Bid Document/ बिड दस्तावेज़

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

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

MSE Purchase Preference/एमएसई खरीद वरीयता

MSE Purchase Preference/एमएसई खरीद वरीयता	Yes

1. If the bidder is a Micro or Small Enterprise as per latest definitions under MSME rules, the bidder shall be exempte
and "Experience Criteria" subject to meeting of quality and technical specifications. If the bidder is OEM of the offere
Average Turnover" criteria also subject to meeting of quality and technical specifications. In case any bidder is seeki
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 "Ex
and technical specifications. If the bidder is OEM of the offered products, it would be exempted from the "OEM Avera
quality and technical specifications. In case any bidder is seeking exemption from Turnover / Experience Criteria, the
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 th
manufactured and supplied same or similar Category Products to any Central / State Govt Organization / PSU for nur
bid document before the bid opening date. Copies of relevant contracts to be submitted along with bid in support of
Financial year. 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
in India), Order 2017 as amended from time to time and its subsequent Orders/Notifications issued by concerned No
minimum local content to qualify as a Class 1 local supplier is denoted in the bid document. If the bidder wants to av
upload a certificate from the OEM regarding the percentage of the local content and the details of locations at which
bid, failing which no purchase preference shall be granted. In case the bid value is more than Rs 10 Crore, the declar
be certified by the statutory auditor or cost auditor, if the OEM is a company and by a practicing cost accountant or
companies as per the Public Procurement (preference to Make-in -India) order 2017 dated 04.06.2020. Only Class-I a
4.6.2020 will be eligible to bid. Non - Local suppliers as per MII order dated 04.06.2020 are not eligible to participate
be allowed to participate.The buyers are advised to refer the OM No.F.1/4/2021-PPD dated 18.05.2023 OM_No.1_4_2
Concurrent application of Public Procurement Policy for Micro and Small Enterprises Order, 2012 and Public Procuren

5. Purchase preference will be given to MSEs having valid Udyam Registration and whose credentials are validated o
in Public Procurement Policy for Micro and Small Enterprises (MSEs) Order, 2012 dated 23.03.2012 issued by Ministry
subsequent Orders/Notifications issued by concerned Ministry. If the bidder wants to avail themselves of the Purchas
/ OEM of the offered product on GeM. Traders are excluded from the purview of Public Procurement Policy for Micro a
products manufactured by some other OEM are not eligible for any purchase preference. In respect of bid for Service
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 a
within L-1+ 15% (Selected by Buyer) of margin of purchase preference /price band defined in relevant policy, such M
price and contract will be awarded for 25% (selected by Buyer) percentage of total quantity. The buyers are advised
18.05.2023 OM_No.1_4_2021_PPD_dated_18.05.2023 for compliance of Concurrent application of Public Procuremen
and Public Procurement (Preference to Make in India) Order, 2017. Benefits of MSE will be allowed only if seller is val
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
Over, Past Performance and Project / Past Experience etc. This has no relevance or bearing on the price to be quotec
impact on bid participation. Also this is not going to be used as a criteria in determining reasonableness of quoted pr
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 simila
least one of the last three Financial years before the bid opening date to any Central / State Govt Organization / PSU
cumulative order quantity in any one financial year) to be submitted along with bid in support of quantity supplied ir
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 bidc
bidder will not be allowed to participate in RA. However, H-1 will also be allowed to participate in RA in following cas

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

Evaluation Method (Item Wise Evaluation Method)

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

Evaluation Schedules	Estimated Value	Item/Category
Schedule 1	4680	Baclofen Tablets (v2)
Schedule 2	28200	Budesonide Respirator Solution For Use In Neb
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 resp 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/रिपोर्टिंग अधिकारी	Address/पता	Delivery Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 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 resp 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**	1 mg

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 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 केटेगरी 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 Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 600 600 600 600

Azathioprine Tablets (V2) (3600 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 केटेगरी 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 Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 900 900 900 900

Ipratropium Bromide Respules (V2) (240 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 केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 60 60 60 60

Amitriptyline Tablets (V2) (720 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 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 Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 180 180 180 180

Levetiracetam Tablet (1440 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 केटेगरी 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 Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 360 360 360 360

Flunarizine Tablet (240 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 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/रिपोर्टिंग अधिकारी	Address/पता	Delivery Scl contract sta
1	**********	**********Rangareddi	Quantity/मात्र 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 resp 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**	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 Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 1500 1500 1500 1500

Bupivacaine Injection (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 केटेगरी 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 Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 15 15 15 15

Adrenaline Injection (V2) (480 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 केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 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 resp 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
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 Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 75 75 75 75

Levetiracetam Injection (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 केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के

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

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

Carbamazepine Tablets (V2) (2160 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 केटेगरी 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 Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 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 resp 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**	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 Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 720 720 720 720

