

CENTRAL MEDICAL SERVICES SOCIETY

(An Autonomous Society Under Ministry of Health & Family Welfare, Govt. of India)

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Amendment no. 1

Tender No. CMSS/PROC/2023-24/NTEP/008 for rate contract for a period of One year for procurement of Tablet Rifapentine 300mg + Isoniazid 300mg for NTEP.

Minutes of Pre-bid meeting held on 08th May 2023 at 11.00 AM

Central Medical Services Society has invited e-Bids from the interested parties for “e- Tender for rate contract for a period of One year for procurement of Tablet Rifapentine 300mg + Isoniazid 300mg for NTEP”, vide Notice Inviting e-Tender No.- CMSS/PROC/2023-24/NTEP/008. Detailed tender document containing eligibility criteria, selection mechanism, other terms and conditions are available on the website of Central Public Procurement Portal; www.eprocure.gov.in and CMSS Website; www.cmss.gov.in.

As per tender schedule, prebid meeting was held on 08/05/2023.

1. Following officials were present during the Pre-bid meeting:-

- (i) Mr. Rajesh Gupta, DG & CEO, CMSS
- (ii) Ms. Anjana, GM (Procurement), CMSS
- (iii) Mr. D. Mohapatra, GM (Finance), CMSS
- (iv) Dr. Alok Mathur, Addl. DDG, CTD, MoHFW
- (v) Ms. Akansha Jain, AGM (QA), CMSS
- (vi) Mr. Inderjeet Yadav, AGM (Proc), CMSS

2. Following representative from prospective bidder was present during the Pre-bid meeting:-

- (i) Mr. Mukul Jerath, Vice President Exports, Lupin Ltd.
- (ii) Mr. Prashant Naik, Finance, Lupin Ltd.
- (iii) Mr. Maneesh Sapte, Director, Svizera Labs. Pvt. Ltd.
- (iv) Mr. Alok Kumar, Director, J. Duncan Healthcare Pvt. Ltd.

3. Queries from following firms were received via email. These are tabulated at Annexure B with remarks:

4. Points raised by representatives of prospective bidders were discussed. After due consideration of the queries, following amendments/changes are issued (Annexure A).



Annexure A
Amendments

1. Section: I (ITB); Point no 3.8 is amended to read as under; **Qualification Criteria** – Only the bidders, who meet the qualification criteria as detailed in Section III of the bid document shall be considered for award of contract. Bidders are required to submit supporting documents, as indicated in Section III (Qualification Criteria) along with their bid.
2. Section: I (ITB); Point no 4.1 sub para 2 is amended to read as under; **Support to local manufacturer** –If the item is not reserved for procurement exclusively from Class-I local suppliers and if Class-II/ Non-local suppliers are also eligible to participate in the tender, as per ITB 3.5, purchase preference shall be given to Class-I local suppliers over Class-II/ Non-local suppliers provided its quoted rates fall within 20% margin of purchase preference, in accordance with PPP-MII Order dated 16.09.2020.

The 'Class-I local Supplier'/ 'Class-II local Supplier' availing aforesaid benefit are required to indicate at the time of tender, bidding, or solicitation the percentage of local content and provide self-certification that the item offered meets the local content requirement for 'Class-I local Supplier'/ 'Class-II local Supplier', as the case may be. In cases of procurement for a tender value above Rs. 10 crores, the 'Class-I local Supplier'/ 'Class-II local Supplier' shall be required to provide a certificate, in the prescribed format, from the statutory auditor of the company (in the case of companies) or a practicing cost accountant or practicing chartered accountant (in respect of Contractors other than companies) giving the percentage of local content. Bids with false declarations regarding Local contents shall be rejected as responsive, in addition to punitive actions under the MII orders and for violating the Code of Integrity as per the Tender Document.

3. Section: I (ITB); Point no 4.2 addition sub para 5; **Support to MSEs** – In accordance with M/o MSME Gazette Notification No S.O. 2119 (E) dt. 26th June 2020, “ In case of reverse-graduation of an enterprise, whether as a result of re-classification or due to actual changes in investment in plant and machinery or equipment or turnover or both, and whether the enterprise is registered under the Act or not, the enterprise will continue in its present category till the closure of the financial year and it will be given the benefit of the changed status only with effect from 1st April of the financial year following the year in which such change took place.”
4. Section: I (ITB); Point no 4.2 addition sub para 6; **Support to MSEs** – In accordance with M/o MSME Gazette Notification No S.O. 4926 (E) dt. 18th October 2022, “ In case of an upward change in terms of investment in plant and machinery or equipment or turnover or both, and consequent re-classification, an enterprise shall continue to



avail of all non - tax benefits of the category (micro or small or medium) it was in before the re-classification, for a period of three years from the date of such upward change."

5. Section: I (ITB); Point no 9.2.1.5.a is amended to read as under; **Documents comprising the bid**; (i) Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life. However, For the drugs recently introduced drugs in the county (introduced in the last two years), the requirement for Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life shall be waived off. Point no (iii) shall be applicable.

(ii) Only for the drugs introduced in Indian Pharmacopoeia in the recent past (last 2yrs), Long Term (Real Time) Stability Data for previously approved Pharmacopoeia or In-house Standards shall be accepted, as the case may be.

(iii) Accelerated Stability data for a period of 6 months in specified packing for at least 3 batches and available Long term (Real Time) stability data as available for the quoted product shall be submitted.

(iv) Certificate of Analysis of one batch of the quoted product should be submitted.

6. Section: II (BDS); ITB 3.5 is amended to read as under; In accordance with DPIIT Public Procurement (Preference to Make in India) Order, 2017 dated 16.09.2020 read with DOP Circular F.No.31026/65/2020-MD dated 30.12.2020 as amended till date, only Class-I & Class- II local suppliers, as defined in aforesaid notifications are eligible to bid.

Minimum local content requirement for bidders- classification as Class-I/ Class-II local Suppliers shall be as per the DOP Circular F.No.31026/65/2020-MD dated 30.12.2020. Accordingly, **Class I Local Supplier** means a supplier or service provider, whose goods, services or works offered for procurement, has local content equal to or more than 80%. **Class II Local Supplier** means a supplier or service provider, whose goods, services or works offered for procurement, has local content more than 50% but less than 80%.

7. Section: II (BDS); ITB 5.2.2 is amended to read as under;; **Basis of Evaluation for Schedules**

5.2.2 As the present tender inquiry is for the conclusion of the rate contract, the stipulation made in ITB 5.2.2 shall not apply. Instead, the bidders are required to offer the quoted items as per the delivery schedule indicated in Section IV; Schedule of Requirement for all purchase orders placed during the currency of the contract. Bids not conforming to delivery schedule, shall be summarily rejected.

8. Section: II (BDS); ITB 13.1.1 is amended to read as under; **Right to vary Quantities at the time of Award** – To be deleted.



9. Section: II (BDS); ITB 13.1.2 is amended to read as under; **Parallel Contracts or Splitting of Award;**

The present tender inquiry is for the conclusion of the Rate contract and purchaser requirements for tendered stores shall be procured by placing Purchase order against the rate contract. Purchase orders against concluded rate contract shall be placed separately after award of the rate contract. As such, ITB 13.1.1 & 13.1.2 shall not apply.

10. Section: II (BDS); ITB 13.1.3 is amended to read as under; **Additional Conditions for Rate Contracts;** There shall be no parallel rate contracts amongst qualified bidders. The rate contract shall be awarded to only lowest qualified bidder.

Although the Rate contract shall be awarded to the lowest awarded bidder and no Parallel Rate contract shall be awarded against subject tender enquiry, the Purchaser reserve the right to place parallel Rate contract with MSEs (Micro & Small Enterprises) & Class I local supplier whose quoted rates falls within the margin of purchase preference as stipulated in PPP MSE and PPP MII order respectively. In case parallel rate contract are awarded to MSEs /Class I local supplier, Purchase order placed against the rate contract shall be divided in the proportion as stipulated in ITB 4.4.

11. Section: III (Qualification Criteria) point b is amended to read as under; Tenderer must submit own manufacturing license in the indicated pharmacopeia (as indicated in technical specification) valid on the date of tender opening (technical bid). If the tendered drug is in Indian Pharmacopoeia (IP), then the manufacturing license has to be submitted in IP only.

