3rd Mile Stone, Faridabad-Gurugram Expressway, Faridabad – 121001
Phone: +91-129-2876433

E-TENDER NOTICE
(RE-TENDER)

BID DOCUMENT
[Two bid system]

THSTI/NIT/03/21-22/IPDRUG/CDSA/01 **29th July 2021**

On behalf of the Executive Director, THSTI, Faridabad, Haryana, India, online bids are invited under two bid systems from reputed manufacturers or their authorized agents for the manufacture, randomization, storage and supply of the following Investigational Product drugs:

S. No.	Name of the Item	Specifications	Number of sites	Qty.
1	Manufacture, randomization, storage, and supply of investigation product Digoxin drug IP tablets	PET Bottle of 150 grooved tablets each OR Box of 15 blister strips with 10 tablets each of Digoxin drug IP tablets of 0.25 mg	12 Sites as per bid document	5280 Bottles OR 5280 boxes of 79200 strips (15 blister strips in each box)
2	Manufacture, randomization, storage, and Supply of placebo drug	PET Bottle of 150 grooved tablets each OR Box of 15 blister strips with 10 tablets each of placebo identical in shape, size, color, appearance, touch, smell and taste to the IP tablets of 0.25 mg		5280 Bottles OR 5280 boxes of 79200 strips (15 blister strips in each box)

Website for Online bid Submission : https://eprocure.gov.in
Last date & Time for online submission of bids : 12.08.2021 15.00 hours
Date/Time for opening of Technical bid : 13.08.2021 15.00 hours

Tender Fee of INR 500/-+18% GST (Non-refundable) is payable by using online payment portal (http://thsti.res.in/notification-tender.php**). The approved modes of payments are Net Banking, Debit Card, Credit Card and UPI**

KINDLY NOTE THAT ONLINE BID RECEIVED SHALL ONLY BE CONSIDERED AGAINST THIS TENDER ENQUIRY. Bids received by post/Fax/email bids shall not be considered and rejected straightway. **Further, requests for postponement will not be entertained.**

Executive Director, THSTI reserves the right to accept/ reject/modify any or all terms & conditions of this tender either in part or in full without assigning any reasons thereof.

(Rajeev Kr. Sharma)
Section Officer (S&P)

Note :

1. **All the bidders are requested to note that all future amendments/corrigendum will be published on THSTI / CPPP website and no separate advertisement will be released for the same. Bidders are therefore requested to regularly visit the cited websites for any such updates till the due date & time of this tender & thereafter too.**

GENERAL CONDITIONS OF CONTRACT (GCC)

1. Definitions

(i) In this Contract, the following terms shall be interpreted as indicated:

(i) "The Order" means the Purchase Order placed by the Purchaser including all the attachments and appendices thereto and all documents incorporated by reference therein;
(ii) "The Contract Price" means the price payable to the Supplier under the Order for the full and proper performance of its contractual obligations;
(iii) "The Goods" means all the equipment, machinery, and/or other materials, which the Supplier is required to supply to the Purchaser under the Contract;
(iv) "Services" means services ancillary to the supply of the Goods, such as transportation and insurance, and any other incidental services, such as installation, commissioning, provision of technical assistance, training and other obligations of the Supplier covered under the Contract
(v) "GCC" mean the General Conditions of Contract contained in this section.
(vi) "SCC" means the Special Conditions of Contract.
(vii) "The Purchaser" as specified in Special Conditions of Contract.
(viii) "The Purchaser's country" is "India".
(ix) "The Supplier" means the individual or firm supplying the Goods and Services under this Contract.
(x) "Day" means calendar day.
(xi) THSTI/ Executive Director/ Purchaser/ and SO represent same entity.

2. Application

These General Conditions shall apply to the extent that they are not superseded by provisions in other parts of the Contract.

3. Standards

The Goods supplied under this Contract shall conform to the standards mentioned in the Technical Specifications. When no applicable standard is mentioned, the authoritative standard appropriate to the Goods' country of origin shall apply. Such standards shall be the latest issued, by the concerned institution.

4. Use of Contract Documents and Information

The bidder shall not, without the Purchaser's prior written consent, disclose the Contract, or any provision thereof, or any specification, plan, drawing, pattern, sample or information furnished by or on behalf of the Purchaser in connection therewith, to any person other than a person employed by the Supplier in performance of the Contract. Disclosure to any such employed person shall be made in confidence and shall extend only so far, as may be necessary for purposes of such performance.

5. Patent Rights

The bidder shall indemnify the Purchaser against all third-party claims of infringement of patent, trademark or industrial design rights arising from use of the Goods or any part thereof in India.

6. Submission of the bids and Tender Fee /Bid Security declaration form

6.1 The procurement will be carried out through submission of online tenders only. No offer in physical form will be accepted and any such offer if received by THSTI will be out rightly rejected. Tender documents can be downloaded from website of CPPP www.eprocure.gov.in. and final bids (Technical and Financial) are to be uploaded on same website i.e www.eprocure.gov.in. The bidders should have a valid digital signature certificate (Class'II or Class'III) issued by any of the valid Certifying Authorities

to participate in the online tender. The bids shall be uploaded in electronic form only on www.eprocure.gov.in website. Before submission of bids, the bidders are requested to kindly read the "Guidelines to bidders on CPPP's e-procurement module" available at the end of this tender document.

6.2 Tender shall be accompanied with Bid security declaration form as per 'Annexure-I'. Failure to provide this bid may not be considered for further process.

6.3 The bidders who are registered with MSME/National Small Industries Corporation (NSIC) for tendered item(s) (Not eligible for service category) are exempted from depositing tender fees. However, valid registration certificate with the tender document is required to be enclosed while submitting the online bid.

