or adulterated or misbranded, such batch/batches of drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier when
  - If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in any of the tests, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/contract depots/ fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer. The buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take back the rejected goods within stipulated time. The buyer will arrange to destroy the “NOT OF STANDARD QUALITY ITEMS” after

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

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

- In case any drug/medicine is found substandard either any of testing stage or during the shelf 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 concerned Drug Control Authorities for getting the drugs/medicines tested, as per their own cost.

The de-registration / debarment action will be taken by the buyer against the manufacturing unit category-A and category-B defects as per guidelines issued by the Ministry of Health & Family Welfare, Government of India, which has been 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 Inspectors. Power of seizure, confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also vested with the DCGI (CDSCO)/ MoH& FW.
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amended, the Controller/ Drug Inspector may exercise their powers as an Inspecting Agency.

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

The suitable conditions may be added by the buyer in the bid through Additional Term & Conditions (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 whole or in part if the supplier fails to promptly replace any drug/medicine/goods rejected submitted for applicable Regulatory Authority in the country of manufacture due to unacceptable quality or reports of 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 unspecified shelf life from the date of delivery of the said stores to the buyer, have overages within and are not subject to recall by the applicable Regulatory Authority due to unacceptable quality. Notwithstanding the above, the fact that the said stores fail to conform to the description and quality decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the stores discovered not to conform to the said description and quality. Losses due to premature deterioration of potency will be made good and supplied by the firm at its own cost at consignee's site.

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

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

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

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

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

### 31. **Bar Coding**

All drugs/medicines supplied should incorporate GS1 barcodes standards at various packaging levels (primary, secondary and tertiary) and should encode the information within the barcodes as mentioned by the buyers in addition to other requirements. Details of bar-coding will be given by the buyer through Additional Terms and Conditions (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) and found that temperature has not been maintained, supply against the said order is liable to be rejected.
  - The items requiring special cold storage conditions shall be supplied with cold chain transporting from the manufacturing unit to the warehouses/consignee location.
33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any other particulars shall be specified 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 the Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authentic quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede special conditions, which shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

## **Special terms and conditions-Version:1 effective from 06-07-2023 for category Adrenaline Injection (V2)**

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

may be verified by the buyer at their end.

## UNDERTAKING

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

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

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

Place:

Date:

.....

*Signature, Name, Designation & Seal*

*on behalf of the Manufacturer*

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

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

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

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

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, which 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)

- 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 product.
  13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia (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 testing) 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 Central or State Government's Drug procurement agencies at the time of submission of bid. Further, the bidder/seller should not have been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Partner should not participate in the bid.
  16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any Central or State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intimated in writing document by the bidder/seller firm/ company within one month.
  17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Government's Drug procurement agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of the buyer.
  18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories should not be involved in any court of India by any department of Govt. under prevention of Corruption Act or for criminal offence Government fund or any criminal conspiracy in the said matter at the time of submission of bid.
  19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred only) that they

*They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs/medicines under the Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended), The (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 notified 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 ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the Government of India order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Pharmaceuticals.
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date on or after 31/03/2020-Policy dated 12-9-2020.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs and Cosmetics Act, 1940.

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

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

#### 24. **Recalls**

If products are recalled because of problems with product quality or adverse reaction to the pharmaceuticals, the bidder/seller shall inform the buyer, providing full details about the reason leading to the recall, and shall take steps to replace the products at their ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund to the buyer. 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** from the bidder's own Quality Control Lab. The Test Report/Certificate of Analysis shall include:
  1. Generic name of the product
  2. Batch No.
  3. Pharmacopoeia Reference and/ or In-house method
  4. Batch quantity
  5. Date of manufacture
  6. Expiry date
  7. Date of test
  8. Description (clarity, color etc)
  9. All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharmacopoeia. 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 as indicated in official compendiums or technical specifications throughout the shelf-life period of the drug. It may also be organized by the buyer post-delivery.

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

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

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would be borne by the supplier.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the supplier.
- If the batch is found to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be rejected.
- **At any of testing stage,** Samples which do not meet quality requirement shall render the relevant batch declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/batches of drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier when the batch is found to be "Not of Standard Quality".
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in any of the tests, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/consignees and replace with fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer. The buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take back the rejected goods within stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after the expiry of the stipulated time.

Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suitable reasons. The concerned State will also be informed by the buyer for initiating necessary action on the supplier if the batch is found to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be rejected.

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

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

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

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the drugs/medicines/goods 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 shall be followed.

- up to date is vested with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Drug confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also with
- 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 in whole or in part If the supplier fails to promptly replace any drug/medicine/goods rejected submitted for approval of applicable Regulatory Authority in the country of manufacture due to unacceptable quality or reports of recall 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 warranty of workmanship and shall be strictly in accordance with the specifications and particulars mentioned in the contract. The stores would continue to conform to the description of and quality aforesaid for a period of the specified shelf life from the date of delivery of the said stores to the buyer, have overages within the specified limits and are not subject to recall by the applicable Regulatory Authority due to unacceptable quality. Notwithstanding the above, the fact that the said stores fail to conform to the description and quality, the decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the stores discovered not to conform to the said description and quality. Losses due to premature deterioration of potency will be made good and supplied by the firm at its own cost at consignee's site.

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

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

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without prejudice to the contract 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 Additional Conditions (ATC) shall be complied with.

### 31. **Bar Coding**

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

### 32. **Delivery Period**

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

### **Special terms and conditions-Version:1 effective from 06-07-2023 for category Carbamazepine Tablets**

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

#### **UNDERTAKING**

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

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

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

Place:

Date:

.....

*Signature, Name, Designation & Seal*

*on behalf of the Manufacturer*

3. All Provisions of Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date will a notifications issued by *Central Drugs Standard Control Organization (CDSCO)*, Ministry of Health & Fam Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
4. All provisions of Narcotic Drugs & Psychotropic Substances Act, 1985 as amended till date will also be a Substances.
5. The purchase shall be made through Bidding/RA only irrespective of the value.

6. Manufacturer shall have a valid own manufacturing license issued by the competent drug licensing authority under the Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly marked with the license number. The valid own manufacturing license shall be submitted to the buyer at the time of bid submission.

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

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

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

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

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

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

*They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs/medicines 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 order of the Controller of India from time to time.*

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the Drugs and Cosmetics Act, 1940 (India) order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Pharmaceuticals.
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date on or after 31/03/2020. 31026/1/2019-Policy dated 12-9-2020.

23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs &

In case pre-dispatch inspection is not applicable, the life of the drugs/medicines shall not have passed 1/6th 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 its ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund if the product has been taken off the market due to safety problems.

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

- All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Report** from the supplier's own Quality Control Lab. The Test Report/Certificate of Analysis shall include:
  1. Generic name of the product
  2. Batch No.
  3. Pharmacopoeia Reference and/ or In-house method
  4. Batch quantity
  5. Date of manufacture
  6. Expiry date
  7. Date of test
  8. Description (clarity, color etc)
  9. All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharmacopoeia. 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 required quality. Buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government approved laboratory or combination of or/ all following stages:

**a) At Pre-Dispatch stage**

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

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

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laboratory for surveillance. 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 acceptance at destination shall in no way be limited or waived by reason of the goods having previously been inspected and 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/ or designated Quality Control Labs in respect of supplied drugs/medicines/goods at any point during the shelf life.