The Tenderer should furnish the domestic Manufacturing License in Form of 25 / 28 issued from State Licensing Authority along with the approval of DCGI in Form of 46/ CT-23 as new drug approved by DCGI.

For drugs that are not available in IP, other official Pharmacopeia (s) are applicable. If a drug is not available in any of the official pharmacopeias, 'In House' standards are applicable as per the Drugs and Cosmetics Act 1940 and the Rules therein.

Bidder is requested to submit an undertaking that the drug is not available in IP or any other approved pharmacopeia.

Note:

1. License certificate should be for the same manufacturing premises from which quoted goods have been offered for supply.
2. Loan license, Contract manufacturing license etc. shall not be considered.
3. License for export of goods shall not be considered.



12. Section: III (Qualification Criteria) point e is amended to read as under; Tenderer must submit Market standing certificate issued by the Licensing Authority, as a Manufacturer of the item quoted, for at least last two financial years i.e. 2020-21 and 2021-22 OR 2021-22 and 2022-23. However, this would not apply to products which have been licensed by DCG (I) less than two years ago.

Note:

1. Unless otherwise stipulated in the Market standing certificate, the said certificate issued on a particular date shall be treated valid certificate for the financial year in which it has been issued. For example, Market Standing Certificate issued on 15.07.2022 for the period 15.07.2022 to 14.07.2023 shall be treated as Market Standing Certificate for the FY 22-23.
2. Market standing certificate should be for the same manufacturing premises from which quoted goods have been offered for supply.
3. Only for the drugs introduced in Indian Pharmacopoeia in the recent past (last 2yrs), Market standing certificate for previously approved Pharmacopoeia or In-house Standards (Export/ Domestic) shall be accepted, as the case may be.
4. For the recently introduced drugs in the county (introduced in the last two years), the requirement for Market standing certificate shall be waived off.

13. Section: III (Qualification Criteria) point I is amended to read as under; The tenderer must have average annual turnover of last three FY i.e. 2019-20, 2020-21 and 2021-22 OR 2020-21, 2021-22 and 2022-23 more than the followings:

Schedule No	Amount (in Rs.)
I	90,00,00,000/- (Rupees Ninety Crores)

Annual turnover statement for 3 financial years i.e. 2019-20, 2020-21 and 2021-22 OR 2020-21, 2021-22 and 2022-23 should be furnished in the format given in Section VIII Form 4.2 duly certified by the practicing Chartered Accountant. The certifying Chartered Accountant must indicate the details along with its UDIN.

Note:- MSEs (Micro and Small Enterprises) and Startup bidders are exempted for the minimum requirement of turnover.

14. Section: IV (Schedule of Requirement); revised Section IV enclosed.
15. Section: V (Technical Specification & Quality Assurance); B is amended to read as under Shelf Life;

Study	Storage condition
Long Term Stability	25 °C ± 2 °C/60% RH ± 5% RH or 30 °C ± 2 °C/65% RH ± 5% RH



16. Section: V (Technical Specification & Quality Assurance); B is amended to read as under Storage; Store protected from light and moisture at room temperature (25°C (77°F); excursions permitted 15–30°C (59–86°F)
17. Section: V (Technical Specification & Quality Assurance); I is amended to read as under Packaging; A strip consisting of individual blisters of the drugs duly identified should be packed in an Aluminum- PVC blister pack/ Alu-Alu strip pack.
18. Section: VI (GCC); 5.8.1 is amended to read as under; Performance Security;

Unless stipulated otherwise in SCC, within fourteen days after the issue of Letter of Award (LoA or the contract, if LoA is skipped) by the Procuring Entity, the contractor shall furnish to the Procuring Entity, performance security as per details given in SCC Section VII.

19. Section: VI (GCC); 5.8.2 is amended to read as under; Performance Security;
Performance security shall be denominated in Indian Rupees or the currency of the contract and shall be in one of the following forms:
 - (a) Unless otherwise stipulated in Tender Document or Contract, Account Payee Demand Draft or Fixed Deposit Receipt or Banker's Cheque drawn on any commercial bank in India, favouring the authority mentioned in SCC
 - (b) Bank Guarantee issued by a commercial bank in India, in the prescribed form provided in Format 1.1.
20. Section: VII (SCC); GCC 5.8.1 is amended to read as under; **Performance Security**; Within fourteen days after the issue of Letter of Award (LoA or the contract, if LoA is skipped) by the Procuring Entity, the contractor shall furnish to the Procuring Entity performance security for an amount equivalent to EMD amount of Rupees valid till 60 days beyond expiry of Rate Contract Period for its commitment to honour the purchase order issued under the Rate Contract.
21. Section: VII (SCC); GCC 8.4.5.4 is amended to read as under; **Certificate of Analysis (COA in case of Drugs)**; (i) A Certificate of Analysis/ Performance Evaluation Report from manufacturer's own Quality Control Lab covering each batch delivered is to be submitted along with shipping documents.

The Certificate of Analysis shall include:

- a) Generic name of the product
- b) Batch No.
- c) Pharmacopoeial Reference and/ or In-house method
- d) Batch quantity



- e) Date of manufacture
- f) Expiry date
- g) Date of test
- h) Description
- i) All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharmacopoeia and/or In-house method. Both the actual results and the limits for the individual tests should be given
- j) Conclusion
- k) The CoA should specify the tests undertaken for quality assurance, including acceptable levels of impurities in general, if any, at the time of supply.
- l) Qualified signatures

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

- (2) The WHO Prequalification Unit - Medicines Assessment Team (PQT/MED) has issued an FAQ around the Nitrosamine concerns for rifapentine and rifampicin in December 2020. This explicitly mentions the CPNP temporary limit of 20 ppm as accepted by USFDA and recognized by PQT/MED as acceptable from the point of view of a benefit/risk assessment.

Bidder has to submit an undertaking in technical bid that Certificate of Analysis (CoA) report shall be submitted by the manufacturers in compliance with tender clause 8.4.5.4.1 and the prevailing global standards as mentioned at 8.4.5.4.2 above at the time of supply. Annexure A Undertaking is attached.

- 22. Form 2; Revised Enclosed
- 23. Form 3; Revised Enclosed
- 24. Form 4.1; Revised Enclosed
- 25. Form 4.2; Revised Enclosed

All other contents of tender document remain unaltered.


General Manager (Procurement)



Section IV
Schedule of Requirement

Ref: Tender Document No. CMSS/PROC/2023-24/NTEP/008 Dated 01/05/2023

Tender Title: Rate contract for a period of one year for procurement of Tablet Rifapentine 300mg + Isoniazid 300mg for NTEP.

A. List of Products

Sch. No.	Item Description	Unit	Tentative Quantity likely to be procured during RC period	Period of Rate Contract	Inspection Methodology (PDI/Non-PDI)	Delivery Place	Terms of Delivery
I	Tablet Rifapentine 300mg + Isoniazid 300mg	No. of Tablets	13,33,88,256	01 (One) Year from the date of award of contract	Non-PDI Items (Delivery Stage Inspection)	At CMSS warehouses across India	DDP (Destination basis).

B. Delivery Schedule:-

1. Purchase Order against the Rate contract for a qty. of 4,66,85,890 tablets is likely to be placed immediately after issuance of Rate Contract with a delivery schedule of 90 days.
2. For supplies against subsequent Purchase order also, the bidder should confirm the delivery qty. of 4,66,85,890 tablets within 90 days of receipt of purchase order.
3. The bidders shall comply with aforesaid delivery schedule failing which their offer shall be summarily ignored.
4. TIA reserves the right to issue the purchase order as per the actual requirement of Programme division within RC period as per aforesaid delivery schedule.