6.4 Tender Fee shall be paid by using online payment portal. The approved modes of payments are Net Banking, Debit Card, Credit Card and UPI, failing which the bid will be rejected.

6.5 Print Final Payment Receipts and include the softcopy of the same in your technical bid.

Following are the steps for online payment:

1. Visit on Notification e Tender Page on THSTI Website (http://thsti.res.in/notification-tender.php) & click on Pay button beside the tender;

2. Fill Vendor Details i.e. Supplier Name, PAN No., Contact Person, Email Id, Mobile No. and click on "Continue to Payment" button;

3. Confirm Payment details after carefully examining the auto-fetched tender details and the filled information and click "Confirm and Redirect" to proceed to the payment gateway. The Email id and Mobile number will be used for the payment confirmation at the later stage;

4. Check Redirect to Payment Portal;

5. Make payment using any payment mode (i.e. Net Banking, Debit Card, Credit Card or UPI); fill in the mobile number, email id to receive email and SMS notification for your payment and click on "Proceed Now";

6. Redirect to Payment Status;

7. Provisional Transaction Receipt (if payment has not failed);

8. See your payment history by providing your details;

7. Inspections and Tests

The Purchaser or its representative shall have right to inspect and/or to test the Goods to ascertain its conformity to the Contract specifications at no extra cost to the Purchaser.

8. Packing

8.1 The Supplier shall provide such packing of the Goods as is required to prevent their damage or deterioration during transit to their final destination as indicated in the Contract. The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt and precipitation during transit and open storage. Packing case size and weights shall take into consideration,

where appropriate, the remoteness of the Goods' final destination and the absence of heavy handling facilities at all points in transit.

8.2 The packing, marking and documentation within and outside the packages shall comply strictly with such special requirements as shall be provided for in the Contract including additional requirements, if any, specified in SCC and in any subsequent instructions ordered by the Purchaser.

09. DETAILS OF DRUG TO BE SUPPLIED

9.1 The details of the required drugs, medicines, etc., are shown in ANNEXURE-II. The tender quantity mentioned herein is a fixed procurement quantity

9.2 The Tenderer shall fill in manufacturing capacity per year in units and Shelf life in months quoted drugs in a required column of ANNEXURE –III and submits along with the technical bid.

9.3 The rates quoted shall not be varied during the contract period.

10. Delivery and Documents

10.1 The drug, details of which given in Annexure –II will be supplied in three batches at the following locations:

SNo	Investigator Name	Site No. / Name	Address	Tel / Fax No. / E-mail
1.	Dr. G Karthikeyan (Principal applicant)	All India Institute of Medical Sciences, New Delhi	Dr. G Karthikeyan Room No. 24, 7th Floor, CN Centre, Department of Cardiology, AIIMS, Sri Aurobindo Marg, Ansari Nagar, Ansari Nagar East, New Delhi, Delhi 110029	karthik2010@gmail.com 9871074832 Dr. Gaurav Purohit: 8882766927
2.	Dr. Mohit Gupta/Dr. MP Girish	GB Pant Hospital, New Delhi	Dr. Mohit D Gupta, Room no 125, 1st floor, academics block, gate no 2, GB Pant Hospital (GIPMER), Jawahar Road, New Delhi	drmohitgupta@yahoo.com9810121311 mpgirish_1999@yahoo.com
3.	Dr. Rishi Sethi	King George Medical College, Lucknow	Dr. Rishi Sethi Administrative block, Department of Cardiology, King George's Medical University, Lucknow, U.P., 226003	drrishisethi1@gmail.com 9415085717

SNo	Investigator Name	Site No. / Name	Address	Tel / Fax No. / E-mail
4.	Dr. Sudeep Kumar	Sanjay Gandhi PG Institute, Lucknow	Dr. Sudeep Kumar C- block, Department of cardiology, Sanjay Gandhi postgraduate institute of medical sciences, Raebareilly road, Lucknow, U.P., India-2260147	sudeepkum@yahoo.com 9415016197
5.	Dr. Chandrabhan Meena	SMS, Jaipur -	Dr. Chandra Bhan Meena Department of Cardiology, SMS Medical College and Hospital, Jawahar Lal Nehru Marg, Jaipur	drcbhan@gmail.com 9414250934
6.	Dr. Sanjeev Asotra	IG Medical College, Simla	Indira Gandhi Medical College & Hospital, Ridge Sanjauli Rd, Lakkar Bazar, Shimla, Himachal Pradesh 171001 Phone: 0177 265 1854	dr.sanjeev00@gmail.com 9418080804
7.	Dr. Harikrishnan	SCTIMST, Trivandrum -	Jai Nagar W Rd, Chalakkuzhi, Thiruvananthapuram, Kerala 695011	drharikrishnan@hotmail.com 9895125101 drsanjayganesh@gmail.com 9447799137 Mr. Vineeth Coordinator: vineethcp2868@gmail.com 9895602356
8.	Dr. Santhosh Satheesh	JIPMER, Pondicherry -	Jipmer Campus Rd, Gorimedu, Puducherry, 605006	drsanthoshsatheesh@gmail.com 9443426244
9.	Dr. Reeta	Sri Satya Sai Institute, Bangalore -	Sri Sathya Sai Institute of Higher Medical Sciences EPIP Area, Whitefield, Bangalore 560 066, Karnataka, INDIA	reeta.v@sssihms.org.in 9448827401 imeprayaag@gmail.com 9900084979
10.	Dr. Ravi S math	Sri Jayadeva Institute, Bangalore	Dr. Ravi S Math, first floor, Sri jay deva Institute of cardiovascular sciences and Research, Bannerg hatta road, Jayanagar 9th Block, Bangalore, Karnataka, 560069	ravismath@rediffmail.com 9535108410
11.	Dr. Nagendra Boopathy	SRMC Chennai-	No.1, Ramachandra Nagar, Porur, Chennai, Tamil	drsnboopathy@gmail.com 9789836339/7358560284