Hydroxyurea Capsule (360 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 केटेगरी 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/रिपोर्टिंग अधिकारी	Address/पता	Delivery Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 90 90 90 90

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 केटेगरी 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/रिपोर्टिंग अधिकारी	Address/पता	Delivery Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 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 केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 270 270 270 270

Labetalol Injection (24 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 केटेगरी 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/रिपोर्टिंग अधिकारी	Address/पता	Delivery Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 6 6 6 6

Metoclopramide Injection (240 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 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	Quantity/मा 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 resp
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
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 Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 150 150 150 150

Sodium Phosphate Enema (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 केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के

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

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

Bisacodyl Tablets (V2) (1200 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 केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification]

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 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 केटेगरी 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 Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 15 15 15 15

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 केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 105 105 105 105

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 केटेगरी 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 Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 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 resp 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**	1 mg

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 360 360 360 360

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 केटेगरी 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/रिपोर्टिंग अधिकारी	Address/पता	Delivery Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 270 270 270 270

Potassium Chloride Injection (96 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 केटेगरी 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/रिपोर्टिंग अधिकारी	Address/पता	Delivery Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 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 resp
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
PACKAGING	**Primary pack size**	30 ml

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 60 60 60 60

Clindamycin Capsule (600 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 केटेगरी 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/रिपोर्टिंग अधिकारी	Address/पता	Delivery Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 150 150 150 150

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 resp
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 specif

Additional Specification Documents/अतिरिक्त विशिष्टि दस्तावेज़

Applicable Specification Document	View

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 90 90 90 90

Dexamethasone 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 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 Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 600 600 600 600

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 केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Sch contract sta

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 90 90 90 90

Metoprolol Injection (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 केटेगरी 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 Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 15 15 15 15

Acyclovir Ointment (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 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/रिपोर्टिंग अधिकारी	Address/पता	Delivery Scl contract sta
1	**********	**********Rangareddi	Quantity/मात्र 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 resp
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
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 Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 38 37 37 38

Dobutamine Injection (30 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 केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 7 7 7 9

Hyoscine Butyl Bromide Injection (900 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 केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification]

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Delivery Sch contract sta
1	**********	**********Rangareddi	Quantity/मात्र 225 225 225 225

Special terms and conditions-Version:1 effective from 06-07-2023 for category Baclofen 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 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 aut 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 b buyer at the time of bid submission. The certificate must have been issued within 12 months from the d
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, whicl 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 d 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, d 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 S State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be inti document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Gov agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of t
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shou 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 d 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 provisi 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 r 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 pharmaceu 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 pharma results and the limits for the individual tests should be given
    10. Conclusion
    11. Qualified Person's signature

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

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

    a) At Pre-Dispatch stage

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

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

    - The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborat 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 th destination shall in no way be limited or waived by reason of the goods having previously been i

dispatch from the place of manufacture.

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

  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 durin

  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 th

  "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 relev 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 Dru 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 an authority, the supplier shall inform the same immediately to the buyer so that the use of the available s the available stock of the product with all consignee/users will be retrieved.

28. **Termination for Default**

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

29. **Warranty**

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

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

  On such rejection, the stores will be at the seller's risk and all provisions herein contained 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 supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer ar period shall apply to the stores replaced from the date of the replacement thereof otherwise the as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice this contract or otherwise".

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

Signature name & designati

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without 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 A 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 othe 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 23-03-2024 for category Budesonide Respirator S

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 aut 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 b buyer at the time of bid submission. The certificate must have been issued within 12 months from the d
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, whicl 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 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 S State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be inti document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Gov agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of t
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shou 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 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 provisi 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 r 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 pharmaceu 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 pharma results and the limits for the individual tests should be given
10. Conclusion
11. Qualified Person's signature

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

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

a) At Pre-Dispatch stage

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

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

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborat 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 th destination shall in no way be limited or waived by reason of the goods having previously been i dispatch from the place of manufacture.
- **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each ba collected and sent to designated laboratories (NABL Accredited/Government approved laboratori

  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
- The supplies will be deemed to be completed only upon receipt of the quality certificates from th

  "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 relev 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 an 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 uni 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 Dru confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also w
- 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 s the available stock of the product with all consignee/users will be retrieved.

28. **Termination for Default**

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

29. **Warranty**

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

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

  On such rejection, the stores will be at the seller's risk and all provisions herein contained 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 supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer ar period shall apply to the stores replaced from the date of the replacement thereof otherwise the as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice this contract or otherwise".