C. Delivery Locations:

The details of CMSS warehouses are given below:-

CMSS Warehouse & Mapped States			
Sr No	Warehouse Location	States/UT's covered by the Warehouse	Address
1	Agartala	Tripura	Near ONGC Complex, PO-Hapania , Agartala-799014
2	Ahmadabad	Gujarat	Opp. P&T Colony, Shahalam, Ahmedabad-380028
3	Bangalore	Karnataka	APMC Yard, Yeswanthpur, Bangalore - 560022
4	Bhopal	Madhya Pradesh	Chhola Road, Near Nishatpura Cabin, Bhopal, M.P.
5	Chandigarh	Chandigarh	Central Medical Services Society



CMSS Warehouse & Mapped States			
Sr No	Warehouse Location	States/UT's covered by the Warehouse	Address
		Punjab	Godown no. B014/3433, Near Vivekanand School, Godown area, Village Bhabat, Thana-Zirakpur, Dist: SAS Nagar-140603(Punjab)
		Haryana	
		Himanchal Pradesh	
		Jammu & Kashmir,	
		Leh Ladakh	
		Uttarakhand	
6	Chennai	Tamil Nadu	Chitalapakkam(P.O), Chennai - 600064, T.N.
		Pondicherry	
		Andaman & Nicobar Islands	
7	Jaipur	Odisha	Dhawalgiri, Post-Jaipur Road, Dist-Jaipur, Odisha
8	Delhi	Delhi	Ware Housing Scheme Block No 2., Kirti Nagar, New Delhi-110015.
9	Guwahati	Assam	EPIP Complex, Amingaon, Guwahati-781031
		Arunachal Pradesh	
		Meghalaya	
		Nagaland	
		Sikkim	
		Manipur	
10	Hyderabad	Mizoram	Behind Gandhibhavan, Nampally, Hyderabad-500001
		Telangana	
		Andhra Pradesh	Plot no SPL-1296, EPIP Sitapura, Ind Area, Jaipur-302002
		Rajasthan	
11	Jaipur	Rajasthan	
12	Kolkata	West Bengal	Rehabilitation Industries Corporation Estate, Bonhooghly, Kolkatta - 700 108
13	Lucknow	Uttar Pradesh	New Mandi Complex, Sitapur Road Lucknow-226020
14	Navi Mumbai	Maharastra	Sector-20 Near APMC Fruit Market , VashiNavi Mumbai-400613
		Goa	
		Dadra and Nagar Haveli	
		Daman and Diu	
15	Patna	Bihar	Bazar Sammittee , Katra Bazar, Patna city-800008
16	Raipur	Chattisgarh	Rawabhata , Raipur -493221
17	Ranchi	Jharkhand	Po-Hehal , Ratu Road , Dist-Ranchi-834005
18	Trivandrum	Kerala	Kinfra Apparel Park, Thumba, Palliphura(PO), Trivandrum-695586
		Lakshadweep	

CMSS reserve to right the change the consignee at any time if required



Form 2: Schedule of Requirements – Compliance & Deviation
Schedule of Requirements

(Ref ITB-clause 9.2, Schedule IV: Schedule of Requirements)

(To be submitted as part of Technical bid) (on Company Letter-head)

Ref: Your Tender Document No. Tender No./ xxxx; Tender Title: GOODS

Bidder's Name _____

[Address and Contact Details]

Bidder's Reference No. _____ Date.....

Note to Bidders: Fill up this Form regarding Section IV: Schedule of Requirements maintaining the same numbering and structure. Add additional details not covered elsewhere in your bid in this regard.

Tender Title				
Tender Reference No				
Schedule	Description of Goods	Local Content (%)	HSN Code	Bidder's GSTIN
1	2	3	4	5

We Shall comply with, abide by, and accept without variation, deviation, or reservation all requirements detailed in Section IV: Schedule of Requirements in the Tender Document including Terms of Delivery, delivery schedule etc, except those mentioned below.

- a.
b.

We understand that if contrary terms and conditions are mentioned elsewhere in our bid, same shall not be recognised and shall be null and void.

(Signature with date)

.....

(Name and designation)

Duly authorized to sign bid for and on behalf of

.....

[name & address of Bidder and seal of company]



Form 3: Technical Specifications and Quality Assurance – Compliance & Deviation
(Ref ITB-clause 9.2, Schedule V: Technical Specifications and Quality Assurance)

(To be submitted as part of Technical bid)

(on Company Letter-head)

Ref: Your Tender Document No. Tender No./ xxxx; Tender Title: GOODS

Bidder's Name _____

[Address and Contact Details]

Bidder's Reference No. _____ Date.....

Note to Bidders: Highlight in this form deviations, if any, from Section VII: Technical Specifications and Quality Assurance, maintaining the same numbering and structure. Add additional details not covered elsewhere in your bid in this regard.

Sl. No.	Technical specification as per tender	Comply (Yes/No)

Note: - (i) Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life. However, For the drugs recently introduced drugs in the county (introduced in the last two years), the requirement for Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life shall be waived off. Point no (iii) shall be applicable.

(ii) Only for the drugs introduced in Indian Pharmacopoeia in the recent past (last 2yrs), Long Term (Real Time) Stability Data for previously approved Pharmacopoeia or In-house Standards shall be accepted, as the case may be.

(iii) Accelerated Stability data for a period of 6 months in specified packing for at least 3 batches and available Long term (Real Time) stability data as available for the quoted product shall be submitted.

(iv) Certificate of Analysis of one batch of the quoted product should be submitted.

We shall comply with, abide by, and accept without variation, deviation, or reservation all Technical Specifications, Quality Assurance and Warranty requirements in the Tender Document, except those mentioned below.

- a.
b.



We understand that if contrary terms and conditions are mentioned elsewhere in our bid, same shall not be recognised and shall be null and void.

.....
(Signature with date)

.....
(Name and designation)

Duly authorized to sign bid for and on behalf of

.....
[name & address of Bidder and seal of company]

DA: Relevant documents like technical data, literature, drawings, and other documents



Form 4.1: PROFORMA FOR PERFORMANCE STATEMENT**(FOR A PERIOD OF LAST 3 YEARS)**

Name of Bidder with Address _____

Manufacturer with Address _____

Tender No & Date _____

Sr. No. of the Quoted Product _____

Name of the Quoted Product _____

Financial Year	2020-21						
Name of Purchaser with Contact Details	Purchase Order No and Date	Description of Goods	Unit	Qty.	Unit Price All Incl.	Total Value	Remarks
Financial Year	2021-22						
Name of Purchaser with Contact Details	Purchase Order No and Date	Description of Goods	Unit	Qty.	Unit Price All Incl.	Total Value	Remarks
Financial Year	2022-23						
Name of Purchaser with Contact Details	Purchase Order No and Date	Description of Goods	Unit	Qty.	Unit Price All Incl.	Total Value	Remarks

Note:

1. Copies of Purchase orders and e-way bills (Maximum 05 for each Purchase order- the ones pertaining to for large consignment) shall be submitted.



2. Proof for the manufacturing (BMR) / importing of the items quoted to be produced, if demanded.

Signature of Tenderer

Name in Capitals

Date:

Seal:

Signature of Practicing Chartered Accountant

Name in Capitals

Date

Seal

UDIN-



Form 4.2: ANNUAL TURNOVER STATEMENT

The Annual Turnover (Sales) of M/s. _____ for the past three years are given below and certified that the statement is true and correct.

Sl. No. (Rs)	Financial Year	Turnover in Lakhs
1.	2019-2020 / 2020-21	-
2.	2020-2021/ 2021-22	-
3.	2021-2022 /2022-23	-

Total - Rs. _____ Lakhs.

Average Turnover Per Annum in the last three years mentioned above -
Rs. _____ Lakh

Date:

Seal:

Signature of Auditor/Chartered Accountant

(Name in Capital)

UDIN-



Annexure A
UNDERTAKING
(On Company's Letter Head)

We,.....(name of bidder), having offices
at.....are participating in Tender
No..... Dated.....

We equivocally and irrevocably undertake that,

- i) The Certificate of Analysis (CoA) will be submitted at the time of supply specifying all details as mentioned at 8.4.5.4.1 (a) to (l) for each batch.
- ii) The Certificate of Analysis (CoA) shall be in compliance with prevailing global standards as mentioned at 8.4.5.4.2 of tender documents/ Corrigendum.

If at any stage, non-compliance of above orders - observed/found we will be liable for stringent actions as per the tender terms and condition including suspension/debarment from any bidding in CMSS/MoHFW tenders for two years.

M/s _____
Authorized Signatory.

