बिड दस्तावेज़ / **Bid Document**

| बिड विवरण/Bid Details | |
|---|---|
| बिड बंद होने की तारीख/समय /**Bid End Date/Time** | 16-01-2026 18:00:00 |
| बिड खुलने की तारीख/समय /**Bid Opening Date/Time** | 16-01-2026 18:30:00 |
| बिड पेशकश वैधता (बंद होने की तारीख से)/**Bid Offer Validity (From End Date)** | 180 (Days) |
| मंत्रालय/राज्य का नाम/**Ministry/State Name** | Andaman & Nicobar |
| विभाग का नाम/**Department Name** | Health Department Andaman & Nicobar |
| संगठन का नाम/**Organisation Name** | N/a |
| कार्यालय का नाम/**Office Name** | Directorate Of Health Services |
| कुल मात्रा/**Total Quantity** | 20500 |
| वस्तु श्रेणी /**Item Category** | Calamine Lotion (V2) (Q2) , Brimonidine |
| उन्हीं/समान सेवा के लिए अपेक्षित विगत अनुभव के वर्ष/**Years of Past Experience Required for same/similar service** | 2 Year (s) |
| वर्षों के अनुभव एवं टर्नओवर से एमएसई को छूट प्राप्त है / **MSE Relaxation for Years Of Experience and Turnover** | Yes \| Complete |
| स्टार्टअप के लिए अनुभव के वर्षों और टर्नओवर से छूट प्रदान की गई है / **Startup Relaxation for Years Of Experience and Turnover** | Yes \| Complete |
| विक्रेता से मांगे गए दस्तावेज़/**Document required from seller** | Experience Criteria,Bidder Turnover,Cer Certificate<br>*In case any bidder is seeking exemptio supporting documents to prove his eligi evaluation by the buyer |
| क्या आप निविदाकारों द्वारा अपलोड किए गए दस्तावेज़ों को निविदा में भाग लेने वाले सभी निविदाकारों को दिखाना चाहते हैं? संदर्भ मेनू है/**Do you want to show documents uploaded by bidders to all bidders participated in bid?** | Yes (Documents submitted as part of a tender/bid process will also be displaye |
| बिड लगाने की समय सीमा स्वतः नहीं बढ़ाने के लिए आवश्यक बिड की संख्या। / **Minimum number of bids required to disable automatic bid extension** | 2 |
| दिनों की संख्या, जिनके लिए बिड लगाने की समय-सीमा बढ़ाई जाएगी। / **Number of days for which Bid would be auto-extended** | 7 |
| ऑटो एक्सटेंशन अधिकतम कितनी बार किया जाना है। / **Number of Auto Extension count** | 2 |
| बिड से रिवर्स नीलामी सक्रिय किया/**Bid to RA enabled** | Yes |

| बिड विवरण/Bid Details | |
|---|---|
| **रिवर्स नीलामी योग्यता नियम/RA Qualification Rule** | H1-Highest Priced Bid Elimination |
| **बिड का प्रकार/Type of Bid** | Two Packet Bid |
| **प्राथमिक उत्पाद श्रेणी/Primary product category** | Calamine Lotion (V2) |
| **तकनीकी मूल्यांकन के दौरान तकनीकी स्पष्टीकरण हेतु अनुमत समय /Time allowed for Technical Clarifications during technical evaluation** | 4 Days |
| **निरीक्षण आवश्यक (सूचीबद्ध निरीक्षण प्राधिकरण /जेम के साथ पूर्व पंजीकृत एजेंसियों द्वारा)/Inspection Required (By Empanelled Inspection Authority / Agencies pre-registered with GeM)** | No |
| **अनुमानित बिड मूल्य /Estimated Bid Value** | 391495 |
| **मूल्यांकन पद्धति/Evaluation Method** | Item wise evaluation |
| **मध्यस्थता खंड/Arbitration Clause** | No |
| **सुलह खंड/Mediation Clause** | No |

**ईएमडी विवरण/EMD Detail**

| | |
|---|---|
| आवश्यकता/Required | No |

**ईपीबीजी विवरण /ePBG Detail**

| | |
|---|---|
| आवश्यकता/Required | No |

बोली विभाजन लागू नहीं किया गया/ Bid splitting not applied.