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would be borne by the supplier.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the supplier. If the batch is found to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be rejected and the cost of entire batch paid will be recovered from the supplier where the batch is found to be "Not of Standard Quality".
- **At any of testing stage,** Samples which do not meet quality requirement shall render the relevant batch declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/batches of drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier where the batch is found to be "Not of Standard Quality".



- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/col fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after

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

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

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

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

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

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

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

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

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

## 28. **Termination for Default**

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

## 29. **Warranty**

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

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

On such rejection, the stores will be at the seller's risk and all provisions herein contained relatir supplier/Seller shall if so called upon to do so by the buyer in writing, replace the stores free of c forty five days or such further period as may be extended from time to time by the buyer at his c

supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer a period shall apply to the stores replaced from the date of the replacement thereof otherwise the as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice this contract or otherwise".

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

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

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

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

### 31. **Bar Coding**

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

### 32. **Delivery Period**

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

## **Special terms and conditions-Version:1 effective from 06-07-2023 for category Amiodarone Injection (V**

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

### **UNDERTAKING**

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

I, \_\_\_\_\_, s/o / d/o / w/o \_\_\_\_\_, aged about \_\_\_\_\_resident of \_\_\_\_\_ undertake that;

1. I am the partner / proprietor / director of \_\_\_\_\_ (name of entity) and duly

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

Place:

Date:

.....

*Signature, Name, Designation & Seal*

*on behalf of the Manufacturer*

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

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

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

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

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

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

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, which are manufacturing the same product, only one bidder will be allowed to submit only one offer for one product.
11. The manufacturer shall have in house testing facilities and valid Good Laboratory Practice (GLP Certificate) issued by Central / State Drug Controller / FDA.
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned drug licensing authority for the product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia (USP, BP, IP) shall be submitted by the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability studies) for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data shall be submitted along with the licensing agreement. (If manufacturer has licensed a formula from another company and such licensed formula is used for the product, the license agreement should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product by the Central or State Government's Drug procurement agencies at the time of submission of bid. Further, the bidder/seller should not be under any legal proceedings.

house testing or testing by any State Government / Central Government / its Drug procurement agencies / been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Partner 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 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 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 should not be under any legal proceedings or pending in any court of India by any department of Govt. under prevention of Corruption Act or for cheating in Government fund or any criminal conspiracy in the said matter at the time of submission of bid.
19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred only) that they will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs and cosmetics.

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

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

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the Government of India order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Pharmaceuticals.
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date on or after 31/03/2026/1/2019-Policy dated 12-9-2020.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs and Cosmetics Act, 1940.

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

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

#### 24. **Recalls**

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

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

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

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

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

##### **a) At Pre-Dispatch stage**

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

inventory.

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

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

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

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would be borne by the supplier.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the concerned State.
- **At any of testing stage,** Samples which do not meet quality requirement shall render the relevant batch declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/batches of drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier when the batch is found substandard.
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in any other way, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/colleges and fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer. The buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take back the rejected goods within stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after the expiry of the stipulated time.

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

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

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

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

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

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 in whole or in part If the supplier fails to promptly replace any drug/medicine/goods rejected submitted for approval by the applicable Regulatory Authority in the country of manufacture due to unacceptable quality or reports of recall.

**29. Warranty**

- Supplies must fully comply in all respect with the Technical specifications and conditions laid down in the 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 guarantee of workmanship and shall be strictly in accordance with the specifications and particulars mentioned in the tender. The stores would continue to conform to the description of and quality aforesaid for a period of the specified shelf life from the date of delivery of the said stores to the buyer, have overages within the tolerance and are not subject to recall by the applicable Regulatory Authority due to unacceptable quality. Notwithstanding the above, the fact that the said stores fail to conform to the description and quality as per the decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the stores discovered not to conform to the said description and quality. Losses due to premature deterioration of potency will be made good and supplied by the firm at its own cost at consignee's site.

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

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

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

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

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

**31. Bar Coding**

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

**32. Delivery Period**

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

- 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 26-10-2023 for category Sodium Phosphate Ener**

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

**UNDERTAKING**

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

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

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

Place:

Date:

.....

*Signature, Name, Designation & Seal*

*on behalf of the Manufacturer*

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

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

Manufacturer shall be responsible for verifying the validity and authenticity of drug license held by 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 the buyer at the time of bid submission. The certificate must have been issued within 12 months from the date of bid submission.
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the concerned authority for the last 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/medicine shall be highlighted.

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

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

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

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

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

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

In case of pre-dispatch inspection, at the time when the stores are offered for inspection, the life of the drugs/medicines shall be 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 at the ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund to the buyer.



been taken off the market due to safety problems.

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

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

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

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

**a) At Pre-Dispatch stage**

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

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

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

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

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would be borne by the supplier.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the supplier.
- **At any of testing stage,** Samples which do not meet quality requirement shall render the relevant batch declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/batches of drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier when the batch is found defective.
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in any of the tests, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/consignees and replace with fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer. The buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take the same within stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after the expiry of the shelf life.

Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suits filed in the concerned State will also be informed by the buyer for initiating necessary action on the supplier if the quality of the supplied drugs/medicines/goods is found substandard.

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

- In case any drug/medicine is found substandard either at any of testing stage or during the shelf life, the supplier shall be responsible to take back the rejected drugs/medicines/goods from the depots/consignees and replace with fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer.



Signature name & designation

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

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

Packaging, Labelling and Marking shall be as per the provisions contained in the Drugs and Cosmetics Rules, 1945 as amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buyer. Additional Terms and Conditions (ATC) shall be complied with.

31. **Bar Coding**

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

32. **Delivery Period**

- Minimum delivery period will be of 45 days from the date of issuing of the purchase order.
  - The supplier should maintain the recommended temperature of the drug/medicine (wherever indicated) and should ensure that temperature has not been maintained, supply against the said order is liable to be rejected.
  - The items requiring special cold storage conditions shall be supplied with cold chain transporting from the manufacturing unit to the warehouses/consignee location.
33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any other particulars shall be given by the buyer through Additional Terms and Conditions (ATC) in the bid will be applicable.
34. Any other Terms and Conditions which is not included or at variance with the conditions specified in the Standard Terms and Conditions (STC) shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

**Special terms and conditions-Version:2 effective from 29-10-2024 for category Bisacodyl Tablets (V2)**

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 submit regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., valid drug/medicine under procurement, the license issuing authority etc. at their end.
2. The Buyer shall ask the seller to submit the "Notarized Undertaking" in the mentioned below format (which may be verified by the buyer at their end).

**UNDERTAKING**

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

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

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

Place:

Date:

.....