Witness

1. Signature



Annexure B

S. No.	Standard Tender Clause	Query Received from Prospective Bidders	Response
A	M/s Centurion Laboratories Pvt. Ltd.		
1.	<p>Section III:- Tenderer must submit own manufacturing license in the indicated pharmacopeia (as indicated in technical specification) valid on the date of tender opening (technical bid). If the tendered drug is in Indian Pharmacopoeia (IP), then the manufacturing license has to be submitted in IP only.</p> <p>Note: 1. License certificate should be for the same manufacturing premises from which quoted goods have been offered for supply. 2. Loan license, Contract manufacturing license etc. shall not be considered. 3. License for export of goods shall not be considered.</p>	In Section III B (3), export licenses not accepted does it mean also experience (MMC) of export not accepted? (Even though local Permission is available recent before tender opening)	Refer Annexure A
2.	<p>Section III:- Tenderer must submit Non-Conviction Certificate issued by the Licensing Authority certifying that the tenderer (as well as the manufacturer firm in case of non-manufacturer bidders) has not been convicted i.e. 2020-21 and 2021-22 OR 2021-22 and 2022-23.</p>	F(1)non-conviction of any two FY or only last two FY requirements?	No Change, As per Tender
3.	From 4.1, to be signed by statutory auditor	From 4.1, to be signed by any CA or statutory auditor when only auditor/ CA mentioned.	Refer Annexure A
4.	From 4.2, to be signed by any CA or statutory auditor when only auditor/ CA mentioned.	From 4.2 average turnover last 3 years is to be signed by any CA or statutory?	Refer Annexure A
5.	<p>Section IV (b), Delivery Schedule:- 1. Ist Tranche of supplies against the Rate contract of qty. of 6,66,94,128 tablets is likely to be placed immediately after issuance of Rate Contract with a</p>	Section IV (b), 2, Deliver;1 st trench immediately in 90 days & second trench 90 days from date of purchase order so both in 90 days is not clear and possible, please clarify	Refer Annexure A



S. No.	Standard Tender Clause	Query Received from Prospective Bidders	Response
	delivery schedule of 90 days. 2. For next tranche of the Purchase order also, the bidder should confirm the delivery qty. 6,66,94,128 of tablets within 90 days of receipt of purchase order.		
6.	Section- V page 66 shelf life 24months	Section- V page 66 shelf life only long-term stability of 2 years of export PRODUCT IS ACCEPTABLE?	Refer Annexure A
7	Section VI- Point 7.1.(b) At Delivery Stage: Delivery stage inspection is done after the goods reach at consignee location. If the contract stipulates inspection at delivery stage, the supplier will deliver/dispatch the manufactured items (as per the technical specifications) to consignees location. The samples will be collected from the consignees location and sent to designate Quality Control Labs, as 102 decided by Purchaser. Sample quantities will be borne by Purchaser. Also, handling and testing charges will be borne by Purchaser. The supplies will be deemed to be completed only upon receipt of the quality certificates from the laboratories. "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be deemed to be rejected goods.	Page 100, no 7.1(b), if Contractor stipulates inspection at consignee place, delivery considered after QC report at consignee place also for non-PDI also, clarify	Refer Annexure A
8.	Section VII-SCC, GCC5.8 1. Within fourteen days after the issue of Letter of Award (LoA or the contract, if LoA is skipped) by the Procuring Entity, the contractor shall furnish to the Procuring Entity	Section VII-SCC, GCC5.8 a. PBG of 10cr where LOA skipped b. Plus 3 % of PO value PBG also to clarify	Refer Annexure A



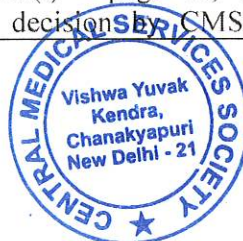
S. No.	Standard Tender Clause	Query Received from Prospective Bidders	Response
	<p>performance security for an amount equivalent to INR 10 Crores of Rupees valid till expiry of Rate Contract Period i.e. till for its commitment to honour the purchase order issued under the Rate Contract.</p> <p>2. Additionally, for each of the purchase order placed against the Rate Contract, within fourteen days of issue of purchase order, the contractor shall furnish to the Procuring Entity performance security for an amount equivalent to 3% of the value of purchase order inclusive of duties and taxes. valid for the period of sixty days after the date of completion of all contractual obligations by the contractor including the shelf life/ warranty obligations of the goods supplied.</p>		
9.	Form 3: Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life and Certificate of Analysis of one batch of the quoted product should be submitted.	Page 160, from-3, Note: COA of any new batch to submit from stability data of 3 batches is for final testing after 2 years or initial. Plz clarify.	Refer Annexure A
10.	Form 4.1; Copies of Purchase orders and e-way bills (Maximum 05 for each Purchase order- the ones pertaining to for large consignment) shall be submitted.	From 4.1, PO with E-way bill maximum 5-for large order required, please clarify large order qty.	Refer Annexure A
11.	Format 1.3; “Certification by Prospective Arbitrators”	Form 1.3 “Certification by Prospective Arbitrators”, by whom to be filled up this certificate. Confirm Arbitrator’s name, etc.	No Change, As per tender Not required at time of bidding.
12.	Section I- ITB Clause 10.3.1; Submission/ Uploading to the Portal No manual Bids shall be made available or accepted for submission (except for originals of scanned copies	See 10.3.1 Digital signed documents to be uploaded (EMD). Please clarify & Check which original document to be submitted some next day of online uploading & some within 5 days after	No Change, As per tender



S. No.	Standard Tender Clause	Query Received from Prospective Bidders	Response
	as per sub-clause 5 below). In the case of downloaded documents, Bidder must not make any changes to the contents of the documents while uploading, except for filling the required information – otherwise, the bid shall be rejected as nonresponsive.	uploading. Please keep 5 days for all documents. Confirm which documents to be required to submit original hard copies.	
13.	Section IV- A- List of Product Non PDI Items	For PDI, order, Dt of delivery should be considered from Dt of offered PDI or within week of PDI offered and same for inspection at consignee place or increase delivery period to 120 days.	Refer Annexure A
14.	The CMSS shall endeavour to make payment within 75 days in respect of items requiring sterility tests and within 60 days in respect of items requiring non- sterility test from the date of submission of invoice or from the date of receipt of material, whichever is later along with all the relevant documents of tender.	Supply: Payment procedure will be delayed due to not getting CRC on time & provide up to date information of contact person (m. no. & mail id) for taking follow ups or keep supply to CMSS depots ONLY.	Refer Annexure A
15.	Section V- Technical Specifications; Point B- Storage and Shelf Life	Stability: As per new ICH guidelines, India comes under 4b zone and for Zone 4b, LT stability should be done at 75% RH \pm 5% & 30 ⁰ C \pm 2 ⁰ C after year 2018. Clarify or amend stability Temp & RH.	Refer Annexure A
16.	Section II- BDS-ITB 13.1.2; There shall be no parallel contracts or splitting of quantity amongst qualified bidders. The contract shall be awarded to only lowest qualified bidder.	Quantity & value of items of the above tenders are too much large so order should be given to L1 & L2 bidders for fast, smooth & uninterrupted supply.	Refer Annexure A
17.	Other	As other anti-TB drugs under “Schedule H1”, do kindly check & confirm “Schedule” for Rifapentin Tab. whether it is under “Schedule H” or “Schedule H1”.	Refer Annexure A
B	M/s Svizera Labs Pvt. Ltd.		