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

Signature name & designati

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without 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 A 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 othe 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 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 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 aut 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 b 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, whicl 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 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 S State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be inti document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Gov agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of t
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shou 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 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 provisi 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 r 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 pharmaceu 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 pharma results and the limits for the individual tests should be given
    10. Conclusion
    11. Qualified Person's signature

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

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

    a) At Pre-Dispatch stage

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

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

    - The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborat 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 th destination shall in no way be limited or waived by reason of the goods having previously been i dispatch from the place of manufacture.
    - **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each ba collected and sent to designated laboratories (NABL Accredited/Government approved laboratori

      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 durin

      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 th

      "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 relev

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 supplie 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 an 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 uni 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 Dru 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 amen 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 s 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 c forty five days or such further period as may be extended from time to time by the buyer at his supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer ar period shall apply to the stores replaced from the date of the replacement thereof otherwise the as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice this contract or otherwise".

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

Signature name & designati

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without 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 A 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 othe 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 Ipratropium Bromide Re

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 (s 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 aut
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 b
buyer at the time of bid submission. The certificate must have been issued within 12 months from the
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, whicl
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
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,

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 S
State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be inti
document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Gov
agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of t
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shou
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 d
    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 provisi
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 n
    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 pharmaceu
    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 pharma
       results and the limits for the individual tests should be given
    10. Conclusion
    11. Qualified Person's signature

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

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

      a) At Pre-Dispatch stage

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

inventory.

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

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborat 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 th destination shall in no way be limited or waived by reason of the goods having previously been i dispatch from the place of manufacture.
- **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each ba collected and sent to designated laboratories (NABL Accredited/Government approved laboratori

  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 durin

  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 th

  "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 relev 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 an 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 uni 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 Dru confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also w
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amen 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 s

the available stock of the product with all consignee/users will be retrieved.

28. **Termination for Default**

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

29. **Warranty**

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

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

  On such rejection, the stores will be at the seller's risk and all provisions herein contained 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 supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer ar period shall apply to the stores replaced from the date of the replacement thereof otherwise the as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice this contract or otherwise".

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

Signature name & designati

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without 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 A 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 othe requirements. Details of bar-coding will be given by the buyer through Additional Terms and Conditions

32. **Delivery Period**

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

manufacturing unit to the warehouses/consignee location.

33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any Additional Terms and Conditions (ATC) in the bid will be applicable.
34. Any other Terms and Conditions which is not included or at variance with the conditions specified in ST Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authent quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede sp shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

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

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

UNDERTAKING

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

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

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

Place:

Date:

.....

Signature, Name, Designation & Seal

on behalf of the Manufacturer

3. All Provisions of Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date will a notifications issued by *Central Drugs Standard Control Organization* (*CDSCO*), Ministry of Health & Fam Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
4. All provisions of Narcotic Drugs & Psychotropic Substances Act, 1985 as amended till date will also be a Substances.
5. The purchase shall be made through Bidding/RA only irrespective of the value.
6. Manufacturer shall have a valid own manufacturing license issued by the competent drug licensing aut 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 b buyer at the time of bid submission. The certificate must have been issued within 12 months from the d
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, whicl 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 d 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, d 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 S State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be inti document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Gov agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of t
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shou 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 d 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 provisi 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 r 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 pharmaceu 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 Repo** own Quality Control Lab. The Test Report/Certificate of Analysis shall include:

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

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

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

a) At Pre-Dispatch stage

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

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

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborat 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 th destination shall in no way be limited or waived by reason of the goods having previously been i dispatch from the place of manufacture.
- **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each ba collected and sent to designated laboratories (NABL Accredited/Government approved laboratori

  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 durin

  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 th

  "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 relev 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 anc submitted within three months, from the date of communication of the disputed test report to th approach the concerned Drug Control Authorities for getting the drugs/medicines tested, as per own cost.

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

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning t buyer. In case of any complaint in the field, the B.M.R/ B.P.R for the particular batch of the produ For New drugs/medicines, complete stability data of 6 months period shall be acceptable.
- The case of admixture of drugs will be treated as a violation of terms and conditions and will not
- Statutory provisions on manufacture, distribution, storage and quality issues of drugs/medicines up to date is vested with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Dru 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 amenc 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 s the available stock of the product with all consignee/users will be retrieved.

28. **Termination for Default**

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

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

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

      On such rejection, the stores will be at the seller's risk and all provisions herein contained 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 ar period shall apply to the stores replaced from the date of the replacement thereof otherwise the as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice this contract or otherwise".

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

Signature name & designati

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without 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 A 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 othe 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 Bupivacaine Injection (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 (s 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 b buyer at the time of bid submission. The certificate must have been issued within 12 months from the d
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, whicl 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 d 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, d 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 S State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be inti document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Gov agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of t
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shou 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 d 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 provisi 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 r 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 pharmaceu 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 pharma results and the limits for the individual tests should be given
    10. Conclusion
    11. Qualified Person's signature

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

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

    a) At Pre-Dispatch stage

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

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

    - The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborat 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 th destination shall in no way be limited or waived by reason of the goods having previously been i dispatch from the place of manufacture.
    - **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each ba collected and sent to designated laboratories (NABL Accredited/Government approved laboratori

    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 durin

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 th

"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 relev 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 Dru confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also w
- 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 s the available stock of the product with all consignee/users will be retrieved.