*Signature, Name, Designation & Seal*

*on behalf of the Manufacturer*

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

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

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

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

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

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

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, which are all licensed, it 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 authority under the Drugs Act and Rules made thereunder as amended up to date issued by Central / State Drug Controller / FDA.
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned drug licensing authority for the product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia shall be submitted by the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability studies) for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data shall be submitted (If manufacturer has licensed a formula from another company and such licensed formula is used for the product, it should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product by any Central / Central or State Government's Drug procurement agencies at the time of submission of bid. Further, the bidder/seller should not have been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Partner 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 / Central or State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intimated to the buyer by 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 / Central 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 blacklisted or pending in any court of India by any department of Govt. under prevention of Corruption Act or for criminal offence or Government fund or any criminal conspiracy in the said matter at the time of submission of bid.

19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred and only) in the following format:-
- They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs and cosmetics as per the provisions of the Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended), The Drugs and Cosmetics (Control) Act, 1950, The Indian Statistical Institute Act, 1959, GST Act.*

*To supply drugs of standard quality as prescribed under the provisions of Drug and Cosmetic Act, 1940 to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" as per the provisions of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 (as amended) and the Drugs and Cosmetics (Control) Act, 1950, The Indian Statistical Institute Act, 1959, GST Act.*

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 (as amended) and the Drugs and Cosmetics (Control) Act, 1950, The Indian Statistical Institute Act, 1959, GST Act.
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date of more than 31026/1/2019-Policy dated 12-9-2020.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs and Cosmetics Act, 1940.

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

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

24. **Recalls**

If products are recalled because of problems with product quality or adverse reaction to the pharmaceuticals, the bidder/seller shall provide 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 to the consignee. The bidder/seller shall also take steps to ensure that the products have not been taken off the market due to safety problems.

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

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

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

- Buyer will embark on stringent quality checks to ensure that drugs/medicines/goods meet required quality standards. Buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government Laboratory or any 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 and inventory.

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

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laboratory for the purpose of inspection, testing and surveillance. The sampling quantities shall be borne by the supplier.
- The buyer's right to inspect, test and, where necessary reject the drugs/medicines/goods after their delivery to the destination shall in no way be limited or waived by reason of the goods having previously been inspected and approved for dispatch from the place of manufacture.

- **Inspection Methodology:** At pre-dispatch and/or delivery stage, samples of supplies in each batch shall be collected and sent to designated laboratories (NABL Accredited/Government approved laboratories).

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

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would be borne by the supplier.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the concerned State.
- **At any of testing stage**, Samples which do not meet quality requirement shall render the relevant batch declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/batches of drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier when the batch is found substandard.
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in any other way, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/colleges/hospitals and replace with fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer. The buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take back the rejected goods within stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after the expiry of 45 days.

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

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

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

The de-registration / debarment action will be taken by the buyer against the manufacturing unit if found defective. Category-A and category-B defects as per guidelines issued by the Ministry of Health & Family Welfare, Government of India, shall 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 are up to date is vested with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Drug Control Authorities. The power of confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also vested with the DCGI (CDSCO)/ MoH& FW.
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amended, the buyer/ Controller/ Drug Inspector may exercise their powers as an Inspecting Agency.

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

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

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

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

## 28. **Termination for Default**

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

## 29. **Warranty**

- Supplies must fully comply in all respect with the Technical specifications and conditions laid down in the Bidding Document.

Pharmacopoeia standards.

- Each supply should be accompanied with a "Warranty Certificate" duly signed by the Bidder as u

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

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

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

Signature name & designation and date with rubber stamp

- 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 preju 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 buye Conditions (ATC) shall be complied with.

### 31. **Bar Coding**

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

### 32. **Delivery Period**

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

## **Special terms and conditions-Version:2 effective from 24-05-2024 for category Brimonidine Drops (V2)**

1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the ur Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submitt

regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., val drug/medicine under procurement, the license issuing authority etc. at their end.

2. The Buyer shall ask the seller to submit the "Notarized Undertaking" in the mentioned below format (sc may be verified by the buyer at their end.

## UNDERTAKING

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

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

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

Place:

Date:

.....

*Signature, Name, Designation & Seal*

*on behalf of the Manufacturer*

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

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

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

*If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the 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 t buyer at the time of bid submission. The certificate must have been issued within 12 months from the c
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the co 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/ highlighted.

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

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, 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 (USP) shall be submitted by the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability studies) for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data (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 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 should not participate in the bid.
16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any Central or State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intimated in writing document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Government's Drug procurement agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of the buyer.
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories should not be blacklisted or pending in any court of India by any department of Govt. under prevention of Corruption Act or for misappropriation of Government fund or any criminal conspiracy in the said matter at the time of submission of bid.
19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred only) that they will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs.

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

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

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

#### 24. **Recalls**

If products are recalled because of problems with product quality or adverse reaction to the pharmaceuticals, the manufacturer/buyer, providing full details about the reason leading to the recall, and shall take steps to replace the product at its ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund to the consumer. The product has been taken off the market due to safety problems.

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

- All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Report** from the manufacturer's own Quality Control Lab. The Test Report/Certificate of Analysis shall include:
  1. Generic name of the product
  2. Batch No.
  3. Pharmacopoeia Reference and/ or In-house method
  4. Batch quantity
  5. Date of manufacture
  6. Expiry date
  7. Date of test

8. Description (clarity, color etc)
9. All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharmaceutical 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 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 their destination shall in no way be limited or waived by reason of the goods having previously been in dispatch from the place of manufacture.
- **Inspection Methodology:** At pre-dispatch and/or delivery stage, samples of supplies in each batch 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 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 of drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier when the batch is found substandard.
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in inspection, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/consignees and replace with fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer. The buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take action within stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after

Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suitable reasons. The concerned State will also be informed by the buyer for initiating necessary action on the supplier if the batch is found substandard without any intimation.

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

- In case any drug/medicine is found substandard either any of testing stage or during the shelf life period, the batch shall be rejected and the cost of entire batch paid will be recovered from the supplier when the batch is found substandard. If the same is disputed by the supplier, the batch shall be sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final and submitted within three months, from the date of communication of the disputed test report to the buyer. The buyer will approach the concerned Drug Control Authorities for getting the drugs/medicines tested, as per guidelines issued by the Ministry of Health & Family Welfare, Government of India, at their own cost.

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

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the drugs/medicines/goods. In case of any complaint in the field, the B.M.R/ B.P.R for the particular batch of the product shall be provided.

- For New drugs/medicines, complete stability data of 6 months period shall be acceptable.
- The case of admixture of drugs will be treated as a violation of terms and conditions and will not
- Statutory provisions on manufacture, distribution, storage and quality issues of drugs/medicines up to date is vested with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Drug Controller, sealing or prosecution with relation to drugs/medicines under the said Act is also with
- 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 (ATC).