S. No.	Standard Tender Clause	Query Received from Prospective Bidders	Response
1.	Section II- BDS; In accordance with DPIIT Public Procurement (Preference to Make in India) Order, 2017 dated 16.09.2020 read with DOP Circular F.No.31026/65/2020-MD dated 30.12.2020 as amended till date, only Class-I local suppliers, as defined in aforesaid notifications are eligible to bid.	Page 1 of Tender Document specifies that Class I & Class II Local Suppliers are eligible to bid. However, BDS on page 50 (ITB 3.5 1st Para) specifies that only Class I is eligible to bid. Please clarify the same.	Refer Annexure A
2.	Section I- ITB, Clause 13.2.3; It shall be mandatory for the successful bidder to be registered on GeM and obtain a unique GeM Seller ID. before the placement of LoA or the contract. This ID shall be incorporated in the contract.	As per your Clause No. 13.2.3(2) (page 45), it is mandatory to be registered on GeM and provide GeM Seller ID. Since this is a new requirement of CMSS, we need sufficient extension of Tender due dates to get the GeM Seller ID. Please extend it suitably. Alternately, you may delete this requirement.	Refer Annexure A
3.	Section III- Clause I; Requirement of Turnover Rs. 180 Crores.	Required Average Turnover of Rs. 180 crores (page 58) is very high & it will eliminate small/medium manufacturers and consequently reduce competition. The amount may please be reduced in line with the previous tender(s).	Refer Annexure A
4.	Section I ITB, Clause 9.2.1.5.a; Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life.	Being new item, the requirement of Long Term Stability Data (9.2.1.5.a – page 26) to be removed & replaced with 6 months Accelerated Stability Data only.	Refer Annexure A
5.	Section II BDS; ITB 5.2 Bidders have the option to submit its bid for any one or more schedules. However, Bidder shall mandatorily quote for 100% of the scheduled quantity. Bids for part quantity shall be summarily ignored.	As per Tender, we are required to mandatorily quote for 100% Quantity (5.2 – page 15 & 50). Earlier it was 50%. Combined capacity of all manufacturers for this item is likely to be less than the Tender Quantity. So it needs to be reduced to 50% quantity. Going for 100% quantity means eliminating MSME companies, who generally have limited capacities. This clause is favourable for large companies only. Since it is restrictive, earlier minimum bid quantity of 50% may please be restored.	Refer Annexure A
6.	Section II- BDS-ITB 13.1.2; There shall be no parallel contracts or splitting of quantity amongst qualified	Awarding 100% contract to L1 (4.4.1.a.(i) – page 13) only is not a good decision by CMSS. Combined	Refer Annexure A



S. No.	Standard Tender Clause	Query Received from Prospective Bidders	Response
	<p>bidders.</p> <p>The contract shall be awarded to only lowest qualified bidder.</p>	<p>capacity of all manufacturers for this item is likely to be less than the Tender Quantity. So it needs to be split up among at least 2 companies. Earlier ratio of 70:30 may please be restored. Since quantity is huge, we advise you to go for 50:30:20 to award it to 3 companies.</p>	
7.	<p>Section VII-SCC, GCC5.8</p> <p>1. Within fourteen days after the issue of Letter of Award (LoA or the contract, if LoA is skipped) by the Procuring Entity, the contractor shall furnish to the Procuring Entity performance security for an amount equivalent to INR 10 Crores of Rupees valid till expiry of Rate Contract Period i.e. till for its commitment to honour the purchase order issued under the Rate Contract.</p> <p>2. Additionally, for each of the purchase order placed against the Rate Contract, within fourteen days of issue of purchase order, the contractor shall furnish to the Procuring Entity performance security for an amount equivalent to 3% of the value of purchase order inclusive of duties and taxes. valid for the period of sixty days after the date of completion of all contractual obligations by the contractor including the shelf life/warranty obligations of the goods supplied.</p>	<p>Performance Security (GCC 5.8.1 – page 149) specified is Rs. 10 crores + 3% of PO value. This is very high. Kindly delete 10 crores & only keep 3% of PO value.</p>	Refer Annexure A
8.	<p>Section IV (b), Delivery Schedule:-</p> <p>1.</p> <p>Ist Tranche of supplies against the Rate contract of qty. of 6,66,94,128 tablets is likely to be placed immediately after issuance of Rate Contract with a delivery schedule of 90 days.</p> <p>2. For next tranche of the Purchase order also, the bidder should confirm the delivery qty. 6,66,94,128 of tablets within 90 days of receipt of purchase order.</p>	<p>Required quantity being huge, the delivery period of 90 days (Section IV-B – page 60) needs relaxation to 180 days from LoA for 1st tranche & 360 days from LoA for 2nd tranche.</p>	Refer Annexure A



S. No.	Standard Tender Clause	Query Received from Prospective Bidders	Response
9.	Section VI GCC;6.8.6 Short-closing or Renegotiation of the Rate Contract During the currency of the Rate Contract, the Procuring Entity can short-close the rate contract or renegotiate the price by serving a suitable notice of thirty days.	There is a provision for Short closing/ renegotiations (6.8.6 page 101) of Rate Contract by giving 30 day notice. The sanctity of the tender is lost in this. Please delete this condition.	No Change, As per tender
10.	Section I ITB 4.3.1; Relaxation in Prior Turnover and Experience: The prior turnover and prior experience requirement for MSEs enterprises shall be as indicated in Qualification Criteria/ Section III. Section I ITB 4.3.2; Relaxation in Prior Turnover and Experience: The prior turnover and prior experience requirement for DPIIT registered start-up enterprises shall be as indicated in Qualification Criteria/ Section III.	Is Turnover & Experience criteria (4.2.4 page 12) fully waived for MSE & Start-ups? Please clarify.	Refer Annexure A
11.	Bid submission end date is 22.05.2023	Some of our documentations from DCGI & FDA Maharashtra are in process & we need about 6 weeks to complete the same. We request you to extend the tender due dates by 6 weeks. Since there are only few manufacturers of this item, this extension will enable us to participate & ensure healthy competition & competitive prices for you.	No Change, As per tender
12.	Section III- Qualification Criteria; Tenderer must submit Market standing certificate issued by the Licensing Authority, as a Manufacturer of the item quoted, for at least last two financial years i.e. 2020-21 and 2021-22 OR 2021-22 and 2022-23. However, this would not apply to products which have been licensed by DCG (I) less than two years ago.	The requirement of Market Standing Certificate (9.2.1.3.d – page 25) to be deleted as this is a new item & most bidders have got DCGI License less than 2 years ago.	Refer Annexure A
13.	Other	Previous tender floated last Nov 2022 and could not be processed because of technical challenges & only few qualified bidders. Similar situation	No Change, As per tender



S. No.	Standard Tender Clause	Query Received from Prospective Bidders	Response
		exists today. So kindly grant sufficient time to us to enable us to bid & qualify in the tender.	
B	M/s J. Duncan Healthcare Pvt. Ltd.		
1	<p>Section II-BDS</p> <p>ITB Clause 5.2, Pg. no 50</p> <p>Bidders have the option to submit its bid for any one or more schedules. However, Bidder shall mandatorily quote for 100% of the scheduled quantity. Bids for part quantity shall be summarily ignored.</p>	<p>Section II-BDS</p> <p>ITB Clause 5.2, Pg. no 50 amended as;</p> <p>Bidders have the option to submit its bid for any one or more schedules. However, Bidder shall mandatorily quote for 25% of the scheduled quantity.</p> <p>Reasons:- Wider participation for small entities.</p>	No Change, As Per tender
2	<p>Section II-BDS</p> <p>ITB Clause 9.4, Pg. no 56</p> <p>EMD For Sch. I- Rs. 4,00,00,000</p>	<p>Section II-BDS</p> <p>ITB Clause 5.2, Pg. no 56 amended as;</p> <p>Bid security declaration also allowed in compliance of GFR 2017 Rule no 170(iii).</p> <p><i>In place of a Bid security, the Ministries/ Departments may require Bidders to sign a Bid securing declaration accepting that if they withdraw or modify their Bids during the period of validity, or if they are awarded the contract and they fail to sign the contract, or to submit a performance security before the deadline defined in the request for bids document, they will be suspended for the period of time specified in the request for bids document from being eligible to submit Bids for contracts with the entity that invited the Bids.</i></p> <p>Reasons:- Wider participation for small entities.</p>	No Change, As per tender



S. No.	Standard Tender Clause	Query Received from Prospective Bidders	Response
3	<p>Section III-Qualification Criteria</p> <p>Clause e, Pg. no 57</p> <p>Tenderer must submit Market standing certificate issued by the Licensing Authority, as a Manufacturer of the item quoted, for at least last two financial years i.e. 2020-21 and 2021-22 OR 2021-22 and 2022-23. However, this would not apply to products which have been licensed by DCG (I) less than two years ago.</p> <p>Note:</p> <ol style="list-style-type: none"> 1. Unless otherwise stipulated in the Market standing certificate, the said certificate issued on a particular date shall be treated valid certificate for the financial year in which it has been issued. For example, Market Standing Certificate issued on 15.07.2022 for the period 15.07.2022 to 14.07.2023 shall be treated as Market Standing Certificate for the FY 22-23. 2. Market standing certificate should be for the same manufacturing premises from which quoted goods have been offered for supply. 3. Only for the drugs introduced in Indian Pharmacopoeia in the recent past, Market standing certificate for previously approved Pharmacopoeia or In-house Standards shall be 	<p>Section III-Qualification Criteria</p> <p>Clause e, Pg. no 57</p> <p>Amended as:</p> <p>Tenderer must submit Market standing certificate issued by the Licensing Authority, as a Manufacturer of the item quoted, for at least last two financial years i.e. 2020-21 and 2021-22 OR 2021-22 and 2022-23- Requirement should be removed.</p> <p>Reasons:- As on date Products is not included in Indian Pharmacopoeia or Any other Pharmacopeia. Product introduce in 2021 in India.</p>	Refer Annexure A