SNo	Investigator Name	Site No. / Name	Address	Tel / Fax No. / E-mail
			Nadu 600116	
12.	Dr. Ananthakrishnan	INHS Aswini, Mumbai	near RC Church, Navy Nagar, Colaba, Mumbai, Maharashtra 400005	anantha25@yahoo.com 7506111334

10.2 Delivery of the Goods shall be made by the Supplier in accordance with the terms specified by the Purchaser in the order within the period as indicated in the SCC. The details of shipping and/or other documents to be furnished by the supplier are specified in SCC.

10.3 The drug is to be supplied in three batches. Site wise detail quantity will be notified later

10.4 Delivery of the goods should be made within **a maximum of 16 weeks (04 months)** from the date of placement of purchase order. Within 24 hours of shipment, the supplier shall notify the purchaser and the insurance company by cable/telex/fax/e mail the full details of the shipment including contract number, railway receipt number/ etc. and date, description of goods, quantity, name of the consignee, invoice etc. The supplier shall mail the following documents to the purchaser with a copy to the insurance company:

(i) Three copies of the Supplier invoice showing contract number, goods' description, quantity, unit price, total amount;
(ii) Acknowledgment of receipt of goods from the consignee(s) by the transporter;
(iii) Insurance Certificate if applicable;
(iv) Manufacturer's/Supplier's warranty certificate;
(v) Inspection Certificate issued by the nominated inspection agency, if any, and the Supplier's factory inspection report; and
(vi) Certificate of Origin.

11. TWO COPIES OF THE PACKING LIST IDENTIFYING THE CONTENTS OF EACH PACKAGEINSURANCE

11.1 The Goods supplied under the Contract shall be fully insured in Indian Rupees against loss or damage incidental to manufacture or acquisition, transportation, storage and delivery.

11.2 For delivery of goods at the purchaser’s premises, the insurance shall be obtained by the Supplier in an amount equal to 110% of the value of the goods from "warehouse to warehouse" (final destinations) against “All Risks" The insurance shall be valid for a period of not less than three months after delivery.

12. Transportation

The bidder is required under the Contract to transport the drugs to the various sites as mentioned in Clause 10 and transport to such destination in India including insurance, as shall be specified in the Contract, shall be arranged by the Supplier, and the related cost shall be included in the Contract Price.

13. Payment

13.1 100% payment shall be made by the Purchaser against the delivery at the site duly certified by the site

13.2 Receipt, report duly signed by the site
13.3 Purchaser is not liable to pay any interest amount on EMD in any condition.

14 PRICES

Prices charged by the Supplier for Goods delivered and Services performed under the Contract shall not vary from the prices quoted by the Supplier in the bid.

15. Subcontracts

15.1 The Supplier shall notify the Purchaser in writing of all subcontracts awarded under this Contract if not already specified in the bid. Such notification, in his original bid or later, shall not relieve the Supplier from any liability or obligation under the Contract.

15.2 Sub-contract shall be only for bought-out items and sub-assemblies.

16. Liquidated Damages

16.1 Since time is the essence of the contract, delivery of the Goods and performance of the Services shall be made by the Supplier in accordance with the time schedule specified by the Purchaser in the Contract.

17. Penalty

If the Supplier fails to deliver any or all of the Goods or to perform services within the period(s) specified in the Contract, the Purchaser shall, without prejudice to its other remedies under the Contract, deduct from the Contract Price, as penalty, a sum equivalent to 0.5% per week and the maximum deduction is 10% of the contract price.

18. Termination for Default

18.1 The Purchaser may, without prejudice to any other remedy for breach of contract, by Written notice of default sent to the Supplier; terminate the Contract in whole or part:
(i) If the Supplier fails to deliver any or all of the Goods within the period(s) specified in the order, or within any extension thereof granted by the Purchaser.
(ii) If the Supplier fails to perform any other obligation(s) under the Contract.
(i) If the Supplier, in the judgment of the Purchaser has engaged in corrupt or fraudulent practices in competing for or in executing the Contract.

18.2 For the purpose of this Clause:
(i) “Corrupt practice” means the offering, giving, receiving or soliciting of gratification to influence the action of a public official(s) in the procurement process or in contract execution.
(ii) “Fraudulent practice” means a misrepresentation of facts in order to influence a procurement process or the execution of a contract to the detriment of the purchaser, and includes collusive practice among Bidders (prior to or after bid submission) designed to establish bid prices at artificial non-competitive levels and to deprive the purchaser of the benefits of free and open competition;’”

19. Force Majeure

19.1 The Supplier shall not be liable for forfeiture of its performance security, liquidated damages or termination for default, if and to the extent that, it’s delay in performance or other failure to perform its obligations under the Contract is the result of an event of Force Majeure.

19.2 For purposes of this Clause, "Force Majeure" means an event beyond the control of the Supplier and not involving the Supplier's fault or negligence and not foreseeable. Such events may include, but are not limited to, acts of the Purchaser either in its sovereign

or contractual capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions, act of God and freight embargoes.

20. Resolution of Disputes

20.1 The Purchaser and the supplier shall make every effort to resolve amicably by direct informal negotiation any disagreement or dispute arising between them under or in connection with the Contract.

