Dated: -23.12.2022

CENTRAL MEDICAL SERVICES SOCIETY

Ministry of Health and Family Welfare (Government of India)
2nd floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Marg,
Opposite Police Station Chankaya Puri, New Delhi-110021

Telephones: 011-21410905, 21410906
Email: gmproc.cmss@gmail.com
agminderjeetyadav.cmss@gmail.com

Tender No: CMSS/PROC/2022-23/NTEP/022
For
Procurement of TB Preventive Therapy Drugs Under NTEP

Minutes of Pre-bid meeting held on 05th December 2022 at 11.00 AM

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

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

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

   (i) Mr. Mukul Jerath, Lupin Ltd.
   (ii) Mr. Kuldeep Waklilor, Lupin Ltd.

Minutes of Pre-bid meeting

S. No.	Query Received from Prospective Bidders	Standard Tender Clause	Response
A	**M/s Oxalis Labs**		
1.	**Query:** **Sch. I** Can these delivery timelines for	**Schedule of Requirements, Sch. I** **Regarding Annexure 1:** Schedule of requirement	**Schedule of Requirements amended as, Sch. I** **Regarding Annexure**

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S. No.	Query Received from Prospective Bidders	Standard Tender Clause	Response
	Tranche 1 extend to 120 days? Also, please confirm if these timelines are for goods to get ready at the factory for inspection or to deliver the goods at the CMSS warehouse in different states.	for 3HP 300mg (Isoniazid 300mg + Rifapentine 300mg) & Rifapentine 150 mg **1st tranche:** 50% of the total quantity to be received within 60 days from the issue of LOA **2nd tranche:** 25% of the total quantity to be received within 180-210 days from issue of LOA **3rd tranche:** 25% of the total quantity to be received within 270-300 days from issue of LOA	**1:** Schedule of requirement for 3HP 300mg (Isoniazid 300mg + Rifapentine 300mg) & Rifapentine 150 mg **1st tranche:** 50% of the total quantity to be received within 90 days from the issue of LOA **2nd tranche:** 25% of the total quantity to be received within 180-210 days from issue of LOA **3rd tranche:** 25% of the total quantity to be received within 270-300 days from issue of LOA
2.	**Query:** a) As per this clause we understand COPP as per any Pharmacopeia as well as for any country (India or any exporting country) will be acceptable. Please confirm. b) if the product is newly developed and if we are in process of obtaining the manufacturing license, please confirm if CMSS shall accept the bid. c) If we have manufacturing data only and do not have marketing experience, then please confirm if the bid will be accepted.	**Eligibility Criteria:** **Clause 4 (b)** Tenderer shall be a manufacturer of the quoted product and have a valid own manufacturing license in the indicated pharmacopeia (in the technical specification at Annexure IA) and Certificate of Pharmaceutical Product (COPP) as recommended by WHO in any of the pharmacopeia IP/BP/USP. The manufacturing license & COPP should be valid on the date of tender opening packet 1. **Clause 6.1 (e)** Manufacturing and Market Standing Certificate / Market Standing Certificate issued by the Licensing Authority as a manufacturer for each item quoted for the last 2 years i.e 2020-21 & 2021-22 for compliance of tender clause 4.c.	Clarifed as; Point a- For Sch. I & II:- Certificate of Pharmaceutical Product (COPP) as per tender may be accepted irrespective of Country. COPP should be valid on the date of tender opening packet 1. Point b- Manufacturing License should be valid on the date of tender opening packet 1. Point c- Tender clause deleted for all Licenses issued under Form 46 from DCGI. If a License issued other than Form 46 tender clause shall be applicable.