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

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

28. **Termination for Default**

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

29. **Warranty**

- Supplies must fully comply in all respect with the Technical specifications and conditions laid down in the 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 contract are of good workmanship and shall be strictly in accordance with the specifications and particulars mentioned in the contract. The stores would continue to conform to the description of and quality aforesaid for a period of the specified shelf life from the date of delivery of the said stores to the buyer, have overages within the specified limits and are not subject to recall by the applicable Regulatory Authority due to unacceptable quality. Notwithstanding the above, the fact that the said stores fail to conform to the description and quality as per the decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the stores discovered not to conform to the said description and quality. Losses due to premature deterioration of potency will be made good and supplied by the firm at its own cost at consignee's site.

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

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

Signature name & designation

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may deem necessary/deemed fit by the buyer, at the suppliers' risk and expense and without prejudice to the contract 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 in the Additional Conditions (ATC) shall be complied with.

31. **Bar Coding**

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

32. **Delivery Period**

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

**Special terms and conditions-Version:2 effective from 23-03-2024 for category Ondansetron Oral Liquid**

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

**UNDERTAKING**

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

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

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

Place:

Date:

.....

*Signature, Name, Designation & Seal*

*on behalf of the Manufacturer*

3. All Provisions of Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date will a notifications issued by *Central Drugs Standard Control Organization (CDSCO)*, Ministry of Health & Fam Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
4. All provisions of Narcotic Drugs & Psychotropic Substances Act, 1985 as amended till date will also be a Substances.
5. The purchase shall be made through Bidding/RA only irrespective of the value.

6. Manufacturer shall have a valid own manufacturing license issued by the competent drug licensing authority under the Drugs and Cosmetics Act, 1940 and Rules made thereunder as amended till date. The Drug/medicine quoted should be clearly marked with the license number. The valid own manufacturing license shall be submitted to the buyer at the time of bid submission.

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

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

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

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

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

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

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

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

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the Drugs and Cosmetics Act, 1940 (India) order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Pharmaceuticals.
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date on or after 31/03/2020. 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 & Cosmetics Act, 1930. In case pre-dispatch inspection is not applicable, the life of the drugs/medicines shall not have passed more than one sixth (1/6th) of the total shelf life of the drugs/medicines at the time of delivery to the consignee.

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

24. **Recalls**

If products are recalled because of problems with product quality or adverse reaction to the pharmaceuticals, the manufacturer 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 to the buyer. The products shall not be taken off the market due to safety problems.

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

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

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

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

**a) At Pre-Dispatch stage**

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

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

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laboratory for surveillance. The sampling quantities shall be borne by the supplier.
- The buyer's right to inspect, test and, where necessary reject the drugs/medicines/goods after their receipt at the destination shall in no way be limited or waived by reason of the goods having previously been inspected and 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 shelf life.

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

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

- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/col fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after

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

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

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

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

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

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

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

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

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

## 28. **Termination for Default**

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

## 29. **Warranty**

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

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

On such rejection, the stores will be at the seller's risk and all provisions herein contained relatir supplier/Seller shall if so called upon to do so by the buyer in writing, replace the stores free of c forty five days or such further period as may be extended from time to time by the buyer at his c

supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer at the period shall apply to the stores replaced from the date of the replacement thereof otherwise the as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice this contract or otherwise".

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

Signature name & designation

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

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

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

31. **Bar Coding**

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

32. **Delivery Period**

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

**Special terms and conditions-Version:1 effective from 24-05-2024 for category Fluoxetine Capsule**

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 submit regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., valid drug/medicine under procurement, the license issuing authority etc. at their end.
2. The Buyer shall ask the seller to submit the "Notarized Undertaking" in the mentioned below format (which may be verified by the buyer at their end).

**UNDERTAKING**

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

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 und information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetic there under will be initiated.

Place:

Date:

.....

*Signature, Name, Designation & Seal*

*on behalf of the Manufacturer*

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

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

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

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

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

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

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

participate in the bid.

16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intimated 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 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 cheating Government fund or any criminal conspiracy in the said matter at the time of submission of bid.
19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred and no paise).

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

*To supply drugs of standard quality as prescribed under the provisions of Drug and Cosmetic Act, 1940 to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" as notified 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 ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the Government of India order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Pharmaceuticals.
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date on or after 31/03/2020.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs and Cosmetics Act, 1940.

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

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

#### 24. **Recalls**

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

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

- All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Report** from the seller's own Quality Control Lab. The Test Report/Certificate of Analysis shall include:

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

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

- Buyer will embark on stringent quality checks to ensure that drugs/medicines/goods meet required quality standards. Buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government Laboratory or any 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 and 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 may also be organized by the buyer post-delivery.

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

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

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

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

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

Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suitable concerned State will also be informed by the buyer for initiating necessary action on the supplier if the batch is found substandard without any intimation.

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

- In case any drug/medicine is found substandard either any of testing stage or during the shelf life, the batch shall be rejected and the cost of entire batch paid will be recovered from the supplier. If the same is disputed by the supplier, the batch shall be sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final and the batch shall be submitted within three months, from the date of communication of the disputed test report to the buyer. The supplier shall approach the concerned Drug Control Authorities for getting the drugs/medicines tested, as per the guidelines issued by the Ministry of Health & Family Welfare.

The de-registration / debarment action will be taken by the buyer against the manufacturing unit if the batch is found substandard 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 drugs/medicines/goods to the buyer. In case of any complaint in the field, the B.M.R/ B.P.R for the particular batch of the product shall be submitted to the buyer. For New drugs/medicines, complete stability data of 6 months period shall be acceptable.
- The case of admixture of drugs will be treated as a violation of terms and conditions and will not be accepted.
- Statutory provisions on manufacture, distribution, storage and quality issues of drugs/medicines/goods up to date is vested with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Drug Control Authorities. Any violation of the provisions of the said Act is also within the purview of the said Act.
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amended, the Controller/ Drug Inspector may exercise their powers as an Inspecting Agency.

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

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

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

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

## 28. **Termination for Default**

The buyer may without prejudice to any other remedy for breach of contract, by written notice of default in whole or in part If the supplier fails to promptly replace any drug/medicine/goods rejected submitted for recall by the applicable Regulatory Authority in the country of manufacture due to unacceptable quality or reports of recall 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 above conditions of workmanship and shall be strictly in accordance with the specifications and particulars mentioned in the tender. The stores would continue to conform to the description of and quality aforesaid for a period of the specified shelf life from the date of delivery of the said stores to the buyer, have overages within the specified limits and are not subject to recall by the applicable Regulatory Authority due to unacceptable quality. Notwithstanding the above, the fact that the said stores fail to conform to the description and quality as per the decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the stores discovered not to conform to the said description and quality. Losses due to premature deterioration of potency will be made good and supplied by the firm at its own cost at consignee's site.

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

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

Signature name & designation

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

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

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

## 31. **Bar Coding**

All drugs/medicines supplied should incorporate GS1 barcodes standards at various packaging levels (primary, secondary and tertiary) and should encode the information within the barcodes as mentioned by the buyers in addition to other requirements. Details of bar-coding will be given by the buyer through Additional Terms and Conditions (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) and should ensure that temperature has not been maintained, supply against the said order is liable to be rejected.
- The items requiring special cold storage conditions shall be supplied with cold chain transporting from the manufacturing unit to the warehouses/consignee location.