20.2 If, after thirty (30) days from the commencement of such informal negotiations, the Purchaser and the Supplier have been unable to resolve amicably a contractual dispute, either party may require that the dispute be referred for resolution to the formal mechanisms. These mechanisms may include, but are not limited to, conciliation mediated by a third party, adjudication in an agreed national or international forum, and national or international arbitration.

20.3 In case of Dispute or difference arising between the Purchaser and a domestic supplier relating to any matter arising out of or connected with this agreement, such disputes or difference shall be settled in accordance with the Indian Arbitration & Conciliation Act, 1996, the rules there under and any statutory modifications or re-enactments thereof shall apply to the arbitration proceedings. The dispute shall be referred to the Director THSTI and if he is unable or unwilling to act, to the sole arbitration of some other person appointed by him willing to act as such Arbitrator. The award of the arbitrator so appointed shall be final, conclusive and binding on all parties to this order.

(i) In the case of a dispute between the purchaser and a Foreign Supplier, the dispute shall be settled by arbitration in accordance with provision of sub-clause (a) above. But if this is not acceptable to the supplier then the dispute shall be settled in accordance with provisions of UNCITRAL (United Nations Commission on International Trade Law) Arbitration Rules.

21. Taxes and Duties

Suppliers shall be entirely responsible for all taxes, duties, license fees, road permits, etc., incurred until delivery of the contracted Goods to the Purchaser. However, GST in respect of the transaction between the Purchaser and the Supplier shall be payable as agreed, if so stipulated in the order.

22 Inspection and Tests:

The successful bidder will have to provide two samples for approval before issue of the supply order.

23. Applicable Law: The place of jurisdiction would be Faridabad, Haryana, INDIA.

24. Notices: For the purpose of all notices, the following shall be the address of the Purchaser and Supplier.

I Purchaser: **Executive Director,**

Translational Health Science and Technology Institute,
3rd Mile Stone, Faridabad-Gurugram Expressway, Faridabad – 121001
Phone: +91-129-2876433

II Supplier: (To be filled in by the supplier)

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SPECIAL TERMS OF CONTRACT

25 THE SUCCESSFUL BIDDER WILL SUPPLY THE IP DRUG AND PLACEBO AS PER THE CONDITIONS LAID DOWN HEREUNDER:-

25.1 IP tablets would be packed in bottle form, 150 tablets in each bottle **OR** blister strips of 10 tablets each (with 15 strips packed in a box that accounts 150 tablets in a box with 15 strips). Total IP to be manufactured would be total 10,560 bottles OR 1,58,400 blister strips (packed in 10,560 boxes) of IP [considering 1:1 randomization 5280 bottles each OR 79200 blister strips (packed in 5280 boxes) each of digoxin and placebo respectively]. The supply is to happen in 3 batches. The supplier shall supply the entire ordered quantity before the end of 120 days from the date of issue of purchase order at the destinations mentioned in the purchase order.

25.2 Warehousing and distribution from the manufacturing site should be the supplier's responsibility

25.3 All supplies will be scheduled for the period from the date of purchase order till the completion of the bid in installments, as may be stipulated in the purchase order

25.4 **Shelf Life:** The labeled shelf life of drugs supplied should be not less 2 years. The remaining shelf life of the drugs at the time of delivery should not be less than 3/4th of the labeled shelf life. Only those bidders shall quote who can manufacture and supply the product with the required shelf life. The product of labeled shelf life lesser than required shelf life will not be accepted. The product must be Stored at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F) [See USP Controlled Room Temperature] in a dry place and protect from light. Dispense in tight, light-resistant container and the same must be ensured during transit of shipments to site.

25.5 Quality Assurance: The supplier shall guarantee that the products as packed for shipment

25.5.1 comply with all provisions of specifications and related documents
25.5.2 meet the recognized standards for safety, efficacy and quality;
25.5.3 are fit for the purpose made;
25.5.4 are free from defects in workmanship and in materials and
25.5.5 the product has been manufactured as per India GMP, Schedule M/WHO-GMP.

25.6 The protocol of the tests should include the requirements given in I.P for tablets and those required specifically for the product specifications. The Bidder must submit its Test/ Analysis Report for every batch of drug to the unblnded designee to be notified later. In case of failure on the part of the supplier to furnish such report, the batch of drugs will be returned back to the supplier and he is bound to replenish the same with approved NABL accredited laboratory test report. The supplier shall provide the validation data of the analytical procedure used for assaying the components and shall provide the protocols of the tests applied and the placebo material when demanded for the purpose of testing.

25.7 The Tablets supplied by the successful Bidder shall be of the best quality and shall comply with the specification, stipulations and conditions specified in the Bid documents. The specifications are attached as Annexure -II

25.8 If supplies are not fully completed in **120 days** from the date of the Purchase Order, the provisions of liquidated damages of Bid conditions will come into force. The Supplier should supply the drugs at the sites specified in the Purchase Order and if the drugs supplied at a designated place other than those specified in the Purchase Order, transports charges will be recovered from the supplier.

25.9 The order stands canceled after the expiration of the delivery period, and if the extension is not granted with or without liquidated damages. Apart from risk/alternate purchase action, the Bidder shall also suffer forfeiture of the performance security and shall invite other penal action like blacklisting/Debarring disqualification from participating in present and future Bids of Bid Inviting Authority/ordering authority.

25.10 It shall be the responsibility of the supplier for any shortage/damage at the time of receipt at the designated places.

25.11 If the supplier or any of its approved items gets debarred/banned/blacklisted in any state after entering into agreement with THSTI, it shall be the responsibility of the supplier to inform THSTI without any delay about the same.