**एमएसई खरीद वरीयता/MSE Purchase Preference**

| | |
|---|---|
| एमएसई खरीद वरीयता/MSE Purchase Preference | No |

**एमआईआई खरीद वरीयता/MII Purchase Preference**

| | |
|---|---|
| एमआईआई खरीद वरीयता/MII Purchase Preference | No |

1. If the bidder is a Micro or Small Enterprise as per latest orders issued by Ministry of MSME, the bidder shall be rela
Criteria" as defined above subject to meeting of quality and technical specifications. The bidder seeking Relaxation f
supporting documents to prove his eligibility for Relaxation.
2. If the bidder is a Micro or Small Enterprise (MSE) as per latest orders issued by Ministry of MSME, the bidder shall
Turnover" as defined above subject to meeting of quality and technical specifications. If the bidder itself is MSE OEM
the "OEM Average Turnover" criteria also subject to meeting of quality and technical specifications. The bidder seeki
supporting documents to prove his eligibility for Relaxation.
3. If the bidder is a DPIIT registered Startup, the bidder shall be relaxed from the the eligibility criteria of "Experience
of quality and technical specifications. The bidder seeking Relaxation from Experience Criteria, shall upload the supp
Relaxation.
4. If the bidder is a DPIIT registered Startup, the bidder shall be relaxed from the the eligibility criteria of "Bidder Tur

quality and technical specifications. If the bidder is DPIIT Registered OEM of the offered products, it would be relaxed subject to meeting of quality and technical specifications. The bidder seeking Relaxation from Turnover shall upload Relaxation.
5. Experience Criteria: In respect of the filter applied for experience criteria, the Bidder or its OEM of the product offe should have regularly, manufactured and supplied same or similar Category Products to any Central / State Govt Org indicated above in the bid document before the bid opening date. Copies of relevant contracts and delivery acceptar with bid in support of having supplied some quantity during each of the Financial year. In case of bunch bids, the cat should meet this criterion.
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 quoted 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. Reverse Auction would be conducted amongst all the technically qualified bidders except the Highest quoting bidd 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

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

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

| मूल्यांकन अनुसूचियां / **Evaluation Schedules** | अनुमानित मूल्य / **Estimated Value** | वस्तु/श्रेणी / **Item/Category** |
|---|---|---|
| Schedule 1 | 377800 | Calamine Lotion (v2) |
| Schedule 2 | 13695 | Brimonidine Tartrate + Tir |

## Calamine Lotion (V2) ( 20000 pieces )

**तकनीकी विशिष्टियाँ /Technical Specifications**

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

| **विवरण/Specification** | **विशिष्टि का नाम /Specification Name** | **बिड के लिए आवश्यक अनुमत** |
|---|---|---|
| PRODUCT INFORMATION | Medicine Name | Calamine |
| | Dosage Form | Lotion |
| PACKAGING | Type of primary packing | Bottle |
| | **Primary pack size (Quantity per bottle)** | 100 ml |
| CERTIFICATIONS & REPORTS | Availability of valid drug manufacturing license issued from the competent authority defined under Drugs and Cosmetic Act and Rules there under as amended till date | Yes |
| | Submission of all necessary certifications, licenses and test reports to the buyer as per buyer requirement at the time of bid submission and along with supplies | Yes |
| SHELF LIFE | Shelf life in months from the date of manufacture | 18, 24, 36 Or higher **(month)** |

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

| क्र.सं./S.No. | परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer | पता/Address | मात्रा /Quar |
|---|---|---|---|
| 1 | Mohammed Mustafa | 744104,Central Medical Store, Directorate of Health Services Andaman & Nicobar Administration | 20000 |

## Brimonidine Tartrate + Timolol Maleate Drops (V2) ( 500 pieces )

**तकनीकी विशिष्टियाँ /Technical Specifications**

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

| विवरण/Specification | विशिष्टि का नाम /Specification Name | बिड के लिए आवश्यक अनुमत |
|---|---|---|
| PRODUCT INFORMATION | Medicine Name | Brimonidine Tartrate + Timolol |
| | Dosage Form | Eye Drop |
| | Strength | 0.2% + 0.5% |
| | Compliance to uploaded Special Terms and Conditions | Yes |
| PACKAGING | Type of primary packing | Bottle |
| | **Primary pack size** | 5 ml |
| CERTIFICATIONS & REPORTS | Availability of valid drug manufacturing license issued from the competent authority defined under Drugs and Cosmetic Act and Rules there under as amended till date | Yes |
| | Submission of all necessary certifications, licenses and test reports to the buyer as per buyer requirement at the time of bid submission and along with supplies | Yes |
| SHELF LIFE | Shelf life in months from the date of manufacture | 24, 36 Or higher **(month)** |