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S. No.	Query Received from Prospective Bidders	Standard Tender Clause	Response
3.	**Query:** a) Please confirm two years of manufacturing experience as per any pharmacopeia i.e, IP, BP, USP, or IH will be acceptable under this clause. b) And also, marketing experience either within India or any exporting country shall be acceptable. c) Please clarify what you mean by regulated products. d) Please confirm that the bid will be accepted if DCGI approval for the product is not obtained yet but is under process. e) If the answer to (d) is yes, then please confirm which documents we shall submit to be eligible to bid.	**Eligibility Criteria:** **Clause 4(c)** For all regulated products, the bidder should have at least two years of manufacturing and marketing experience of the particular items as a manufacturer for each regulated product quoted in the tender. However, this would not apply to regulated products which have been licensed by DCG (I) less than two years ago. DCG(I) is permission shall be required for all newly regulated products to this effect.	Clarified as:- Point a- Tender clause deleted for all Licenses issued under Form 46 from DCGI. If a License issued other than Form 46 tender clause shall be applicable. Point b- Agreed, Domestic/ Export market standing certificate is acceptable. Point c- All products regulated by Central & State regulator for regulation of Drugs & Cosmetics Act 1940 and Rules 1945. Point d- No, Manufacturing License should be valid on the date of tender opening packet 1.
5.	**Query:** Please confirm, if the tendered product is in any pharmacopeia other than IP then a manufacturing license in any pharmacopeia other than IP will be considered and the BID will not be rejected.	**Technical specification** **Clause 6(c)** The Tenderer should furnish the Manufacturing License valid on tender opening for each item quoted been duly renewed up to date and the items quoted shall be clearly highlighted in the license. Original documents should be produced for verification when demanded. If the tendered drug is in Indian Pharmacopoeia (IP), then the manufacturing license has to be submitted in IP only.	Clarified as; 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 there. **Bidder is requested to submit an undertaking that the drug is not available in IP or any other approved pharmacopeia.**
6.	**Query:** Please clarify what is meant by	**Technical specification** **Clause 6.2(b)**	Clarified as; Conditional bids means there is any deviation from the tender terms &

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S. No.	Query Received from Prospective Bidders	Standard Tender Clause	Response
	conditional bids.	Conditional Bids shall be summarily rejected.	conditions.
7.	**Query:** This clause may please be amended and the condition of placing of 50% additional quantities may please be removed because our costing is based on the indicative quantities in the tender to be kept effective till the validity of the bid.	**Other conditions** **Clause 10.1(ii)** In exceptional situations where the requirement is of an emergent nature and it is necessary to ensure continued supplies from the existing vendors, the purchaser reserves the right to place repeat orders up to 50% of the quantity of the goods and/or services contained in the running tender/contract up to a period of twelve months from the earliest date of acceptance of award at the same rate or a rate negotiated(downwardly) with the existing vendors considering the reasonability of rates based on prevailing market conditions and the impact of the reduction in duties and taxes, etc.	No Change
8.	**Query:** Please clarify how 25% of batch supply cost will be determined.	**Other conditions:** **Clause 16.8** In the event of the samples of Drugs/goods supplied fail in quality tests or are found to be not as per specifications at any of the testing stages (as mentioned in clause no. 16.3), depending upon the type, nature, and seriousness of the failure, consequences resulting from such default, availability of alternate sources, the CMSS is at liberty to either : (i)Ask the supplier to replace the entire quantity of relevant batches, in addition to the imposition of penalty @ 25% of batch supply cost	Clarified as; If the batch fails in QC report, then the batch shall be replaced by the supplier. In addition to this, 25% penalty would be levied on the total cost of the failed batch. It will be determined on the total cost of the failed batch.
9.	**Query** Please consider part payment after	**Other conditions:** **Clause 17.5** Lot/Tranche/PO vise Part	No Change