25.12 In case the Firm is black listed/debarred/banned after submission of bid document, it should inform the THSTI Authority within 15 days of blacklisting/debarring/banning. If the blacklisted/debarred / banned firm does not inform THSTI within stipulated time, a penalty amounting to two per cent of purchase orders issued between the date of blacklisting /debarring/banning and the date of informing to THSTI, both dates inclusive, shall be imposed, subject to a minimum penalty of Rs 20,000 and a maximum penalty up to Rs 2,00,000 only.

25.13 If it is brought to the notice of THSTI that the similar drug of the supplier firm has been found spurious / adulterated in any other state (whether the firm / product has been blacklisted/ debarred/ banned or not); then no further purchase orders shall be issued for the product and the purchase order with the firm for the product shall be cancelled.

25.14 If the supplier fails to execute full supply of the quantity mentioned in a purchase order then a penalty of 15 % of Value of unsupplied quantity shall be charged. Cases of zero supply against a purchase order shall also be dealt with in same manner.

25.15 Tablets should be supplied in bottle of 150 tablets each OR box of 15 blister strips with 10 tablets each with the labels provided by IIPH. (Indian Institute of Public Health).The tablet will come with a demarcation groove for being able to break in half and the placebo should also be identical. The bottle/ blister strip box should bear the words "**Not for sale only for use in Digoxin Trial, QC – Passed" overprinted.**

25.16 Storage directions should be clear, legible, preferably with yellow highlighted background.

25.17 Both the bottles/boxes of blister strips and the box in which the bottles/ boxes of blister strip for each participant are packed should have identical labels and should contain the following information on it

Trial name: Digoxin trial, Trial ID xxxx
KIT ID: **xxxxx** (5 digits numeric)
Batch ID: XXXXX (it should be same for both drug and placebo)
Manufacture date: mm/yyyy (it should be same for both drug and placebo)
Expiry date: mm/yyyy (it should be same for both drug and placebo)

Name and address of the manufacturer: To be finalized
Name and address of contact person- Dr. G Karthikeyan, Professor Cardiology, AIIMS, New Delhi

Store at 25°C (77°F) in a dry place and protect from light.
Dispense in tight, light resistant container. Keep out of reach of children.
Do not use if printed safety seal is broken or missing.

25.18 A uniform colour theme and artwork will be necessary. Apart from this "**Not for Sale only for use in Digoxin Trial, QC – Passed"** will be printed on each bottle/ blister strip boxes. The storage directions should be clear, legible and preferably with yellow highlighted background.

25.19 Bids for the supply for Tablets etc., shall be considered only if the Bidder gives undertaking in his Bid that the supply will be prepared and packed with the logogram printed on the b and labels of outer cartons per the design mentioned above.

25.20 All tablets have to be supplied in standard packing in bottle/ blister strip boxes also conform to schedule P1 of the Drugs & Cosmetics Act 1940 & Rules wherever it applies. Affixing of stickers and rubber stamps shall not be accepted.

25.21 **PACKING**

25.21.1 The item shall be supplied in the package schedule given below and the. The labeling of different packages should be as specified below. The packing in each carton shall be strictly as per the specification mentioned. Failure to comply with this shall lead to non-acceptance of the goods besides imposition of penalties.

25.21.2 It should be ensured that only first-hand fresh packaging material of uniform size is used for packing. All packaging must be properly sealed and temper proof.

25.21.3 The packing of Digoxin and Placebo both should be identical in all aspects.

25.21.4 All packing containers should strictly conform to the specifications prescribed in the relevant pharmacopoeia/Act.

25.21.5 Packing should be able to prevent damages or deterioration during transit.

25.22 QUALITY TESTING

25.22.1 Sampling of supplies from each batch will be done at the point of supply or distribution/storage points for testing. (The samples would be sent to different empaneled laboratories for testing by the ordering authority after coding).

25.22.2 Its mandatory for supplier to provide the Certificate of Analysis (COA) in the attached form which shall include:

- Generic name of the product
- Batch No.
- Pharmacopoeial Reference and/ or In-house method
- Batch quantity
- Date of manufacture
- Expiry date
- Date of test
- Description (clarity, colour etc)
- All identity, potency, purity, sterility, pyrogen and all the 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
- Conclusion
- Qualified signatures

25.22.3 The analysis report will be submitted to the unblinded designee nominated by THSTI.

25.23 The Drugs shall have the active ingredients within the permissible level throughout the shelf life period of the drug. The samples may also be drawn periodically during the shelf life period. The

supplies will be deemed to be completed only upon receipt of the quality certificates from the laboratories. Samples which do not meet quality requirements shall render the relevant batches liable to be rejected. If the sample is declared to be not of Standard Quality or spurious or adulterated or misbranded, such batch/batches will be deemed to be rejected goods.

25.24 In the event of the samples of the Tablets supplied failing quality tests or found to be not as per specification the ordering authority is at liberty to make alternative purchase of items of Tablets for which the Purchase orders have been placed from any other sources or from the open market or from any other Bidder who might have quoted higher rates at the risk and the cost of the supplier and in such cases the ordering authority has every right to recover the cost and impose penalty as mentioned in the NIT.

25.25 **Used, Unused/Expired drug Collection and disposal**

25.25.1 The selected firm (tenderer) shall be responsible for the handling, collection, transport and disposal of used, Unused/Expired drugs available at clinical sites mentioned in clause 10

25.25.2 It shall be the legal duty of the firm to ensure that used, unused/expired drugs are collected, transported and disposed in such a manner that they do not cause any adverse effect on human health or environment, as per the provisions of Bio-Medical Waste (Management & Handling) Rule 2016 (Rules)

25.25.3 All legal responsibility of used, unused/ Expired drugs shall be of the Contractor immediately after it being picked up from the sites

25.25.4 If any mishap happens during transportation all responsibility shall be that of the contractor.

25.25.5 Irrespective of shut down/ break down of the plant/ incinerator/ CTF of the Contractor, it will be the responsibility of the contractor to collect Expired drugs from sites.