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

| क्र.सं./S.No. | परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer | पता/Address | मात्रा /Quar |
|---|---|---|---|
| 1 | Mohammed Mustafa | 744104,Central Medical Store, Directorate of Health Services Andaman & Nicobar Administration | 500 |

**Special terms and conditions-Version:1 effective from 06-07-2023 for category Calamine Lotion (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 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. **<u>Recalls</u>**

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:1 effective from 06-07-2023 for category Brimonidine Tartrate + T**

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 in 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 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.

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

1. **Generic**

   OPTION CLAUSE: The Purchaser reserves the right to increase or decrease the quantity to be ordered up to 25 of contract. The purchaser also reserves the right to increase the ordered quantity up to 25% of the 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.

2. **Scope of Supply**

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

3. **Certificates**

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

4. **Buyer Added Bid Specific ATC**

   Buyer Added text based ATC clauses

   1. OEM Authorization Certificate

   2.Copy of Valid Drug License for manufacturing/import of the product issued by th rugs & Cosmetic Act, 1940 and Medical Devices Rules, 2017 as amended till date

   3. In case of reseller, copy of the valid drug license for sale or distribution of the r facturer may also be uploaded

   4. Good Manufacturing Practice Certificate of the Manufacturer.

   5. **Notarized Undertaking**" in the format **Annexure-I**.

   6. Bidder/Seller shall submit a valid **non-Conviction** certificate issued by the **Con** the buyer at the time of bid submission. The certificate must have been issued wit al opening of the bid

   7.Turnover during last **03 year** duly authorized by Chartered Accountant

   8. PAN & GST certificate of the firm

   9. 1. The bidder shall submit **02 years** of experience in supply of medicines to G s.

   .

5. **Buyer Added Bid Specific ATC**

   Buyer uploaded ATC document Click here to view the file.

## अस्वीकरण/Disclaimer

The additional terms and conditions have been incorporated by the Buyer after approval of the Competent Authority organization is solely responsible for the impact of these clauses on the bidding process, its outcome, and 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 attache 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
15. Buyer added ATC Clauses which are in contravention of clauses defined by buyer in system generated bid ter EMD Detail, ePBG Detail and MII and MSE Purchase Preference sections of the bid, unless otherwise allowed b
16. In a category based bid, adding additional items, through buyer added additional scope of work/ additional te needs more items along with the main item, the same must be added through bunching category based item BoQ with the main category based item, the same must not be done through ATC or Scope of Work.

Further, if any seller has any objection/grievance against these additional clauses or otherwise on any aspect of this same by using the Representation window provided in the bid details field in Seller dashboard after logging in as a 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 shall ensure full compliance with all applicable labour laws, including guidelines under the four Labour Codes i.e. the Code on Wages, 2019; the Industrial Relations Code, 20 Working Conditions Code, 2020; and the Code on Social Security, 2020 as and when notified and brougl**

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

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

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

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

यह बिड सामान्य शर्तों के अंतर्गत भी शासित है /This Bid is also governed by the General Te

जेम की सामान्य शर्तों के खंड 26 के संदर्भ में भारत के साथ भूमि सीमा साझा करने वाले देश के बिडर से खरीद पर प्रतिबंध के संबंध में भा इस निविदा में बिड देने के लिए तभी पात्र होगा जब वह बिड देने वाला सक्षम प्राधिकारी के पास पंजीकृत हो।बिड में भाग लेते समय बिडर को जाने व इसका अनुपालन न करने पर अनुबंध को तत्काल समाप्त करने और कानून के अनुसार आगे की कानूनी कार्रवाई का आधार होगा।/In term of a country which shares a land border with India, any bidder from a country which shares a land border with India will be eligible to bid in this tender only if the bidder is regi undertake compliance of this and any false declaration and non-compliance of this would be a ground for immediate termination of the contract and further legal action in acc

**---धन्यवाद/Thank You---**