S. No.	Standard Tender Clause	Query Received from Prospective Bidders	Response
	accepted, as the case may be.		
4	<p>Section III-Qualification Criteria</p> <p>Clause i, Pg. no 58</p> <p>Turnover Requirement- Rs. 180,00,00,000 for Sch. I</p>	<p>Section III-Qualification Criteria</p> <p>Clause i, Pg. no 58 amended as;</p> <p>Turnover Requirement- Rs. 50,00,00,000 for Sch. I</p> <p>OR</p> <p>Bidders have the option to submit its bid for any one or more schedules. However, Bidder shall mandatorily quote for 25% of the scheduled quantity.</p> <p>The applicable turnover has been indicated in above and is for 100% quantity of the schedule. If quoted quantity is anywhere between 25% to 100% of the quantity of schedule (as allowed under tender clause no. (ITB 5.2), the applicable Turnover may be calculated by the tenderer proportionately.</p> <p>All procurement entities in India for rate contract tender Max. requirement of Turnover is Rs. 20,00,00,000</p> <p>Reasons:- Huge volume of procurement, Procurement qty. not fixed. Procurement will be done on the basis of requirement of end user.</p>	Refer Annexure A



S. No.	Standard Tender Clause	Query Received from Prospective Bidders	Response
5	<p>Section IV-Schedule of Requirement</p> <p>Clause B, Pg. no 60</p> <p>Delivery Schedule- 90 days</p>	<p>Section IV-Schedule of Requirement</p> <p>Clause B, Pg. no 60 amended as;</p> <p>Delivery Schedule- 120 days</p> <p>Reasons:- Huge Qty. and new drug in India time consuming for ensure the supply of API.</p>	Refer Annexure A
6	<p>Section VI-GCC</p> <p>Clause 9.12, Pg. no 117</p> <p>Liquidated damages</p> <p>1) Subject to GCC clause 9.11, if the contractor fails to deliver any or all of the Goods or fails to perform the incidental Works/ Services within the time frame(s) incorporated in the contract, the Procuring Entity shall, without prejudice to other rights and remedies available to the Procuring Entity under the contract, deduct from the contract price, as agreed liquidated damages, but not as a penalty, a sum equivalent to the 2½ % of the delivered price (including elements of GST & freight) of the delayed Goods and/ or incidental Works/ Services for each week of delay to be applied proportionately on per day basis subject to a</p>	<p>Section VI-GCC</p> <p>Clause 9.12, Pg. no 117 amended as;</p> <p>Liquidated damages</p> <p>Subject to GCC clause 9.11, if the contractor fails to deliver any or all of the Goods or fails to perform the incidental Works/ Services within the time frame(s) incorporated in the contract, the Procuring Entity shall, without prejudice to other rights and remedies available to the Procuring Entity under the contract, deduct from the contract price, as agreed liquidated damages, but not as a penalty, a sum equivalent to the 0.5 % of the delivered price (including elements of GST & freight) of the delayed Goods and/ or incidental Works/ Services for each week of delay to be applied proportionately on per day basis subject to a maximum deduction of the 10% (or any other percentage if prescribed in the contract) of the</p>	No Change, As per tender



S. No.	Standard Tender Clause	Query Received from Prospective Bidders	Response
	<p>maximum deduction of the 10% (or any other percentage if prescribed in the contract) of the delayed Goods' or incidental Works/ Services' contract price(s). Besides liquidated damages during such a delay, the denial clause as per GCC-clause 9.11-2(b) shall also apply.</p>	<p>delayed Goods' or incidental Works/ Services' contract price(s). Besides liquidated damages during such a delay, the denial clause as per GCC-clause 9.11-2(b) shall also apply.</p> <p>Reasons:- As per provision of GFR and Manual of Procurement and Guidelines of MoF (DoE).</p>	
7	<p>Section VII-SCC (Special Conditions of Contract)</p> <p>Clause GCC 5.8 (i), Pg. no 149</p> <p>1. Within fourteen days after the issue of Letter of Award (LoA or the contract, if LoA is skipped) by the Procuring Entity, the contractor shall furnish to the Procuring Entity performance security for an amount equivalent to INR 10 Crores of Rupees valid till expiry of Rate Contract Period i.e. till for its commitment to honour the purchase order issued under the Rate Contract.</p> <p>2. Additionally, for each of the purchase order placed against the Rate Contract, within fourteen days of issue of purchase order, the contractor shall furnish to the Procuring Entity performance security for an amount equivalent to 3% of the value of purchase order inclusive of duties and taxes. valid for the period of sixty days after the date of completion of all</p>	<p>Section VII-SCC (Special Conditions of Contract)</p> <p>Clause GCC 5.8 (i), Pg. no 149 amended as;</p> <p>1. Within fourteen days after the issue of Letter of Award (LoA or the contract, if LoA is skipped) by the Procuring Entity, the contractor shall furnish to the Procuring Entity performance security for an amount equivalent to INR 10 Crores of Rupees valid till expiry of Rate Contract Period i.e. till for its commitment to honour the purchase order issued under the Rate Contract. – Requirement of Security (Rs. 10 Cr.) for RC should be removed.</p> <p>Reasons:- If we are L1 in 5 schedules. We have to pay Rs.50 Cr. As security However we will submit the requisite PBG (3 % of PO</p>	Refer Annexure A



S. No.	Standard Tender Clause	Query Received from Prospective Bidders	Response
	contractual obligations by the contractor including the shelf life/warranty obligations of the goods supplied.	<p>value) as per standard provision.</p> <p>As per our understanding PBG required for security of execution of supplies. For defaulter supplier all penalty provisions including Blacklisting already inbuilt in tender.</p> <p>It is humble request to remove this conditions.</p> <p>2. Additionally, for each of the purchase order placed against the Rate Contract, within fourteen days of issue of purchase order, the contractor shall furnish to the Procuring Entity performance security for an amount equivalent to 3% of the value of purchase order inclusive of duties and taxes. valid for the period of sixty days after the date of completion of all contractual obligations by the contractor including the shelf life/warranty obligations of the goods supplied.</p>	
8	Bid submission end date is 22/05/2023 at 4.00PM	<p>Kindly extend the Bid submission end date is 05/06/2023 at 4.00PM</p> <p>Reasons:- we had applied for approval of new product in form CT 23 to CDSCO, after approval from CDSCO, 7 working days required for obtaining the manufacturing License for domestic from SLA (State Licensing Authority). we are still waiting for approval from CDSCO.</p>	No Change, As per tender
D	M/s Lupin Ltd.		CMSS
1	13. Award of Contract 13.1.1 Right to Vary Quantities at the	In case of any increase in quantity, our request is that the delivery timelines for	Refer Annexure A