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S. No.	Query Received from Prospective Bidders	Standard Tender Clause	Response
	the supply of 10% of the item order in the individual tranche/lot in the purchase order provided a report of standard quality of samples testing is received from approval laboratories of CMSS as the quantities to be supplied under schedule 1 are very large and release of payment on completion of 50% of the supplies in the individual tranches/lot largely affect our working capital requirements, hence would request you to consider the release of payment on starting completion of 10% supplies.	payments for supply will be considered only after completion of supply of at least 50% of the quantity ordered in the individual Purchase Order/Lot/ Tranche PROVIDED original consignee receipts (or on GeM by the consignee for the receipt, with original CRC to be submitted before next payment is released) are produced and the quality pass reports of Standard Quality on samples testing are received from approved laboratories of CMSS.	
10.	**Query:** Liquidated damages of 2.5% per week are very high. Please consider 0.25% or less per week to a maximum of 10%.	**Liquidated Damages and Other Penalties:** **Clause 18.2** If the supply reaches the designated consignee places or CMSS Warehouse after the scheduled delivery date mentioned in LOA/P.O, liquidated damages will be levied @ 2.5% per week to be applied proportionately on per day basis up to a maximum of 10% of P.O. Cost, irrespective of the fact that whether the CMSS has suffered any damage/ loss or not, on account of delay in effecting supply. If the last scheduled delivery day happens to be a holiday the supply will be accepted on the next working day without any penalty.	No Change
11.	**Query:** a) Please confirm product with a Shelf life of 24 months, proven by accelerated shelf life and not full real-time data, is acceptable. We will provide 12 months of real-time data and 6	**Technical specification:** **Clause 6.1(m)** **Regarding specific requirements:** **E. Shelf Life:**	Accelerated data for a period of 6 months and available Long term real-time stability data of the quoted product is acceptable.

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S. No.	Query Received from Prospective Bidders	Standard Tender Clause	Response
	months of accelerated data. As per ICH, this much data is sufficient to give 24 months of shelf life to a finished product. b) We have long-term stability data as per USP. We would like to bring to your kind attention that the quality and performance parameters in IP/BP/USP are all same and the specifications available in the stability data assigned by us are all well covered and very well in limit also. Hence request you to please consider.	Shelf life should be minimum 24 months from the date of manufacture. **Clause 6.1(m)** Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life.	
12.	**Query:** Apart from the Manufacturing license what else is required from the bidder to submit under this clause?	**Technical specification:** **Regarding Specific requirements:** The drug contained in the product shall have valid registration in the country of manufacture and shall meet all requirements of the licensing authority of the country of manufacture. The drug contained in the product shall also have valid registration in India and shall meet all the requirements of the licensing authority in India.	Clarified as; Manufacturing license for domestic use only is acceptable.
13.	If the tendered drug is in BP or USP or In-house pharmacopeia, will the manufacturing license in BP or USP or other pharmacopeias apart from IP is acceptable? Please advise.	**Technical specification** **Regarding Specific requirements:** If the tendered drug is in Indian Pharmacopoeia (IP), then the manufacturing license has to be submitted in IP only. 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	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 there. **Bidder is requested to submit an undertaking that**

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S. No.	Query Received from Prospective Bidders	Standard Tender Clause	Response
		Drugs and Cosmetics Act 1940 and the Rules there.	**the drug is not available in IP or any other approved pharmacopeia.**
B	**M/s J. Duncan**		
1.	**Query:** **Tender Clause 6.2(d) Amended as** : Duly notarized general power of Attorney (on non-judicial stamp paper of worth Rs. 50/- or more)	**Technical Specification: Clause 6.1(d)** Duly notarized general power of Attorney (on non-judicial stamp paper of worth Rs. 50/-)	**Tender Clause 6.2(d) Amended as** : Duly notarized general power of Attorney (on non-judicial stamp paper of worth Rs. 50/- or more)
2.	**Query:** **Tender Clause 6.2(e) Amended as:** Manufacturing and Market Standing Certificate Market Standing Certificate issued by the Licensing Authority as a manufacturer for each item quoted for the last 2 years i.e 2020-21 & 2021-22 for compliance of tender clause 4.c. For All Schedules : Market standing certificate may be provided in **IH/IP/BP/USP/any other previously approved pharmacopeia (Including Domestic & Export)** for at least last 2 financial years i.e. 2020-21 and 2021-22. **Reasons:- As on date Products is not included in Indian Pharmacopoeia or Any other Pharmacopeia.**	**Technical Specification: Clause 6.1(e)** Manufacturing and Market Standing Certificate Market Standing Certificate issued by the Licensing Authority as a manufacturer for each item quoted for the last 2 years i.e 2020-21 & 2021-22 for compliance of tender clause 4.c.	Clarified as- Tender clause deleted for all Licenses issued under Form 46 from DCGI. If a License issued other than Form 46 tender clause shall be applicable.
3.	**Query:** **Tender Clause no 6.2 (m) :- Amended as:-** Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life. For All schedules: Long Term Stability Data may be provided in **IH/IP/BP/USP/any other previously**	**Technical Specification, Clause no 6.1(m)** Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life	Accelerated data for a period of 6 months and available Long term real-time stability data of the quoted product is acceptable.