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

34. Any other Terms and Conditions which is not included or at variance with the conditions specified in the STC shall be rejected.

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 06-07-2023 for category Budesonide + Formoterol**

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

**UNDERTAKING**

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

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

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

Place:

Date:

.....

*Signature, Name, Designation & Seal*

*on behalf of the Manufacturer*

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

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

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

*If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the 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 t

- buyer at the time of bid submission. The certificate must have been issued within 12 months from the date of manufacture.
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the concerned authority for the last 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/medicine shall be highlighted.

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

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

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

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

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the Drugs (Price Control) Order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Pharmaceuticals.
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date more than 18 months from the date of manufacture.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs and Cosmetics Act, 1940.

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

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

24. **Recalls**

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

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

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

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

- Buyer will embark on stringent quality checks to ensure that drugs/medicines/goods meet requirements. Buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government approved laboratory. A 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 and inventory.

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

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

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

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would be borne by the supplier.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the 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 of drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier where the batch is found defective.
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in any test, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/consignees and replace with fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer. The buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take corrective action within stipulated time. The buyer will arrange to destroy the “NOT OF STANDARD QUALITY ITEMS” after intimation.

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

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

- In case any drug/medicine is found substandard either at any of testing stage or during the shelf life, the batch shall be rejected. The batch shall be accepted by the supplier/seller. If the same is disputed by the supplier, it shall be sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final and binding if submitted within three months, from the date of communication of the disputed test report to the buyer.

approach the concerned Drug Control Authorities for getting the drugs/medicines tested, as per own cost.

The de-registration / debarment action will be taken by the buyer against the manufacturing unit category-A and category-B defects as per guidelines issued by the Ministry of Health & Family 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 Controller, sealing or prosecution with relation to drugs/medicines under the said Act is also with the DCGI (CDSCO)/ MoH& FW.
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amended, the Controller/ Drug Inspector may exercise their powers as an Inspecting Agency.

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

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

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

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

**28. Termination for Default**

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

**29. Warranty**

- Supplies must fully comply in all respect with the Technical specifications and conditions laid down in the 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 guarantee of workmanship and shall be strictly in accordance with the specifications and particulars mentioned in the tender. The stores would continue to conform to the description of and quality aforesaid for a period of the specified shelf life from the date of delivery of the said stores to the buyer, have overages within the specified limits and are not subject to recall by the applicable Regulatory Authority due to unacceptable quality. Notwithstanding the above, the fact that the said stores fail to conform to the description and quality as specified in the tender, or the decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the stores discovered not to conform to the said description and quality. Losses due to premature deterioration of potency will be made good and supplied by the firm at its own cost at consignee's site.

On such rejection, the stores will be at the seller's risk and all provisions herein contained relating to replacement. The supplier/Seller shall if so called upon to do so by the buyer in writing, replace the stores free of cost within forty five days or such further period as may be extended from time to time by the buyer at his cost. The provisions of the tender shall apply to the stores replaced from the date of the replacement thereof otherwise the provisions shall not apply. The provisions as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice the contract or otherwise".

Sl. No. & Date	Nomenclature & Specification	Name & Address of Manufacturing Unit	Batch No.	DOM & DOE
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- If the supplier, having been notified, fails to replace within the period specified above, the buyer may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without prejudice against the supplier under the contract.

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

Packaging, Labelling and Marking shall be as per the provisions contained in the Drugs and Cosmetics Rules, 1954 as amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buyer. The Additional Terms and Conditions (ATC) shall be complied with.

### 31. **Bar Coding**

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

### 32. **Delivery Period**

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

## **Special terms and conditions-Version:1 effective from 26-10-2023 for category Potassium Chloride 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 submit regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., valid drug/medicine under procurement, the license issuing authority etc. at their end.
2. The Buyer shall ask the seller to submit the "Notarized Undertaking" in the mentioned below format (scanned copy may be verified by the buyer at their end).

### **UNDERTAKING**

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

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

1. I am the partner / proprietor / director of \_\_\_\_\_ (name of entity) and duly authorized to sign on behalf of \_\_\_\_\_ (Name of entity)
2. We are the manufacturers of the drug/medicine \_\_\_\_\_ ("Product") and intend to offer the same for sale.
3. We state that the license for the Product has been granted/obtained by us as per the provisions of the Drugs and Cosmetics Rules, 1954 as amended till date.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the website of the Drugs and Cosmetics Rules, 1954 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 understand that if any false information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetics Rules, 1954 there under will be initiated.

Place:

Date:

.....

*Signature, Name, Designation & Seal*

*on behalf of the Manufacturer*

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

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

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

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

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

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

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, which are licensed by the concerned Drug Licensing Authority, only one bidder will be allowed to submit only one offer for one product.
11. The manufacturer shall have in house testing facilities and valid Good Laboratory Practice (GLP Certificate) issued by the concerned Drug Licensing Authority under the 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 product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia products shall be submitted by the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability studies) for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data shall be submitted. (If manufacturer has licensed a formula from another company and such licensed formula is used for the product, the license shall be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product by any Central or State Government's Drug procurement agencies at the time of submission of bid. Further, if the bidder/seller has been blacklisted / 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 blacklisted or pending in any court of India by any department of Govt. under prevention of Corruption Act or for criminal conspiracy in the said matter at the time of submission of bid.
19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred only) that they will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs/medicines.

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

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

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

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

In case of pre-dispatch inspection, at the time when the stores are offered for inspection, the life of the one sixth (1/6th) of the total shelf life of the drugs/medicines.

#### 24. **Recalls**

If products are recalled because of problems with product quality or adverse reaction to the pharmaceutical buyer, providing full details about the reason leading to the recall, and shall take steps to replace the product at its ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund if the product has been taken off the market due to safety problems.

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

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

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

- Buyer will embark on stringent quality checks to ensure that drugs/medicines/goods meet requirements. Buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government approved 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 impurities indicated in official compendiums or technical specifications throughout the shelf-life period of the drug. This may also be organized by the buyer post-delivery.

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

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

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would
  - The supplies will be deemed to be completed only upon receipt of the quality certificates from the
- “Not of Standard Quality” or spurious or adulterated or misbranded, such batch/ batches will be

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

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

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

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

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

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the 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 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 Authorities. Confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also within the purview of the concerned authorities.
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amended, the Controller/ Drug Inspector may exercise their powers as an Inspecting Agency.

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

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

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

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

28. **Termination for Default**

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

29. **Warranty**

- Supplies must fully comply in all respect with the Technical specifications and conditions laid down in the 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 contract are of good workmanship and shall be strictly in accordance with the specifications and particulars mentioned in the tender. The stores would continue to conform to the description of and quality aforesaid for a period of 12 months from the date of supply.”

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 of potency will be made good and supplied by the firm at its own cost at consignee's site.