25.25.6 The firm shall transport the Expired drugs in a dedicated covered vehicle to an authorized waste treatment facility center as per Rules and time to time according to instructions issued from the THSTI

25.25.7 It would be the inescapable duty of the firm to ensure that the instrument and practices used for the treatment and disposal of the waste is duly comply with the standards prescribed in Bio-Medical Waste (Management & Handling) Rules, 2016. The rules were amended in 2019 and these are mainly applicable to hospitals. There must be someth9ng else for manufacturing facilities.

25.25.8 The firm will provide Photo and video proof of the entire disposal process of the expired drugs collected from the sites.

25.25.9 The entire process of collection, transportation & disposal of drugs will be executed in presence of site and THSTI officials.

The Contractor will keep THSTI informed about the submission of annual reports and other reports as mandated by the appropriate pollution control authorities from time to time.

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INSTRUCTIONS TO BIDDERS (ITB)

INTRODUCTION

1. Eligible Bidders

1.1 This invitation for Bids is open to all manufacturers or their dealers specifically authorized by the manufacturers to quote on their behalf for this tender as per manufacturer's authorization form and Indian agents of foreign principals, if any who possess the qualifying requirements specified

1.2 Bidder shall be a manufacturer having valid drug manufacturing license duly licensed by licensing authorities or its authorized dealer who may participate on its behalf.

1.3 Manufacturer should have valid WHO-GMP and India GMP (Good Manufacturing Practices) certificate issued by licensing authority.

1.4 Distributors/Suppliers/Marketer/Agents/ /Loan Licensee are eligible to participate in the Tenders. The responsibility and the liability for the supply of the IP drug will be jointly shared with the Original drug Manufacturer. The Authorization form to be submitted as per Annexure – IV

1.5 Non-conviction Certificate not older than 12 months issued by the licensing authority of the State certifying that the firm/company has not been convicted.

1.6 Bids should not be submitted for the product(s) for which the firm / company has been blacklisted/debarred/de-registered/banned by any State Government /Central Government / its Drug procurement agencies due to quality failure of the drugs at the time of submission of bid.

1.7 The Bidder should have not been blacklisted/debarred/de-registered/banned due to quality failure for the quoted product /firm by any State Government / Central Government / its Drug procurement agencies at the time of submission of bid. Further, quoted drugs have not been failed in house testing or testing by any State Government/Central Government / its Drug procurement agencies/BPPI during last two years.

2. Cost of Bidding

The Bidder shall bear all costs associated with the preparation and submission of its bid, and "the Purchaser", will in no case be responsible or liable for these costs, regardless of the conduct or outcome of the bidding process.

THE BIDDING DOCUMENTS

3. Contents of Bid Document

The Bidder is expected to read all instructions, forms, terms (ITB/GCC/SCC etc.), and specifications in the bidding documents. Failure to comply with all information sought by the purchaser in the bidding documents or submission of a bid not substantially responsive shall result in rejection of the bid.

4. Amendment to Bid Document

The prospective bidders are required to keep a watch on the CPPP/THSTI website w.r.t. any amendment to the tender document or to clarification to the queries raised by the bidders up to seven days prior to the opening of the tender. The Purchaser reserves the right to reject the bids if the bids are submitted without taking into account these amendments/clarifications. In order to allow prospective bidders reasonable time in which to take the amendment into account in preparing their bids, the Purchaser, at its discretion, may extend the deadline for the submission of bids.

PREPARATION OF BIDS

5. Documents Comprising the Bid

The bidder is required to be uploaded bids on the CPP portal in **two parts**. One part is the Techno-Commercial Unpriced Bid and the other part is the Financial/Price Bid.

5.1 The Techno-Commercial Unpriced Bid prepared by the Bidder shall include the following without indicating the price in the Bid Form.

(i) Scanned copy of Tender fees as specified in the invitation to Bids.
(ii) Scanned Copy of Solvency Certificate
(iii) Bid security declaration from
(iv) Service Support Details Form;
(v) T&C Deviation Statement Form;
(vi) Technical Specification Compliance Form;
(vii) Manufacturer's Authorization Form.
(viii) Documentary evidence establishing that the bidder is eligible to bid and is qualified to perform the contract if its bid is accepted as per qualification requirements/criteria.
(ix) The Bidders are required to submit in original undertaking on stamp paper duly notarized by authorized signatory **(ANNEXURE – III)** confirming that they are holding the valid drug license, valid WHO-GMP and GMP certificate, valid Non-conviction certificate not older than 6 months issued by licensing authority. The drug manufacturing units participating in the bid process through an authorized supplier /dealer will also sign the given undertaking.
(x) Authorization letter nominating an officer of the Tenderer on the printed letter head of the company to transact the business with the THSTI to be uploaded. **Please also certify in authorization letter that nominated person of tenderer shall not represent any other tenderer in THSTI.**
(xi) The Bidders should submit Scanned copy of valid drug Manufacturing License for the product, duly approved by the Licensing Authority for the product quoted as per specification in the tender. The license must have been duly renewed up to date and the items quoted shall be clearly highlighted in the license.
(xii) The Bidders are required to submit attested copies of all critical documents including **Product Permission, Non-Conviction certificate, GMP certificate to THSTI**
(xiii) Scanned copy of Non-Conviction Certificate issued by the licensing authority of the State certifying that the firm/company has not been convicted should be uploaded. **The certificate should not be more than 12 months old at the time of submission of technical bid.**
(xiv) Scanned copy of Valid WHO_GMP and GMP (Good Manufacturing Practices) Certificate (for manufacturer only) issued by the Licensing Authority should be uploaded.