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S. No.	Query Received from Prospective Bidders	Standard Tender Clause	Response
	approved pharmacopeia for at least for 3 batches, to support shelf life. **Reasons:- As** on **date Products are not included in Indian Pharmacopoeia** **Any other Pharmacopeia.**		
4.	**Query:** **Tender Clause 6.1.f amended as:** For Sch. I & II- relaxed COPP conditions. or **Please refer technical specification- As per requirement of technical specification only WHO GMP standard.** **Reasons:- As on date Products are not included in Indian Pharmacopoeia or Any other Pharmacopeia.**	**Technical Specification, Clause 6.1(f)** A valid Certificate of Pharmaceutical Product (COPP) as recommended by WHO in any pharmacopeia IP/BP/USP and a valid WHO-GMP	Clarified as; For Sch. I & II:- Certificate of Pharmaceutical Product (COPP) as per tender may be accepted irrespective of Country. COPP should be valid on the date of tender opening packet 1.
5.	**Query** **Tender Clause 18.2 amended as:** If the supply reaches the designated consignee places or CMSS Warehouse after scheduled delivery date mentioned in LOA/P.O, liquidated damages will be levied @ 0.5% per week to be applied proportionately on per day basis up to a maximum of 10% of P.O. Cost, irrespective of the fact that whether the CMSS has suffered any damage/ loss or not, on account of delay in effecting supply. If the last scheduled delivery day happens to be a holiday the supply will be accepted on the next working day without any penalty.	**Liquidated Damaged and Other Penalty:** **Clause 18.2** If the supply reaches the designated consignee places or CMSS Warehouse after scheduled delivery date mentioned in LOA/P.O, liquidated damages will be levied @ 2.5% per week to be applied proportionately on per day basis up to a maximum of 10% of P.O. Cost, irrespective of the fact that whether the CMSS has suffered any damage/ loss or not, on account of delay in effecting supply. If the last scheduled delivery day happens to be a holiday the supply will be accepted on the next working day without any penalty.	No Change

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S. No.	Query Received from Prospective Bidders	Standard Tender Clause	Response
6.	**Query:** Delivery Schedule for Sch. I & II amended as: 1st tranche: 50% of the total quantity- to be received within 120 days from issue of LOA 2nd tranche: 25% of the total quantity to be received within 121-240 days from issue of LOA 3rd tranche: 25% of the total quantity to be received within 241-360 days from issue of LOA	**Schedule of Requirements:** Delivery Schedule for Sch. I & II: **1st tranche**: 50% of the total quantity- to be received within 60 days from issue of LOA **2nd tranche**: 25% of the total quantity to be received within 180-210 days from issue of LOA **3rd tranche**: 25% of the total quantity to be received within 270-300 days from issue of LOA	**Schedule of Requirements amended as:** Delivery Schedule for Sch. I & II: **1st tranche**: 50% of the total quantity- to be received within 90 days from issue of LOA **2nd tranche**: 25% of the total quantity to be received within 180-210 days from issue of LOA **3rd tranche**: 25% of the total quantity to be received within 270-300 days from issue of LOA
C	**M/s Cipla**		
1.	**Query:** We are in receipt of tender enquiry no. CMSS/PROC/2022-23/NTEP/022 dated 25th Nov'22 for ONLINE TENDER FOR PROCUREMENT OF TB PREVENTIVE THERAPY DRUGS UNDER NTEP FOR THE YEAR 2022-23. In the light of above we would like to submit that, we have received the approval from DCGI for manufacturing unit detailed as M/s Cipla Ltd., C/o M/s Themis Medicare Ltd., Sector-6A, Plot No. 16, 17 & 18, IIE, SIDCUL Distt. Haridwar Uttarakhand (India)-249403 under Loan License Arrangement. Cipla (Bidder in this case) have developed the product including the **bioavailability / bioequivalence studies** of the product In this regard, we had given our	**Eligibility Criteria:** **Clause 4(b)** Tenderer shall be a manufacturer of quoted product and having valid own manufacturing license in the indicated pharmacopeia (in technical specification at Annexure IA) and Certificate of Pharmaceutical Product (COPP) as recommended by WHO in any of the pharmacopeia IP/BP/USP. The manufacturing license & COPP should be valid on the date of tender opening packet 1.	No Change, Loan License is not acceptable.