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

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

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

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

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

#### 31. **Bar Coding**

All drugs/medicines supplied should incorporate GS1 barcodes standards at various packaging levels (primary, secondary and tertiary) and should encode the information within the barcodes as mentioned by the buyers in addition to other requirements. Details of bar-coding will be given by the buyer through Additional Terms and Conditions (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) and should ensure that temperature has not been maintained, supply against the said order is liable to be rejected.
  - The items requiring special cold storage conditions shall be supplied with cold chain transporting facilities from the manufacturing unit to the warehouses/consignee location.
33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any other particulars shall be given by the buyer through Additional Terms and Conditions (ATC) in the bid will be applicable.
34. Any other Terms and Conditions which is not included or at variance with the conditions specified in the Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authentic source and quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede special terms and conditions, which shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

### **Special terms and conditions-Version:1 effective from 14-10-2022 for category Anti TB Drugs - Levofloxacin**

#### 1. **Special Terms and Conditions of Anti TB Drugs for NTEP**

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 submit the regulatory documents applicable with the bid. Buyers must also check and validate the details e.g. validity of the license under procurement, the license issuing authority etc. at their end.
2. The seller to be onboarded on GeM mandatorily submit the "Notarized Undertaking" in the mentioned format.

## UNDERTAKING

**(to be on non-judicial stamp paper of Rs 10 and not less than Rs 100)**

I, \_\_\_\_\_, s/o / d/o / w/o \_\_\_\_\_, aged about \_\_\_\_\_ resident of \_\_\_\_\_, do hereby declare

1. I am the partner / proprietor / director of \_\_\_\_\_ (name of entity) and duly authorized to sign on behalf of the entity)
2. We are the manufactures of the drug / medicine \_\_\_\_\_ ("Product") and intend to offer the same for sale.
3. We state that the license for the Product has been granted/obtained by us as per the provisions of the Drugs and Cosmetics Act, 1940 and Rules made there under.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the website of the Drugs and Cosmetics Rules, 1945 as amended till date. Reference no. for SUGAM portal is \_\_\_\_\_.
5. We undertake that all the information provided above is true and complete in all respect. We undertake that if any information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetics 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. The bidder shall comply with all the notifications issued by *Central Drugs Standard Control Organisation (CDSCO)*, Ministry of Health & Family Welfare, Government of India, *Department of Pharmaceuticals (DOP)*, Ministry of Chemicals & Fertilizers time to time in this regard.
4. The purchase shall be made through bidding/RA only irrespective of the value.
5. Supplies should be made directly by the bidder and not through any other Agency/Dealer/Distributor.
6. Drugs must fully comply in all respect with the uploaded Technical specifications and in accordance with the applicable standards.
7. Bidder shall be a manufacturer of the product and having valid own manufacturing license in the indicated form. The bidder shall submit a valid Certificate of Pharmaceutical Product (COPP) as recommended by WHO in any of the pharmacopeia IP/USP/EP. The COPP shall be valid on the date of technical bid opening.
8. Third party manufacturers/Loan Licensee / Distributors / Agents / Contract Manufacturers / Importers are not allowed to bid for the drugs.
9. The bidder should furnish the Manufacturing License valid on bid opening for each item quoted been displayed. The license should be clearly highlighted in the license. Original documents should be produced for verification when demanded. If the manufacturing license has to be submitted in IP only.
10. The bidder should have at least two years of manufacturing and marketing experience of the particular product quoted in the bid. However, this would not apply to regulated products which have been licensed by DC. The bidder shall be required for all new regulated products to this effect.
11. The bidder should submit the Market Standing Certificate issued by the Licensing Authority as a Manufacturer.
12. The bidder should submit the Capacity certificate issued by the licensing authority to the buyer.
13. The bidder should have Non-Conviction Certificate issued by the FDA/ Drugs Controller of the State certifying that the bidder has not been convicted and the products quoted have not been cancelled during last two years.
14. The bidder should have valid Certificate of Pharmaceutical Product (COPP) as recommended by WHO in accordance with GMP.
15. The bidder should have Long Term (Real Time) Stability Data of the quoted product in specified packaging.
16. All goods must be of fresh manufacturing and must bear the dates of manufacturing and expiry. The bidder shall ensure that the goods are fresh and of good quality.

have, at least 5/6th of the minimum shelf life must remain at the time of delivery to the consignee. The data substantiating the claimed shelf life in the offered package.

17. Bid should not be submitted by the firm/company for the product(s) for which the firm/company has been any State Government / Central Government /CMSS/ its Drug procurement agencies due to quality failure as a whole by any of these agencies.
18. During the period of contract if the firm / Company is blacklisted/debarred/deregistered/banned by any Drug procurement agencies / convicted by any Court of law in India, it shall be intimated to buyer along with in one month.
19. The price offered by the seller shall not, in any case exceed the DPCO controlled price, if any, fixed by the Price (MRP) and the selling price. The seller must reduce the prices if there is any reduction in DPCO ceiling.
20. The bidder should quote at least for 50% of the bid quantity of the items quoted and the bidder shall have at least half times the quantity quoted for each schedule.
21. Generally speaking the draft artwork should be given in technical specifications however, in those cases where specific specifications, the vendor must need to coordinate with respective programme division of ministry to furnish the same would be given on this pretext.
22. A Certificate of Analysis from manufacturer's own Quality Control Lab covering each batch delivered is required. The Certificate of Analysis shall include:
  - Generic name of the product
  - Batch No.
  - Pharmacopoeia Reference and/ or In-house method
  - Batch quantity
  - Date of manufacture
  - Expiry date
  - Date of test
  - Description (clarity, color etc)
  - 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
  - Conclusion
  - Qualified Person's signatures.

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

### 23. Quality Control and Post Delivery Surveillance

**23.1** Quality Control is an essential part of the drug procurement, and it is the responsibility of the supplier to ensure that the products conform to the specifications/bid document. The products should conform to the standards as specified in attached specifications.

**23.2** The bidder/ supplier understand that the bid item/items is/are critical health goods, and the quality during complete specified shelf life as indicated in technical specification/bid document/ official compendium or quality checks is serious default as it may derail entire programme and can also risk the life of users.

**23.3** The buyer will embark on stringent quality checks to ensure that drugs/goods meet required standards. The buyer reserves the right to carry necessary inspections/tests at any of, or any combination of or/ all of following stages:

- a. **At Pre-Dispatch stage.**
- b. **At Delivery Stage:** inspection done once the goods reach at consignee location and before taking possession.
- c. **Post Delivery Surveillance:** The drugs/goods shall have the active ingredients and all other parameters as per official compendiums or technical specifications throughout the shelf-life period of the drug/goods. The surveillance shall be organized by buyer post-delivery.

**23.4** The buyer may engage the services of a Quality Control Agent & Quality Control Testing Laboratory. The sampling quantities shall be borne by the supplier.

**23.5 Inspection Methodology:** At pre-dispatch and/or delivery stage, samples of supplies in each batch shall be collected and sent to designated laboratories (Government/NABL Accredited Drug Testing Laboratories). The testing charges will be borne by buyer.