Original documents should be produced for verification when demanded. However, if renewal application for manufacturing license has been filed, Scanned copy of same duly receipted by drug authorities must be uploaded along with the validity certificate from State Licensing Authority (SLA). The Note: - Clear copy of valid drug license highlighting the drug code should be uploaded. In case scanned copy of license uploaded is not visible or tempered, THSTI shall not consider the license for such drug.

5.2 The Price/Financial Bid shall comprise the Techno Commercial Bid with price indicated in the bid form. Also, Price Schedule 'Part A' and 'Part B' given with tender to be uploaded after filling all relevant information like Rate, freight, insurance, custom duty etc. The Rate should be inclusive of all charges and no other charges shall be considered. The priced bid should be uploaded strictly as per the format available with the tender failing which the offer is liable for rejection (renaming or changing format of Price schedule sheet will not be accepted by system).

6. Bid Prices

6.1 The Bidder shall indicate the unit prices and total bid prices of the goods it proposes to Supply under the order and enclose it with the priced bid.

6.2 Prices indicated shall be entered separately in the following manner:

(i) The price of the goods, quoted (ex-works, ex-factory, ex-showroom, ex-warehouse, or off-the-shelf, as applicable), including all duties and sales and other taxes already paid or payable

(ii) **Taxes:** THSTI is exempted from payment of concessional GST as per the New Notification No. 45/2017-Central Tax (Rate) and 47/2017-Integrated Tax Rate dated 14th November 2017 and Customs Duty under notification No.51/96 dated 23.07.1996. Please mention the applicable taxes (GST) clearly. We don't issue any 'Form C' or 'Form D'. However, being R&D Organization Concessional customs duty Forms can be issued. **No other charges except those mentioned clearly in the bid will be admissible.**

(iii) Rates should be quoted F.O.R. at site at THSTI, Faridabad inclusive of packing, forwarding, loading & unloading, shifting up to the site of installation at THSTI, installation and commissioning charges etc. If ex-works prices are quoted then packing, forwarding, documentation, freight and insurance charges must be clearly mentioned separately and clearly. Vague terms like packing, forwarding, transportation etc. without mentioning the specific amount/ percentage of these charges will not be accepted. Such offers shall be treated as incomplete and rejected. **Where there is no mention of packing, forwarding, freight, insurance charges, such offers shall be assumed as all-inclusive of above charges.**

6.3 Prices quoted by the bidder shall remain fixed during the entire period of contract and shall not be subject to variation on any account. A bid submitted with an adjustable price the bid will be treated as non - responsive and rejected.

7. Bid Currencies

Prices shall be quoted in Indian Rupees Only.

8. Documents Establishing Bidder's Eligibility and Qualifications

8.1 Pursuant to THSTI, the bidder shall furnish, as part of the bid, documents establishing the bidders' eligibility to bid and qualification to perform the contract if the bid is accepted.

8.2 That the bidder meets the qualification criteria listed in Bid Document.

9. Resolution of Queries

Bidders participating in this Tender and who have any queries are requested to send their queries -both Technical and Commercial in advance by email to the e-mail: **Prashantbhujbal.cdsa@thsti.res.in** on or before 06 Aug 2021. Queries/clarification/ information sought in any other manner shall be ignored. Bidders are requested to update themselves by visiting the e-portal https://eprocure.gov.in frequently. It may be noted that no queries will be entertained after the expiry of abovementioned date.

10. Period of Validity of Bids

Bids shall remain valid for 90 days from the date of opening the bid prescribed by the Purchaser. A bid valid for a shorter period may be rejected by the Purchaser as non-responsive.

11. Format and Signing of Bid

11.1 The Bidder shall upload the bids in two parts. One part shall contain Techno commercial un-priced bid and the other shall contain the priced bid.

11.2 All pages of the bid, except for un-amended printed literature, shall be initialed by the person or persons signing the bid.

11.3 Any interlineations, erasures or overwriting shall be valid only if the persons or persons signing the bid endorse them.

11.4 The Bidder shall furnish information on commissions or gratuities, if any paid or to be paid to agents relating to this Bid, and to contract execution if the Bidder is awarded the contract as per the bid form.

11.5 The bid once accepted and awarded the contract the bidder will be obliged to execute the contract for the delivery and commissioning of the product at THSTI.

12. Modification and Withdrawal of Bids

12.1 Bid once submitted cannot be modified subsequent to the deadline for online submission of bids.

12.2 Further, Bid once submitted cannot be withdrawn in between the interval of deadline for online submission of bids and the expiration of the period of bid validity specified by the bidder on the bid form. Withdrawal of a bid during this interval may result forfeiture of the bid security of bidder.

OPENING AND EVALUATION OF BIDS

13. Opening of Bids by the Purchaser

13.1 The Purchaser will open all Techno Commercial Un-priced Bids, as per the schedule given in invitation to bids.

13.2 In the event of the specified date of Bid opening being declared a holiday for the Purchaser, the Bids shall be opened on the next working day.

13.3 The Financial/price bid of technically qualified bidders only will be opened at the date and time to be informed to the qualified bidders.

14. Clarification of Bids

To assist in the examination, evaluation and comparison of bids, the Purchaser may, at its discretion ask the bidder for any clarification(s) of its bid. The request for clarification and the response shall be in writing and no change in the price substance of the bid shall be sought, offered or permitted. However no post Bid clarifications at the initiative of the Bidder shall be entertained.