28. **Termination for Default**

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

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

"The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under th

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

On such rejection, the stores will be at the seller's risk and all provisions herein contained 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 ar
period shall apply to the stores replaced from the date of the replacement thereof otherwise the
as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice
this contract or otherwise".

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

Signature name & designati

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without 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 A 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 othe 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 Adrenaline Injection (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 (s

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 auth 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 b buyer at the time of bid submission. The certificate must have been issued within 12 months from the d
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, whicl 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 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, house testing or testing by any State Government / Central Government / its Drug procurement agenci been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Par participate in the bid.
16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be inti document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Gov agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of t
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shou 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 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 provisi 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 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 pharmaceu 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 Repo** own Quality Control Lab. The Test Report/Certificate of Analysis shall include:
    1. Generic name of the product
    2. Batch No.
    3. Pharmacopoeia Reference and/ or In-house method
    4. Batch quantity
    5. Date of manufacture
    6. Expiry date
    7. Date of test
    8. Description (clarity, color etc)
    9. All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharma results and the limits for the individual tests should be given

10. Conclusion
11. Qualified Person’s signature

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

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

a) At Pre-Dispatch stage

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

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

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborat 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 th destination shall in no way be limited or waived by reason of the goods having previously been i dispatch from the place of manufacture.
- **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each ba collected and sent to designated laboratories (NABL Accredited/Government approved laboratori

  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 durin

  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 th

  “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 relev 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 an 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 uni 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 Dru 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 s the available stock of the product with all consignee/users will be retrieved.

28. **Termination for Default**

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

29. **Warranty**

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

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

  On such rejection, the stores will be at the seller's risk and all provisions herein contained 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 ar period shall apply to the stores replaced from the date of the replacement thereof otherwise the as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice this contract or otherwise".

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

Signature name & designati

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without 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 A 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 othe
    requirements. Details of bar-coding will be given by the buyer through Additional Terms and Condition

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. 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 aut
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 b
buyer at the time of bid submission. The certificate must have been issued within 12 months from the d
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, whicl
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
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, d
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 S
State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be inti
document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Gov
agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of t
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shou
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 d
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 provisi
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 r 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 pharmaceu 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 pharma results and the limits for the individual tests should be given
    10. Conclusion
    11. Qualified Person's signature

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

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

    a) At Pre-Dispatch stage

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

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

    - The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborat 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 th destination shall in no way be limited or waived by reason of the goods having previously been i dispatch from the place of manufacture.
    - **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each ba collected and sent to designated laboratories (NABL Accredited/Government approved laboratori

      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 durin

      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 th

      "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 relev 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 supplie 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 an 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 uni 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 Dru confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also w
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amen 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 s 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 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 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

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

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

Signature name & designati

- If the supplier, having been notified, fails to replace within the period specified above, the buyer
may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without 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 A
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 othe
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 Amiodarone Injection (V

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

UNDERTAKING

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

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

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

_____. *(Name of entity)*

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

Place:

Date:

.....

Signature, Name, Designation & Seal

on behalf of the Manufacturer

3. All Provisions of Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date will a
notifications issued by *Central Drugs Standard Control Organization* (*CDSCO*), Ministry of Health & Fam
Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
4. All provisions of Narcotic Drugs & Psychotropic Substances Act, 1985 as amended till date will also be a
Substances.
5. The purchase shall be made through Bidding/RA only irrespective of the value.
6. Manufacturer shall have a valid own manufacturing license issued by the competent drug licensing aut
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 b
buyer at the time of bid submission. The certificate must have been issued within 12 months from the
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, whicl
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
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,

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 S
State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be inti
document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Gov
agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of t
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shou
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 d
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 provisi
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 r
    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 pharmaceu
    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 pharma
       results and the limits for the individual tests should be given
    10. Conclusion
    11. Qualified Person's signature

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

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

      a) At Pre-Dispatch stage

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

inventory.

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

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborat 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 th destination shall in no way be limited or waived by reason of the goods having previously been i dispatch from the place of manufacture.
- **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each ba collected and sent to designated laboratories (NABL Accredited/Government approved laboratori

  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 durin

  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 th

  "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 relev 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 an 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 uni 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 Dru confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also w
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amen 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 s

the available stock of the product with all consignee/users will be retrieved.

28. **Termination for Default**

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

29. **Warranty**

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

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

On such rejection, the stores will be at the seller's risk and all provisions herein contained 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 supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer ar period shall apply to the stores replaced from the date of the replacement thereof otherwise the as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice this contract or otherwise".