**At post-delivery surveillance:** The samples will be collected from the warehouse of buyer/or final consignee. Quality Control Labs in respect of supplied drugs at any point during specified shelf life as per decision of the buyer.

In case of failure of batches during or at any stage (indicated at 23.3), the testing charges shall be borne by the supplier.

**23.6** The supplies will be deemed to be completed only upon receipt of the quality certificates from the testing laboratories.

**23.7 At any of testing stage,** samples which do not meet quality requirement shall render the relevant batch as defective.

declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches of entire batch paid will be recovered from the supplier whether consumed fully/ partially. Besides action against supplier for suitable period.

**23.8** In the event of the samples of Drugs/goods supplied fails in quality tests or found to be not as per upon the type, nature and seriousness of failure, consequences resulting from such default, availability either:

- i. Ask the supplier to replace entire quantity of the relevant batches, in addition to imposition of penalty.
- ii. To make alternative purchase of the items from other approved suppliers or in the open market at higher rates, at the risk and the cost of the supplier.
- iii. In addition to (i) or (ii) above, action to debar/blacklist the supplier for suitable period, as decided by the Government.
- iv. In addition, the FDA/ Drugs Control Authority of concerned State will be informed for initiating necessary action. The deposit will also be forfeited without any intimation.
- v. The decision of the buyer or any officer authorised by the buyer, as to the quality of the supplied goods.

**23.9** In the event of replacement of rejected drugs/goods by the supplier, all the above-mentioned provisions shall apply from the date of replacement thereof, otherwise the supplier shall pay to the buyer such damages as may be determined under the conditions here in contained and the facts will be notified to the Drugs Controller of India/State Drug Controller.

**23.10** If the product is non-Pharmacopeial then the supplier must provide the in house test method also for by the buyer.

**23.11** The Master Formula of the products shall be provided whenever asked for by the buyer.

24. If the samples do not conform to bid specifications, the supplier will be liable for relevant action under 13. The goods has to be taken back by the supplier within a period of 30 days of the receipt of the letter from the buyer to the supplier. The buyer has the right to destroy such "NOT OF STANDARD QUALITY ITEMS" if the supplier does not comply within the stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after the expiry of notice, and shall also collect demurrage charges calculated at the rate of 0.5% per week on the value of the goods.

**25. WARRANTY**

- The supplier shall warrant that goods/items to be supplied shall be new and free from all defects in manufacturing and shall be of the highest grade and consistent with the established and general practice in the industry and shall perform in full conformity with the specifications. Supplier shall warrant that goods conform to specification throughout specified shelf life. The supplier shall be responsible for any defects that arise because of improper quality of API, Excipients in packaging material etc. manufacturing /packaging workmanship or otherwise and shall remedy such defects at his own cost when called upon to do so. If the defect in respect stores is faulty.
- The portion of clause 23.8 (i) to (v) would also apply in case the goods/items supplied doesn't meet the specifications.
- Replacement under warranty clause shall be made by the supplier within 60 days period, free of other incidental charges.
- If any defect is not remedied within a reasonable time, the buyer may proceed to procure such defective goods from open market, but without prejudice to many other rights which the buyer may have against the supplier.

26. Loss or premature deterioration due to biological and other activities during the life potency of the drug shall be at the cost of or shall have to refund the cost of rejected drug.

**27. Packing**

- i. The drugs shall be supplied strictly in the packaging specified in the uploaded Technical specifications.
- ii. The Weight, Volume & Dimensions of shipping cartons & intermediate packaging carton may be mentioned in the specifications.
- iii. The packaging shall be of a sturdy quality to provide adequate protection of the product for carriage to various locations under adverse climate and storage conditions and high humidity. Used cartons should never be reused.
- iv. Products with specific temperature requirements will be packed, stored and delivered in appropriate containers.
- v. The packaging unit should be strong, able to be stacked to a height of 4 pallets as static storage and 2 pallets as dynamic storage.
- vi. The supplier to ensure that the material is of good quality and is free from development of fungus/termite. The date of delivery at specified locations, suppliers at their own cost would lift the entire batch from various locations. For LD purposes the date of receipt of replaced batches would count.

28. Any other Terms and Conditions which is not included or at variance with the conditions specified in STC shall be void. The Terms and Conditions in the bid to ensure drugs are procured from authentic/validated source with appropriate quality standards are in reverse order of precedence i.e. ATC shall supersede specific STC which shall supersede General Conditions if there are any conflicting provisions.



## Special terms and conditions-Version:1 effective from 26-10-2023 for category Metoprolol Injection

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

### UNDERTAKING

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

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

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

Place:

Date:

.....

*Signature, Name, Designation & Seal*

*on behalf of the Manufacturer*

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

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

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

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

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

2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/ highlighted.

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

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

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

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

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

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

In case of pre-dispatch inspection, at the time when the stores are offered for inspection, the life of the one sixth (1/6th) of the total shelf life of the drugs/medicines.

#### 24. **Recalls**

If products are recalled because of problems with product quality or adverse reaction to the pharmace buyer, providing full details about the reason leading to the recall, and shall take steps to replace the p ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refun been taken off the market due to safety problems.

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

- All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Repor** own Quality Control Lab. The Test Report/Certificate of Analysis shall include:

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

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

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

**a) At Pre-Dispatch stage**

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

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

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

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

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would be borne by the supplier.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the 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 of drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier when the batch is rejected.
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in any of the tests, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/consignees and replace with fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer. The buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take the same within stipulated time. The buyer will arrange to destroy the “NOT OF STANDARD QUALITY ITEMS” after the expiry of the stipulated time.

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

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

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

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

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the 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
- 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 confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also with
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amended Controller/ Drug Inspector may exercise their powers as an Inspecting Agency.

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

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

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

If any batch of any product(s) supplied by the supplier is declared "NOT OF STANDARD QUALITY", by 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 for applicable Regulatory Authority in the country of manufacture due to unacceptable quality or reports of recall.

**29. Warranty**

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

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

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

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

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

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

Packaging, Labelling and Marking shall be as per the provisions contained in the Drugs and Cosmetics Rules, 1945 as amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buyer. Conditions (ATC) shall be complied with.