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S. No.	Query Received from Prospective Bidders	Standard Tender Clause	Response
	representation with details of the difference between LL and P2P dated 6th Oct 2022. In Loan License Arrangement, the license holder (bidder in this case) is responsible for all the processes including procurement of raw material, quality guidelines and ensuring **quality standards confo rmance** for finished product. We would also like to bring to your notice that some state procurement agencies like **T NMSC** and **RMSCL** are already accepting the supplies manufactured under Loan Licence Manufacturing arrangement which are also on the governing body of your esteemed organization. Also, an opinion can be sought in this regard from Central Drugs Standard Control Organisation (**CDSCO**), India's national regulatory body for pharmaceuticals. If any subsequent documentation in this regard is requested, we are willing the submit the same for your perusal. We can also give undertaking for fulfilment of all terms and conditions of the tender as a bidder along with responsibility for supplies and quality of the product.		
4.	**M/s Lupin Limited**		
1.	**Query:** Since, the procurement of Rifapentine 300 mg-Isoniazid 300mg tablets and Rifapentine 150 mg tablets has been initiated for the first time by the agency, we would like to submit that there would be certain amount of lead time involved towards finalization	**Schedule of Requirements:** **Sch. I & II** **1st tranche:** 50 % of the total quantity to be received within 60 days from issue of LOA **2nd tranche:** 25% of the total quantity to be received within 180-210 days from issue of LOA **3rd tranche:** 25 % of the total	**Schedule of Requirements amended as:** Delivery Schedule for Sch. I & II: **1st tranche**: 50% of the total quantity- to be received within 90 days from issue of LOA

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S. No.	Query Received from Prospective Bidders	Standard Tender Clause	Response
	of artworks within the system and the deliverance of packaging material by the vendor. Further, considering that 50 % quantities of the product that would be required in the first tranche tender, we request you to kindly consider the following delivery schedule: **1st Tranche:** 50 % of the quantities within 150 days from the date of LOA/PO **2nd Tranche**: 25 % of the quantities within 180-210 days from the date of LOA/PO **3rdTranche:** 25 % of the quantities within 270-300 days from the date of LOA/PO	quantity to be received within 270-300 days from issue of LOA	**2nd tranche**: 25% of the total quantity to be received within 180-210 days from issue of LOA **3rd tranche**: 25% of the total quantity to be received within 270-300 days from issue of LOA
2.	**Query:** Since Rifapentine-Isoniazid and Rifapentine are newly approved drugs by the DCGI, two years of manufacturing and marketing experience of these products will not be available. Kindly clarify.	**Eligibility Criteria** **Clause 4 (c)** For all regulated products, the bidder should have at least two years of manufacturing and marketing experience of the particular items as a manufacturer for each regulated product quoted in the tender. However, this would not apply to regulated products which have been licensed by DCG (I) less than two years ago. DCG(I) is permission shall be required for all new regulated products to this effect.	Clarified as- Tender clause deleted for all Licenses issued under Form 46 from DCGI. If a License issued other than Form 46 tender clause shall be applicable.
3.	**Query:** (a) Since Rifapentine-Isoniazid and Rifapentine are newly approved drugs by the DCGI, the requirement of MMC/ MSC for last 2 years may please be deleted. (b) Since Rifapentine-Isoniazid	**Technical Specification:** **Clause 6 (e)** (a) Manufacturing and Market Standing Certificate / Market Standing Certificate issued by the Licensing Authority as a manufacturer for each item quoted for the last 2 years i.e 2020-21 & 2021-22 for	Clarified as- Tender clause deleted for all Licenses issued under Form 46 from DCGI. If a License issued other than Form 46 tender clause shall be applicable.

