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,
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Dated 22.02.2023

AMENDMENT NO. 12

Tender No- CMSS/PROC/2022-23/NTEP/022 for Procurement of TB Preventive Therapy Drugs for NTEP.

The following amendment in the subject bid document is made.

Sr. No	Queries	Existing Entry as per Tender Documents	Amendment
1	**Queries raised by M/s Oxalis-** Government of India's vision to Control TB in country can be successful only if patients get treated with quality product. We would like to inform you that 3HP (Rifapentine 300 mg + Isoniazid 300 mg) is a product which requires stringent manufacturing controls otherwise there can be generation of impurity in the product which is genotoxic and can cause cancer. We would request the program should establish the quality of the product and ensure that the product which is supplied for the program has impurities within the limits as specified by regulatory agencies like USFDA / WHO. Apart from our ability to provide a product with 36 months life, we reaffirm our ability to supply a product with proven efficacy which	Tender clause 14.6 - 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) Qualified signatures as applicable	Amended Tender clause 14.6- For Sch. I & II:- 1. 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

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	has impurities well within limits and will not have any toxic side effects.	OR/And The Performance Evaluation Report shall include: a) Product name b) Lot/Batch Number c) Date of manufacture d) Date of Expiry e) Manufacturer's name f) Number of samples tested g) Testing principle Information about reference used h) TESTING PROCEDURE- Sensitivity, Specificity etc i) Results j) report number k) Date of Analysis l) Designation and signature of analyst m) Authorized signatory of lab The above mentioned batch shall be manufactured in accordance with the applicable GMP/QMS regulations.	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.** **3. Bidder has to submit an undertaking in technical bid that Certificate of Analysis (CoA) report shall be submitted by the manufacturers in compliance withtender caluse 14.6 (1) and the prevailing global standards as mentioned at 14.6 (2) above at the time of supply.** **Annexure XII Undertaking is attached.**

All other terms and conditions of the bid document shall remain unchanged.

GM (Procurement)
Central Medical Services Society

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Annexure XXII
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 14.6 (1) (a) to (l) for each batch.

ii) The Certificate of Analysis (CoA) shall be in compliance with prevailing global standards as mentioned at 14.6 (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

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