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

Signature name & designati

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without 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 A 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 othe 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 26-10-2023 for category Sodium Phosphate Enem

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 aut
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 b buyer at the time of bid submission. The certificate must have been issued within 12 months from the d
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, whicl 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 d 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, d 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 S State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be inti document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Gov agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of t
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shou 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 d 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 provisi 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 r 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 pharmaceu 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 pharma results and the limits for the individual tests should be given
10. Conclusion
11. Qualified Person's signature

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

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

a) At Pre-Dispatch stage

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

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

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborat 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 th destination shall in no way be limited or waived by reason of the goods having previously been i dispatch from the place of manufacture.
- **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each ba collected and sent to designated laboratories (NABL Accredited/Government approved laboratori

  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 durin

  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 th

  "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 relev 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 anc submitted within three months, from the date of communication of the disputed test report to th approach the concerned Drug Control Authorities for getting the drugs/medicines tested, as per own cost.

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

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning t buyer. In case of any complaint in the field, the B.M.R/ B.P.R for the particular batch of the produ For New drugs/medicines, complete stability data of 6 months period shall be acceptable.
- The case of admixture of drugs will be treated as a violation of terms and conditions and will not
- Statutory provisions on manufacture, distribution, storage and quality issues of drugs/medicines up to date is vested with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Dru 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 amenc 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 s the available stock of the product with all consignee/users will be retrieved.

28. **Termination for Default**

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

29. **Warranty**

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

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

On such rejection, the stores will be at the seller's risk and all provisions herein contained 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 ar period shall apply to the stores replaced from the date of the replacement thereof otherwise the as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice this contract or otherwise".

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

Signature name & designati

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without 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 A 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 othe 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 29-10-2024 for category Bisacodyl 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 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 aut 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 b buyer at the time of bid submission. The certificate must have been issued within 12 months from the d
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, whicl 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 d 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, d 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 S State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be inti document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Gov agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of t
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shou 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 d 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 provisi 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 r 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 pharmaceu 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 pharma results and the limits for the individual tests should be given
    10. Conclusion
    11. Qualified Person's signature

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

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

    a) At Pre-Dispatch stage

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

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

    - The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborat 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 th destination shall in no way be limited or waived by reason of the goods having previously been i dispatch from the place of manufacture.

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

  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 durin

  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 th

  "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 relev 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 Dru 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 s the available stock of the product with all consignee/users will be retrieved.

28. **Termination for Default**

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

29. **Warranty**
    - Supplies must fully comply in all respect with the Technical specifications and conditions laid dov

Pharmacopoeia standards.

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

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

  On such rejection, the stores will be at the seller's risk and all provisions herein contained 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 supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer ar period shall apply to the stores replaced from the date of the replacement thereof otherwise the as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice this contract or otherwise".

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

Signature name & 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 A 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 othe 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. 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 b buyer at the time of bid submission. The certificate must have been issued within 12 months from the d
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, whicl

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
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 S
State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be inti
document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Gov
agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of t
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shou
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
    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 provisi
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
    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 pharmaceu
    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 pharma results and the limits for the individual tests should be given
10. Conclusion
11. Qualified Person's signature

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

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

a) At Pre-Dispatch stage

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

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

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborat 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 th destination shall in no way be limited or waived by reason of the goods having previously been i dispatch from the place of manufacture.
- **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each ba collected and sent to designated laboratories (NABL Accredited/Government approved laboratori

  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
- The supplies will be deemed to be completed only upon receipt of the quality certificates from th

  "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 relev 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 an 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 uni 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 Dru 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 an authority, the supplier shall inform the same immediately to the buyer so that the use of the available s 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 of 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 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 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 ar period shall apply to the stores replaced from the date of the replacement thereof otherwise the as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice this contract or otherwise".

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

Signature name & designati

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without 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 A 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 othe
    requirements. Details of bar-coding will be given by the buyer through Additional Terms and Condition

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. 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 aut
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 b
buyer at the time of bid submission. The certificate must have been issued within 12 months from the d
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, whicl
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
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, d
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 S
State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be inti
document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Gov
agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of t
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shou
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 d
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 provisi
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 r 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 pharmaceu 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 pharma results and the limits for the individual tests should be given
    10. Conclusion
    11. Qualified Person's signature

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

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

    a) At Pre-Dispatch stage

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

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

    - The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborat 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 th destination shall in no way be limited or waived by reason of the goods having previously been i dispatch from the place of manufacture.
    - **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each ba collected and sent to designated laboratories (NABL Accredited/Government approved laboratori

      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 durin

      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 th

      "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 relev 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 supplie 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 an 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 uni 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 Dru confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also w
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amen 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 s 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 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 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

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

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

Signature name & designati

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without 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 A 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 othe 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 24-05-2024 for category Fluoxetine Capsule