S. No.	Standard Tender Clause	Query Received from Prospective Bidders	Response
	Time of Award At the time of contract award, the Procuring Entity reserves the right to increase or decrease, without any change in the unit prices or other terms and conditions of the bid and the Tender Document, the quantity of Goods originally stipulated in Section IV: Schedule of Requirements, provided this increase/ decrease does not exceed 25 (twenty-five) percent of tendered quantity (or any other percentage indicated in the Tender Document).	the increased quantity should be mutually agreed upon. Also, request you to kindly clarify if quantities required in the second tranche can increase or decrease more the 25 %, as it is mentioned that the TIA reserves the right to issue the PO as per the actual requirement of programme division within contract period.	
2	12 : Evaluation of Bids and Award of Contract 12.4.5 Reasonableness of Rates Received : Procuring Entity shall evaluate whether the rates received in the Bids in the zone of consideration are reasonable.	Kindly clarify the mechanism that would be followed by the authority to determine reasonableness of Rates	No Change, As per tender
3	Section III - Qualification Criteria b) Tenderer must submit own manufacturing license in the indicated pharmacopeia (as indicated in technical specification) valid on the date of tender opening (technical bid). If the tendered drug is in Indian Pharmacopoeia (IP), then the manufacturing license has to be submitted in IP only.	Kindly clarify if the manufacturing license issued under Form 28 by FDA must be submitted alongwith Form CT-23 issued by the Central Licensing authority since the product is classified as a New Drug (Less than 4 years old)	Refer Annexure A
4	Section III - Qualification Criteria e) Tenderer must submit Market standing certificate issued by the Licensing Authority, as a Manufacturer of the item quoted, for at least last two financial years i.e. 2020-21 and 2021-22 or 2021-22 and 2022-23. However, this would not apply to products which have been licensed by DCG (I) less than two years ago.	Kindly clarify if Market standing certificate would apply for Rifapentine 300 mg + Isoniazid 300 mg Tablets since this product has been licensed by DCG(I) less than 2 years ago. The date of issue of first License by DCG(I) for Rifapentine 300 mg + Isoniazid 300 mg is 28th June 2021	Refer Annexure A
5	Section V; Technical Specification and Quality Assurance; 01) HP is a blister strip pack of 12 tablets, each tablet consisting of Isoniazid and Rifapentine in fixed dose combination (HP-Fixed Dose Combination).	Kindly clarify if the primary packaging is Alu- Alu strip	Refer Annexure A



S. No.	Standard Tender Clause	Query Received from Prospective Bidders	Response
	09) A Alu-Alu strip consisting of 12 tablets of the drugs duly identified should be packed in Alu Alu foil/Aluminium Cold Forming Blister pack. The Alu-ALu strip should be tropicalized with regard to moisture.		
6	From 3; Technical Specification and quality Assurance- Compliance & Deviation Kindly refer Table provided detailing technical specification to be filled	Kindly clarify as to the details of the technical specifications that needs to be filled in the tender.	No Change, As per tender
7	Purchase Preference Policies of the Government; If the item is not reserved for procurement exclusively from Class-I local suppliers and if Class-II/ Non-local suppliers are also eligible to participate in the tender, purchase preference shall be given to Class-I local suppliers over Class-II/ Non-local suppliers provided its quoted rates fall within 20% margin of purchase preference, in accordance with PPP-MII Order dated 16.09.2020.	Kindly clarify if value addition for local content evaluation would be considered inclusive of both API (Bulk drug) manufacturing and Formulation Manufacturing .	No Change, As per tender
8	Denial Clause; (i) No increases in price on account of any statutory increase in or fresh Imposition of GST, customs duty or on account of any other taxes/ duty/ cess/ levy), leviable in respect of the Goods and incidental Works/ Services stipulated in the said contract which takes place after the original delivery date, shall be admissible on such of the said Goods, as are delivered after the said date; and (ii) Notwithstanding any stipulation in the contract for an increase in price on any other ground, including price variation clause or foreign exchange rate variation, or any other variation clause, no such increase after the original delivery date shall be admissible on such goods delivered after the said date. (iii) Nevertheless, the Procuring Entity shall be entitled to the benefit of any decrease in price on account of reduction in or remission of GST, customs duty or on account of	While it is mentioned that the Procuring Entity shall be entitled to the benefit of any decrease in price on any decrease in taxes/levy/duties, any increase as applicable in taxes/duty/cess/levy should also be considered during the term of the contract	No Change, As per tender



S. No.	Standard Tender Clause	Query Received from Prospective Bidders	Response
	any other Tax or duty or any other ground as stipulated in the price variation clause or foreign exchange rate variation or any other variation clause which takes place after the expiry of the original delivery date.		
E	M/s Oxalis Labs		CMSS
1.	2. Tender timelines are as under: (d) Last date and time for bid submission :- 22/05/2023 at 4:00PM	As the format of the tender book has changed and we need more time to go through the same, also multiple tenders are floated at a time for TB products and we being one of the TB products supplier having a wide range of TB products , so we request you to extend the deadline to submit the bid.	No Change, As per tender
2.	ITB 13.1.2: - There shall be no parallel contracts or splitting of quantity amongst qualified bidders. The contract shall be awarded to only lowest qualified bidder.	Please clarify why 100% quantity will be awarded to single lowest qualified bidder? It will lead to supplier security issue.	Refer Annexure A
3.	Refer to Section IV – Schedule of Requirement- B- Delivery Schedule:- 1. Ist Tranche of supplies against the Rate contract of qty. of 6,66,94,128 tablets is likely to be placed immediately after issuance of Rate Contract with a delivery schedule of 90 days. 2. For next tranche of the Purchase order also, the bidder should confirm the delivery qty. 6,66,94,128 of tablets within 90 days of receipt of purchase order. 3. TIA reserves the right to issue the purchase order as per the actual requirement of programme division within contract period.	a) This clause may please be amended as the supply period for Tranche I 6,66,94,128 tablets within 180 days plus (as we would use to produce API as well after receipt of LOA plus as we would need to produce API as well & Tranche II 6,66,94,128 tablets within 180 days after the receipt of Purchase Order instead of 90 days, as because the quantities are huge. b) We also request you to kindly increase the no. of Tranches supply period so that you can get staggered deliveries and you will not face overstock issues.	Refer Annexure A
4.	Refer to Section VII: Special Condition of Contract - (GCC- 5.8)		Refer Annexure A



S. No.	Standard Tender Clause	Query Received from Prospective Bidders	Response
	<p>Performance Security (page # 149)</p> <p>1) Unless stipulated otherwise in SCC, within fourteen days after the issue of Letter of Award (Loa or the contract, if Loa is skipped) by the Procuring Entity, the contractor shall furnish to the Procuring Entity, performance security, valid for the period as specified in SCC (for sixty days after the date of completion of all contractual obligations by the contractor including the shelf life/warranty obligations).</p> <p>1. Within fourteen days after the issue of Letter of Award (LoA or the contract, if LoA is skipped) by the Procuring Entity, the contractor shall furnish to the Procuring Entity performance security for an amount equivalent to INR 10 Crores of Rupees valid till expiry of Rate Contract Period i.e. till for its commitment to honour the purchase order issued under the Rate Contract.</p> <p>2) The amount of Performance security shall be for an amount as indicated in SCC (@ 3% of the contract Price) denominated in Indian Rupees or the currency of the contract and shall be in one of the following forms: etc.</p>	<p>This clause may please be amended as to submit the Performance Security as per some percentage on the contract value (For eg 1% of the Contract Value). As it is mention in the tender clause to submit Rs. 10 Crore Performance Security.</p> <p>Also if we are submitting Performance Security on the Contract value as per the LOA, then why again to give 3% Performance Security against each Purchase Order.</p>	
5.	<p>Refer Form 4.1: PROFORMA FOR PERFORMANCE STATEMENT :-</p> <p>Copies of Purchase orders and e-way bills (Maximum 05 for each Purchase order- the ones pertaining to for large</p>	<p>This clause may please be amended as to submit the Purchase order copies along with the Performance Statement.</p> <p>Please confirm E-way bills means Commercial Invoice copy or the Bill of Lading / Airway Bill, if yes then we would not be able to provide BL /</p>	Refer Annexure A