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S. No.	Query Received from Prospective Bidders	Standard Tender Clause	Response
	and Rifapentine are newly approved drugs by the DCGI, the Long Term (Real Time) Stability Data may please be deleted & replaced with the requirement of Accelerated stability Data.	compliance of tender clause 4.c. (b) Clause 6 (m): Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life.	
4.	**Query:** Rifapentine-Isoniazid & Rifapentine are new drugs approved by the DCGI. The product has been commercialized in FY 22-23. Kindly advise if it is acceptable to incorporate quantities manufactured in FY 22-23	**Schedule of Requirements:** **Clause 6.1(e)** Manufacturing and Market Standing Certificate / Market Standing Certificate issued by the Licensing Authority as a manufacturer for each item quoted for the last 2 years i.e 2020-21 & 2021-22 for compliance of tender clause 4.c.	Clarified as- Tender clause deleted for all Licenses issued under Form 46 from DCGI. If a License issued other than Form 46 tender clause shall be applicable.
5.	**Query:** Payment needs to be kindly considered as per invoice basis and request not to wait until supply of 50% of drugs ordered in the individual PO has been made.	**Payment Provision:** **Clause 17.5** Lot/Tranche/PO vise Part payments for supply will be considered only after completion of supply of at least 50% quantity ordered in the individual Purchase Order/Lot/Tranche PROVIDED original consignee receipts (or on GeM by consignee for the receipt, with original CRC to be submitted before next payment is released) are produced and the quality pass reports of Standard Quality on samples testing are received from approved laboratories of CMSS.	No Change
6.	**Query:** Rifapentine is not included in any Pharmacopoeia yet. Isoniazid is included in India Pharmacopoeia. Further, the fixed dose formulation of Rifapentine 300 mg + Isoniazid 300 mg Tablets is	**Technical Specification:** Each FDC tablet shall contain - Isoniazid 300 mg, Pharmacopeia* (IP/ BP/USP/Other International pharmacopeia) Rifapentine 300 mg, Pharmacopeia* (IP/ BP/USP/Other International	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

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S. No.	Query Received from Prospective Bidders	Standard Tender Clause	Response
	not official in any Pharmacopoeia as on date. We request your clarification if in house specifications of fixed dose formulation of Rifapentine 300 mg + Isoniazid 300 mg Tablets and Rifapentine 150 mg tablets is acceptable.	pharmacopeia) The quality of Isoniazid and Rifapentine shall conform to the requirements of the individual monograph given in IP or any other International Pharmacopoeia of equivalent accuracy. If the tendered drug is in Indian Pharmacopoeia (IP), then the manufacturing license has to be submitted in IP only. For drugs which are not available in IP, other official Pharmacopeia (s) are applicable. If a drug is not available in any of the official pharmacopeia, 'In House' standards are applicable as per Drugs and Cosmetics Act 1940 and Rules there under.	applicable as per the Drugs and Cosmetics Act 1940 and the Rules there. **Bidder is requested to submit an undertaking that the drug is not available in IP or any other approved pharmacopeia.**

Rest all Terms and Conditions remains same.

General Manager (Procurement)

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