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 (s 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 aut
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 b
buyer at the time of bid submission. The certificate must have been issued within 12 months from the
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, whicl
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
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,
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 S State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be inti document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Gov agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of t
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shou 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 d 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 provisi 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 r 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 pharmaceu 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 pharma results and the limits for the individual tests should be given
    10. Conclusion
    11. Qualified Person's signature

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

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

    a) At Pre-Dispatch stage

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

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

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborat 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 th destination shall in no way be limited or waived by reason of the goods having previously been i dispatch from the place of manufacture.
- **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each ba collected and sent to designated laboratories (NABL Accredited/Government approved laboratori

  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 durin

  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 th

  "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 relev 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 an 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 uni 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 Dru confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also w
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amen 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 an authority, the supplier shall inform the same immediately to the buyer so that the use of the available s the available stock of the product with all consignee/users will be retrieved.

28. **Termination for Default**

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

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

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

      On such rejection, the stores will be at the seller's risk and all provisions herein contained 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 supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer ar period shall apply to the stores replaced from the date of the replacement thereof otherwise the as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice this contract or otherwise".

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

      Signature name & designati

    - If the supplier, having been notified, fails to replace within the period specified above, the buyer may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without 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 A 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 othe 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 Budesonide + Formoterc

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
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   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
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10. If a company/firm has two or more separate manufacturing units at different sites / States/region, whicl 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.
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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
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24. **Recalls**

    If products are recalled because of problems with product quality or adverse reaction to the pharmaceu 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 Repo** own Quality Control Lab. The Test Report/Certificate of Analysis shall include:

1. Generic name of the product
2. Batch No.
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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
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The above-mentioned batch shall be manufactured in accordance with the applicable GMP regulations.

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a) At Pre-Dispatch stage

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- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amend
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The suitable conditions may be added by the buyer in the bid through Additional Term & Conditions (AT

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

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this contract or otherwise".

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

Signature name & designati

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

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

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

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    - 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 26-10-2023 for category Potassium Chloride Inje

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 (s 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 aut 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 b buyer at the time of bid submission. The certificate must have been issued within 12 months from the d
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, whicl 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 d 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, d 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 S State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be inti document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Gov agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of t
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shou 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 d 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 provisi 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 r 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 pharmaceu 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 pharma results and the limits for the individual tests should be given
    10. Conclusion
    11. Qualified Person's signature

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

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

    a) At Pre-Dispatch stage

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

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

    - The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborat 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 th destination shall in no way be limited or waived by reason of the goods having previously been i dispatch from the place of manufacture.
    - **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each ba collected and sent to designated laboratories (NABL Accredited/Government approved laboratori

      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 durin

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 th

  "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 relev 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 Dru 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 an authority, the supplier shall inform the same immediately to the buyer so that the use of the available s the available stock of the product with all consignee/users will be retrieved.

28. **Termination for Default**

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

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

      "The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under th workmanship and shall be strictly in accordance with the specifications and particulars mentione the stores would continue to conform to the description of and quality aforesaid for a period of u

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

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

Signature name & designati

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without 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 A 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 othe 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 14-10-2022 for category Anti TB Drugs - Levoflox

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 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. vali 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 b

UNDERTAKING

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

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 sig *entity)*

2. We are the manufactures of the drug / medicine _____(“Product”) and intend to offer the sa

3. We state that the license for the Product has been granted/obtained by us as per the provisions there under.

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 Organisation* (*CDSCO*), Ministry of Health & Fam 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 wit applicable
7. Bidder shall be a manufacturer of the product and having valid own manufacturing license in the indica Certificate of Pharmaceutical Product (COPP) as recommended by WHO in any of the pharmacopeia IP/I be valid on the date of technical bid opening.
8. Third party manufacturers/Loan Licensee / Distributors / Agents / Contract Manufacturers / Importers ar the drugs.
9. The bidder should furnish the Manufacturing License valid on bid opening for each item quoted been du be clearly highlighted in the license. Original documents should be produced for verification when dem then 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 quoted in the bid. However, this would not apply to regulated products which have been licensed by DC 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 Manufa the buyer.
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 cert 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 GMP.
15. The bidder should have Long Term (Real Time) Stability Data of the quoted product in specified packing
16. All goods must be of fresh manufacturing and must bear the dates of manufacturing and expiry. The bi

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 be any State Government / Central Government /CMSS/ its Drug procurement agencies due to quality failu 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 alon within one month.
19. The price offered by the seller shall not, in any case exceed the DPCO controlled price, if any, fixed by t Price (MRP) and the selling price. The seller must reduce the prices if there is any reduction in DPCO ce
20. The bidder should quote at least for 50% of the bid quantity of the items quoted and the bidder shall ha and half times the quantity quoted for each schedule.
21. Generally speaking the draft art work should be given in technical specifications however, in those case specifications, the vendor must need to coordinate with respective programme division of ministry to fr would be given on this pretext.
22. A Certificate of Analysis from manufacturer's own Quality Control Lab covering each batch delivered is 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 pharma 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 regula