31. **Bar Coding**

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

32. **Delivery Period**

- Minimum delivery period will be of 45 days from the date of issuing of the purchase order.
  - The supplier should maintain the recommended temperature of the drug/medicine (wherever indicated). If found that temperature has not been maintained, supply against the said order is liable to be rejected.
  - The items requiring special cold storage conditions shall be supplied with cold chain transporting facility from manufacturing unit to the warehouses/consignee location.
33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any other particulars shall be given by the buyer through Additional Terms and Conditions (ATC) in the bid will be applicable.
34. Any other Terms and Conditions which is not included or at variance with the conditions specified in Standard Terms and Conditions (STC) and 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 STC and STC shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

**Special terms and conditions-Version:1 effective from 06-07-2023 for category Acyclovir Ointment (V2)**

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

**UNDERTAKING**

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

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

1. I am the partner / proprietor / director of \_\_\_\_\_ (name of entity) and duly authorized to sign on behalf of \_\_\_\_\_ (Name of entity)
2. We are the manufacturers of the drug/medicine \_\_\_\_\_ ("Product") and intend to offer for sale.
3. We state that the license for the Product has been granted/obtained by us as per the provisions of the Drugs and Cosmetics Rules, 1945 as amended till date.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the website of the Drugs and Cosmetics Rules, 1945 as amended till date. Reference no. for SUGAM portal is \_\_\_\_\_.
5. We undertake that all the information provided above is true and complete in all respect. We understand that any false information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetics Rules, 1945 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 notified by Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
4. All provisions of Narcotic Drugs & Psychotropic Substances Act, 1985 as amended till date will also be applicable to the 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 under the Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly marked with the valid own 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 or reseller who are operating in compliance with all relevant laws and regulations and are properly licensed to sell the drug/medicine.

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

*If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the copy of the application must be submitted with a certificate that application for renewal was made within time frame as per Drugs and Cosmetics Act, 1940 that has not been deleted by drug licensing authority.*

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

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

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, which are all licensed by the concerned Drug Licensing Authority, only one bid for all units but necessary document regarding separate manufacturing units shall be submitted. One bidder will be allowed to submit only one offer for one product.
11. The manufacturer shall have in house testing facilities and valid Good Laboratory Practice (GLP) Certificate issued by the concerned Drug Licensing Authority under 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 product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia (USP, BP, IP) shall be submitted by the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability studies) for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data shall be submitted along with the licensing agreement. (If manufacturer has licensed a formula from another company and such licensed formula is used for the product, the stability data of 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 or testing by any State Government / Central Government / its Drug procurement agencies or 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 buyer by a document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Government's Drug procurement agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of the buyer.
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories should not be blacklisted or pending in any court of India by any department of Govt. under prevention of Corruption Act or for criminal conspiracy or Government fund or any criminal conspiracy in the said matter at the time of submission of bid.
19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred and no paise) that the bidder/seller and its partners/proprietors/directors/authorized signatories shall not be blacklisted or pending in any court of India by any department of Govt. under prevention of Corruption Act or for criminal conspiracy or Government fund or any criminal conspiracy in the said matter at the time of submission of bid.

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

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

*Controller of India from time to time.*

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

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

In case of pre-dispatch inspection, at the time when the stores are offered for inspection, the life of the one sixth (1/6th) of the total shelf life of the drugs/medicines.

#### 24. **Recalls**

If products are recalled because of problems with product quality or adverse reaction to the pharmaceutical buyer, providing full details about the reason leading to the recall, and shall take steps to replace the product at its ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund if the product has been taken off the market due to safety problems.

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

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

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

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

##### **a) At Pre-Dispatch stage**

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

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

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

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

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would
  - The supplies will be deemed to be completed only upon receipt of the quality certificates from the
- “Not of Standard Quality” or spurious or adulterated or misbranded, such batch/ batches will be
- **At any of testing stage**, Samples which do not meet quality requirement shall render the relevant batch declared to be “Not of Standard Quality” or spurious or adulterated or misbranded, such batch/batches of drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier when the batch is found to be substandard.
  - If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in the inspection, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/colleges and fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer. The buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take back the rejected goods within stipulated time. The buyer will arrange to destroy the “NOT OF STANDARD QUALITY ITEMS” after

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

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

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

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

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

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

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

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

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

## 28. **Termination for Default**

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

## 29. **Warranty**

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

“The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under the tender are of good quality and workmanship and shall be strictly in accordance with the specifications and particulars mentioned in the tender. The stores would continue to conform to the description of and quality aforesaid for a period of the specified shelf life from the date of delivery of the said stores to the buyer, have overages within the specified limits and are not subject to recall by the applicable Regulatory Authority due to unacceptable quality.



Notwithstanding the above, the fact that the said stores fail to conform to the description and quality decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the stores discovered not to conform to the said description and quality. Losses due to premature deterioration of potency will be made good and supplied by the firm at its own cost at consignee's site.

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

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

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

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

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

31. **Bar Coding**

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

32. **Delivery Period**

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

**Special terms and conditions-Version:1 effective from 06-07-2023 for category Betamethasone Injection**

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

**UNDERTAKING**

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

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

Place:

Date:

.....

*Signature, Name, Designation & Seal*

*on behalf of the Manufacturer*

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

In case of authorized resellers/distributors, it will be the legal & regulatory liability of the manufacturer and its authorized resellers/distributors 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 their

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

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

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

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

13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia and the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability studies for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product by Central or State Government's Drug procurement agencies at the time of submission of bid. Further, the bidder/seller should not have been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Partner should not participate in the bid.
16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any Central or State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intimated in writing document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Government's Drug procurement agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of the buyer.
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories should not be blacklisted or pending in any court of India by any department of Govt. under prevention of Corruption Act or for criminal offence Government fund or any criminal conspiracy in the said matter at the time of submission of bid.
19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred and no paise).

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

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

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

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

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

#### 24. **Recalls**

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

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

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

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

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

**a) At Pre-Dispatch stage**

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

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

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

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

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would be borne by the supplier.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the concerned State.

"Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be rejected.

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

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

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

- In case any drug/medicine is found substandard either at any of testing stage or during the shelf life period, the batch shall be accepted by the supplier/seller. If the same is disputed by the supplier, it shall be sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final and binding if 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 the guidelines of the Government of India at its own cost.

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

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

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

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

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

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

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

28. **Termination for Default**

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

29. **Warranty**

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

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

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

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

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

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

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

31. **Bar Coding**

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

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

### 32. Delivery Period

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

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

### 1. Generic

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

## Disclaimer/अस्वीकरण

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

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

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 are mandated to ensure compliance with all the applicable laws / Labour Laws such as The Minimum Wages Act, 1948, The Payment of Wages Act, 1936, The Payment of Gratuity Act, 1972 etc. Any non-compliance will be treated as breach of contract per GeM Contract.**

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

In terms of GeM GTC clause 26 regarding Restrictions on procurement from a bidder of a country which shares a land border with India, any bidder from a country which share is registered with the Competent Authority. While participating in bid, Bidder has to undertake compliance of this and any false declaration and non-compliance of this will be taken as action in accordance with the laws./जेम की सामान्य शर्तों के खंड 26 के संदर्भ में भारत के साथ भूमि सीमा साझा करने वाले देश के बिडर से खरीद वाले देश का कोई भी बिडर इस निविदा में बिड देने के लिए तभी पात्र होगा जब वह बिड देने वाला सक्षम प्राधिकारी के पास पंजीकृत हो। बिड कोई भी गलत घोषणा किए जाने व इसका अनुपालन न करने पर अनुबंध को तत्काल समाप्त करने और कानून के अनुसार आगे की कानूनी कार्य

**---Thank You/धन्यवाद---**