S. No.	Standard Tender Clause	Query Received from Prospective Bidders	Response
	consignment) shall be submitted. It is mention to update the Unit Price All Incl & Total Value details along with the past performance.	AWB copy this is because all our consignment goes through Ex-Factory. Refer to this clause, we hereby request you to kindly remove this column, as those details are confidential details and we have confidentiality agreement with other buyers which cannot be shared and same was not asked in the past tenders too.	
6.	Refer to Section IV – Schedule of Requirement – A. List of Products – Refer to Inspection Methodology (PDI / Non-PDI):- It is mentioned as NON –PDI Items.	Refer to tender clause, request you to kindly clarify if the said product is under Non-PDI Item then is the CRC form mandatory to submit at the time of payment process, please clarify.	Refer Annexure A
7.	Refer Section VI: General Conditions of Contract (GCC) – In Point #7 -3(a) At Pre- Dispatch Stage details are mentioned (Page # 102) Refer to Section VII – Special Conditions of Contract – Refer to GCC 7.1.6 - The goods supplied under the contract shall be subjected to PDI at manufacturer's manufacturing premises before dispatch.	Refer to tender clause mention in Section IV Schedule of Requirement – A. List of Products – Refer to Inspection Methodology (PDI / Non-PDI), it is mentioned that this product is NON- PDI Items, so please confirm is Pre Shipment Inspection is to be done or not ?.	Refer Annexure A
8.	Refer to Clause 13 – Award of Contract – Point # 13.1.2 Parallel Contracts or Splitting of Award Unless otherwise stipulated in BDS, there shall be no parallel orders or splitting quantities among more than one Bidder.	Refer to this clause, request you to kindly guide us what does Parallel Contracts or Spitting Award means. Is this means whether lowest bidder will get 100 % quantity?	Refer Annexure A
9.	Refer to Section V – Technical Specifications and Quality Assurance – A. Specific Requirement- In Item Description It is mentioned that the item is a Blister Strip Pack.	Refer to this point, request you to amend the pack to be in Strip pack instead of Blister Strip pack. Please clarify, Also please confirm, we understand all	Refer Annexure A



S. No.	Standard Tender Clause	Query Received from Prospective Bidders	Response
	It is mention in Description that the said product is considered in IP/BP/USP/International Pharmacopeia, but refer to point 2 (Protocol and Testing) it is mentioned that the Microbial Count test is conducted as per IP	our technical documents like Stability Data, Market Standing certificate etc. we can submit like from any one of the Pharmacopeia (IP/BP/USP/International Pharmacopeia/ In House), please confirm.	
10.	Refer to Form 6: Checklist for Bidders – Point # 3.a - Self-attested copy of Registration certificate for bidders/ subcontractors from restricted neighbouring countries	Refer to this point, request you to kindly clarify what does Restricted Neighbouring Countries means.	No Change, As per tender
11.	Miscellaneous query	The Online bid submission documents which are to be uploaded in the portal size of the file details are not mentioned, so please confirm the same previously the limit was freeze to 40 MB. Kindly increase the limit.	No Change, As per tender
12.	<p>Refer to Form 1.1: Bidder Information –</p> <p><u>Point 3- Authorization of Person(s) signing the bid on behalf of the Bidder</u></p> <p>(a) Full Name: _____</p> <p>(b) Designation: _____</p> <p>–</p> <p>(c) Signing as:</p> <p>♦ A sole proprietorship firm. The person signing the bid is the sole proprietor/ constituted attorney of the sole proprietor,</p> <p>♦ A partnership firm. The person signing the bid is duly authorized being a partner to do so, under the partnership agreement or the general</p>	Refer to this point we hereby request you to kindly confirm whether any employee who is authorised to sign the documents on behalf of Sole Proprietor / Partnership / Constituted by sharing Power of Attorney.	No Change, As per tender



S. No.	Standard Tender Clause	Query Received from Prospective Bidders	Response
	<p>power of attorney.</p> <p>♦ A company. The person signing the bid is the constituted attorney by a resolution passed by the Board of Directors or in pursuance of the Authority conferred by Memorandum of Association. Documents to be submitted: Partnership Agreement/ Power of Attorney/ Registration Certificate/ Memorandum of Association/ Board Resolution.</p> <p>Point 4 - Bidder's Authorized Representative Information:-</p> <p>(a) Name:</p> <p>(b) Address:</p> <p>(c) Telephone/ Mobile numbers:</p> <p>(d) Email Address:</p>	<p>Refer to this clause we hereby need the clarification whether we need to mention our Agent details who is authorised on behalf of our company or if any names need to be mentioned or if any employee of the company can sign the documents.</p>	
13.	<p>Refer to Section 1- Instructions to Bidder- Clause # 10.3.1 Submission/ Uploading to the Portal- Point # 3. Only one copy of the bid can be uploaded, and Bidder shall digitally sign all statements, documents, certificates uploaded by him, owning sole and complete responsibility for their correctness/ authenticity as per the provisions of the IT Act 2000 as amended from time to time.</p>	<p>Refer to this clause, we need to confirm whether we can sign manually on the set of documents along with stamp and can upload it on the portal as digitally signing is mentioned.</p>	No Change, As per tender
14.	<p>Refer to Section VI: General Conditions of Contract (GCC) – Clause # 9 – Point # 9.12 (Liquidated damages)-</p> <p>1) Subject to GCC clause 9.11, if the contractor fails to deliver any or all of the Goods or fails to perform the incidental Works/ Services within the time frame(s) incorporated in the contract, the Procuring Entity shall,</p>	<p>Refer to this clause, we request you to kindly remove this clause or reduce the percentage.</p>	No Change, As per tender



S. No.	Standard Tender Clause	Query Received from Prospective Bidders	Response
	without prejudice to other rights and remedies available to the Procuring Entity under the contract, deduct from the contract price, as agreed liquidated damages, but not as a penalty, a sum equivalent to the 2½ % of the delivered price (including elements of GST & freight) of the delayed Goods and/ or incidental Works/ Services for each week of delay to be applied proportionately on per day basis subject to a maximum deduction of the 10% (or any other percentage if prescribed in the contract) of the delayed Goods' or incidental Works/ Services' contract price(s). Besides liquidated damages during such a delay, the denial clause as per GCC-clause 9.11-2(b) shall also apply.		
15.	<p>Refer to Section VI: General Conditions of Contract (GCC) – Clause # 10 – Point # 10.3.2 (Terms and Mode of Payment)-</p> <p>g) Undertaking that the payment being claimed is strictly in terms of the contract and all the obligations on the part of the contractor for claiming that payment has been fulfilled as required under the contract.</p> <p>h) Undertaking for Fall Clause as per GCC 10.1.6</p> <p>i) Undertaking for Statutory reduction in duties and taxes as per GCC 10.2.4</p> <p>j) Undertaking that the contractor is agreeable to receive payment of goods by recovering liquidated damages for delayed supplies in accordance with the conditions of the contract.</p>	<p>Refer to this clause, we request you to kindly remove this clause.</p>	No Change, As per tender



S. No.	Standard Tender Clause	Query Received from Prospective Bidders	Response
16.	<p>Refer to Section VI: General Conditions of Contract (GCC) – Clause # 10 – Point # 10.1.2 (Controlled Prices) -</p> <p>1) The price charged by the contractor shall not be higher than the controlled price fixed by law for the Goods, or where there is no 118 controlled price, it shall not exceed the minimum of Maximum Retail Price (MRP) at which the same or similar Goods are available in the market in the relevant region, or contravene the norms for fixation of prices laid down by Government, or where the Government has not fixed such prices or norms, it shall not exceed the price appearing in any agreement relating to price regulation by any industry in consultation with the Government.</p>	Refer to this clause, request you to kindly guide us from where we can get the controlled price list..	No Change, As per tender
17.	<p>CMSS Warehouse & Mapped States – Page 61</p> <p>CMSS reserve to right the change the consignee at any time if required.</p>	Please let us know in advance before the goods are ready if the consignees are changes, so that we can make necessary changes	Refer Annexure A
18.	Miscellaneous query	As there is Nitrosamine impurity in Rifapentine so we request CMSS to add the clause asking the supplier to provide proof of this impurity limit less than 20 ppm as per WHO PQ, Eg. COA or specification, etc.	Refer Annexure A
19.	Miscellaneous query	We request CMSS to ask supplier to provide 2 years manufacturing and marketing experience of the same product and not similar product.	Refer Annexure A
20.	<p>9.4 Bid Security - Related Documents</p> <p>1. Bidders shall submit Earnest Money Deposit (EMD) for the amount as indicated in Bid Data Sheet.</p> <p>2. The EMD shall be paid by</p>	<p>Refer to this clause, we hereby understand that even the Tender is getting extended; we do not have to extend the EMD Bank Guarantee validity, Kindly confirm.</p> <p>This is because, if you extend the tender for 1 week extension, then it is not possible for us to get extended Bank Guarantee from bank within a</p>	No Change, As per tender



S. No.	Standard Tender Clause	Query Received from Prospective Bidders	Response
	Account payee Demand Draft/ Fixed Deposit Receipt/ Banker's Cheque /Bank Guarantee or RTGS/NEFT/Insurance Surety Bonds.	week. So request you to kindly confirm to avoid further misunderstanding.	