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 sup specifications/bid document. The products should conform to the standards as specified in attached sp

    23.2 The bidder/ supplier understand that the bid item/items is/are critical health goods, and the qualit during complete specified shelf life as indicated in technical specification/bid document/ official compe in 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 stan reserves the right to carry necessary inspections/tests at any of, or any combination of or/ all of followi

    a. **At Pre-Dispatch stage.**
    b. **At Delivery Stage**: inspection done once the goods reach at consignee location and before taki
    c. **Post Delivery Surveillance**: The drugs/goods shall have the active ingredients and all other pa official compendiums or technical specifications throughout the shelf-life period of the drug/good organized by buyer post-delivery.

    23.4 The buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborato 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 ba collected and sent to designated laboratories (Government/NABL Accredited Drug Testing Laboratories testing charges will be borne by buyer.

    At post-delivery surveillance: The samples will be collected from the warehouse of buyer/or final co Quality Control Labs in respect of supplied drugs at any point during specified shelf life as per decision

    In case of failure of batches during or at any stage (indicated at 23.3), the testing charges shall be borr

    23.6 The supplies will be deemed to be completed only upon receipt of the quality certificates from the

    23.7 At any of testing stage, samples which do not meet quality requirement shall render the releva

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 actio 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 pe
ii. To make alternative purchase of the items from other approved suppliers or in the open market 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 forfeiture of PSD.
iv. In addition, the FDA/ Drugs Control Authority of concerned State will be informed for initiating ne 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

23.9 In the event of replacement of rejected drugs/goods by the supplier, all the above-mentioned pro from the date of replacement thereof, otherwise the supplier shall pay to the buyer such damages as m conditions here in contained and the facts will be notified to the Drugs Controller of India/State Drug Co

23.10 If the product is non-Pharmacopeial then the supplier must provide the in house test method alo 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 t has to be taken back by the supplier within a period of 30 days of the receipt of the letter from the buy the supplier. The buyer has the right to destroy such “NOT OF STANDARD QUALITY ITEMS” if the suppli stipulated time. The buyer will arrange to destroy the “NOT OF STANDARD QUALITY ITEMS” after the ex notice, and shall also collect demurrage charges calculated at the rate of 0.5% per week on the value o
25. **WARRANTY**
    - The supplier shall warrant that goods/items to be supplied shall be new and free from all defects manufacturing and shall be of the highest grade and consistent with the established and genera ordered and shall perform in full conformity with the specifications. Supplier shall warrant that g specification throughout specified shelf life. The supplier shall be responsible for any defects tha because of improper quality of API, Excipients in packaging material etc. manufacturing /packagi workmanship or otherwise and shall remedy such defects at his own cost when called upon to do respect stores is faulty.
    - The portion of clause 23.8 (i) to (v) would also apply in case the goods/items supplied doesn’t ma
    - 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 d from open market, but without prejudice to many other rights which the buyer may have against
26. Loss or premature deterioration due to biological and other activities during the life potency of the dru of cost 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 mentio
iii. The packaging shall be of a sturdy quality to provide adequate protection of the product for carriage to locations under adverse climate and storage conditions and high humidity. Used cartons should never b
iv. Products with specific temperature requirements will be packed, stored and delivered in appropriate co
v. The packaging unit should be strong, able to be stacked to a height of 4 pallets as static storage and 2
vi. The supplier to ensure that the material is of good quality and is free from development of fungus/term days of delivery at specified locations, suppliers at their own cost would lift the entire batch from variou 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 Terms and Conditions in the bid to ensure drugs are procured from authentic/validated source with appropriat conditions are in reverse order of precedence i.e. ATC shall supersede specific STC which shall supersede Gen are any conflicting provisions.

Special terms and conditions-Version:1 effective from 26-10-2023 for category Metoprolol Injection

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 aut 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 b buyer at the time of bid submission. The certificate must have been issued within 12 months from the
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, whicl 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 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 S State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be inti document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Gov agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of t
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shou 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 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 provisi 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 r 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 pharmaceu 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 pharma results and the limits for the individual tests should be given
10. Conclusion
11. Qualified Person's signature

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

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

a) At Pre-Dispatch stage

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

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

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborat 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 th destination shall in no way be limited or waived by reason of the goods having previously been i dispatch from the place of manufacture.
- **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each ba collected and sent to designated laboratories (NABL Accredited/Government approved laboratori

  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
- The supplies will be deemed to be completed only upon receipt of the quality certificates from th

  "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 relev 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 an 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 Dru confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also w
- 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 s the available stock of the product with all consignee/users will be retrieved.

28. **Termination for Default**

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

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

    “The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under th workmanship and shall be strictly in accordance with the specifications and particulars mentione the stores would continue to conform to the description of and quality aforesaid for a period of u specified shelf life from the date of delivery of the said stores to the buyer, have overages 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 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 supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer ar period shall apply to the stores replaced from the date of the replacement thereof otherwise the as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice this contract or otherwise".

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

Signature name & designati

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without 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 A 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 othe 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 Acyclovir Ointment (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 (s 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 aut 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 b 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, whicl 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 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 S State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be inti document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Gov agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of t
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shou 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 d 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 provisi 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 r 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 pharmaceu 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 pharma results and the limits for the individual tests should be given
    10. Conclusion
    11. Qualified Person's signature

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

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

    a) At Pre-Dispatch stage

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

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

    - The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborat 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 th destination shall in no way be limited or waived by reason of the goods having previously been i dispatch from the place of manufacture.
    - **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each ba collected and sent to designated laboratories (NABL Accredited/Government approved laboratori

      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 durin

      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 th

  "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 relev 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 Dru 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 an authority, the supplier shall inform the same immediately to the buyer so that the use of the available s the available stock of the product with all consignee/users will be retrieved.

28. **Termination for Default**

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

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

      "The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under th workmanship and shall be strictly in accordance with the specifications and particulars mentione the stores would continue to conform to the description of and quality aforesaid for a period of u specified shelf life from the date of delivery of the said stores to the buyer, have overages withir and are not subject to recall by the applicable Regulatory Authority due to unacceptable quality

Notwithstanding the above, the fact that the said stores fail to conform to the description and qu decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the discovered not to conform to the said description and quality. Losses due to premature deteriora potency will be made good and supplied by the firm at its own cost at consignee's site.

On such rejection, the stores will be at the seller's risk and all provisions herein contained 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 ar period shall apply to the stores replaced from the date of the replacement thereof otherwise the as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice this contract or otherwise".

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

Signature name & designati

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without 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 A 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 othe 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 Betamethasone Injectio

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 (s 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 auth 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 b buyer at the time of bid submission. The certificate must have been issued within 12 months from the
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, whicl 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
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,
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
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shou
or pending in any court of India by any department of Govt. under prevention of Corruption Act or for c
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
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 provisi
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
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 pharmaceu
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 Repo**
    own Quality Control Lab. The Test Report/Certificate of Analysis shall include:
    1. Generic name of the product
    2. Batch No.
    3. Pharmacopoeia Reference and/ or In-house method
    4. Batch quantity
    5. Date of manufacture
    6. Expiry date
    7. Date of test
    8. Description (clarity, color etc)
    9. All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharma
    results and the limits for the individual tests should be given
    10. Conclusion
    11. Qualified Person's signature

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

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

a) At Pre-Dispatch stage

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

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

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborat 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 th destination shall in no way be limited or waived by reason of the goods having previously been i dispatch from the place of manufacture.
- **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each ba collected and sent to designated laboratories (NABL Accredited/Government approved laboratori

  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 durin

  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 th

  "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 relev 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 an 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 uni 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 Dru confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also w
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amen

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 s the available stock of the product with all consignee/users will be retrieved.

28. **Termination for Default**

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

29. **Warranty**

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

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

  On such rejection, the stores will be at the seller's risk and all provisions herein contained 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 ar period shall apply to the stores replaced from the date of the replacement thereof otherwise the as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice this contract or otherwise".

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

Signature name & designati

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

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.

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 contracte the contracted rates. The delivery period of quantity shall commence from the last date of original delivery or during the extended delivery period the additional time shall commence from the last date of extended delive (Increased quantity ÷ Original quantity) × Original delivery period (in days), subject to minimum of 30 days. I the additional time equals the original delivery period. The Purchaser may extend this calculated delivery dur 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 conseque arising in the bidding process due to these ATCs and due to modification of technical specifications and / or terms ar are incorporated by the Buyer regarding following, the bid and resultant contracts shall be treated as null and void a 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 iss
2. Seeking EMD submission from bidder(s), including via Additional Terms & Conditions, in contravention to exe
3. Publishing Custom / BOQ bids for items for which regular GeM categories are available without any Category
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 specifyir
10. Seeking experience from specific organization / department / institute only or from foreign / export experienc
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 m

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 s is duty bound to reply to all such representations and would not be allowed to open bids if he fails to reply to such re

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 Act, 1976, The Payment of Gratuity Act, 1972 etc. Any non-compliance will be treated as breach of con per GeM Contract.

This Bid is also governed by the General Terms and Conditions/ यह बिड सामान्य शर्तों दे

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 wo 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 कार

---Thank You/धन्यवाद---