15. Preliminary Examination

15.1 The Purchaser will examine the bids to determine whether they are complete, whether required sureties have been furnished, whether the documents have been properly signed, and whether the bids are generally in order. Bid from suppliers, without proper Authorization from the manufacturers and from Indian agents without DGS&D Registration Certificate in case the items fall under the restricted list of the current EXIM/Foreign.

15.2 The Purchaser may waive any minor informality, non-conformity, or irregularity in a bid, which does not constitute a material deviation, provided such a waiver, does not prejudice or affect the relative ranking of any Bidder.

15.3 Prior to the detailed evaluation, the Purchaser will determine the substantial responsiveness of each bid to the Bid Document. For purposes of these Clauses, a

substantially responsive bid is one, which conforms to all the terms and conditions of the Bid Document without material deviations.

15.4 On downloading from the web site, the language of standard clauses etc. mentioned in this 'Bid Document' should not be tampered with/ changed/modified in any manner whatsoever. If any such modification etc. is noticed by the purchaser at any stage, the bid shall be rejected immediately and the bidder shall liable to be blacklisted for future participation in Institute tender.

16. Conversion to Single Currency

To facilitate evaluation and comparison, the Purchaser will convert all bid prices expressed in the amounts in various currencies in which the bid prices are payable to Indian Rupees at the selling exchange rate established by any bank in India as notified in the Newspapers/banks' website on the date of Price/Financial Bid opening.

17. Evaluation & Comparison of Bids

17.1 For the bids qualifying for the technical evaluation which have been found to be responsive the evaluation & comparison shall be made as under:

17.2 The final landed cost of purchase after all discounts, freight, forwarding, insurance (ware house to ware house), custom clearing charges taxes etc. shall be the basis of evaluation.

17.3 The final landed cost (ware house to ware house) of purchase taking into account, freight, forwarding, insurance, taxes etc. (CIF/CIP with customs duty, customs clearance charges, Bank/LC charges, transportation, delivery up to the site of installation at THSTI, Faridabad as per available records with THSTI for imported goods) shall be the basis of evaluation.

17.4 Conditional tenders/discounts etc. shall not be accepted. Rates quoted without attached conditions (viz. Discounts having linkages to quantity, payment terms etc.) will only be considered for evaluation purpose. Thus conditional discounted rates linked to quantities and prompt/advance payment etc, will be ignored for determining *inter-se* position. The Purchaser however reserves the right to use the discounted rate/rates considered workable and appropriate for counter offer to the successful tenderers.

18. Contacting the Purchaser

Any attempt by any Bidder to influence the Purchaser in its decisions on bid evaluation, bid comparison or contract award may result in rejection of the bid.

19. Purchaser's Right To Accept Any Bid and To Reject Any or All Bids

19.1 The Purchaser reserves the right to accept or reject any bid, and to annul the bidding process and reject all bids at any time prior to award of Contract, without thereby incurring any liability to the affected Bidder or bidders or any obligation to inform the affected Bidder or bidders of the grounds for the Purchaser's action.

19.2 Evidence regarding credibility of stable performance and maintenance service capability must be provided. The purchaser reserves the right to make judgment on this score and reject bids that, in the purchaser's view, do not carry sufficient credibility for performance and/or service.

20. Notification of Award

20.1 Prior to expiry of the period of bid validity, the purchaser will notify the successful bidder in writing by Purchase Order.

20.2 Upon the successful Bidder's furnishing of performance security the purchaser will promptly notify each unsuccessful Bidder and will discharge its bid security.

21. Order Acceptance

The successful bidder should submit acceptance of the Purchase Order immediately but not later than 21 days in any case from the date of issue of the Purchase Order failing which it shall be presumed that the vendor is not interested and his bid security is liable to be forfeited

22. Performance Security

22.1 The successful Bidder shall furnish the performance security equivalent to 03 % of the contract/order value, in the form of Bank Guarantee from any Nationalized Bank. Performance security should remain be valid for 14 months effective from date of delivery. The Bank guarantee template is annexed as **Annexure-V**

22.2 The payment will be released on receipt of performance security as per 22.1 above.

23. Supplier Integrity

The Supplier is responsible for and obliged to conduct all contracted activities in accordance with the Contract using state of the art methods and economic principles and exercising all means available to achieve the performance specified in the contract.

Annexure-I

BID SECURITY DECLARATION

(To be submitted by bidder on Non-Judicial Stamp Paper of Rs.100/-only duly attested by Notary)

We, (*Name of bidding firm with its address*_____) do hereby certify and declare that we are interested and genuinely participating in the Tender Enquiry No. _____ for (tender description _____) invited by the THSTI.

We further undertake that if we withdraw or modify the submitted bid during the period of Bid validity, or if we will be awarded the order / contract and If we fail to acknowledge the order / sign the contract, or to submit a performance security before the deadline defined in the Tender document, the order awarded / work contract issued shall be terminated at the discretion of Competent Authority, THSTI and our firm will be suspended / blacklisted for the period of 03 years from being eligible to submit Bids for tenders with the THSTI in future.

Date:

Name and Signature of Authorized
Signatory of bidding firm along with stamp

ANNEXURE-II

Details of Drug to be supplied (Clause 10)

(1)	(2)	(3)	(4)	(5)
Sr. No.	**Generic name of the drug**	**Composition / Strength**	**Unit Size**	**Tender quantity in unit size**
1	Digoxin IP Tablet	The Investigation product consists of tablets of Digoxin drug 0.25 mg strength. The tablet will come with a demarcation groove for being able to break in half. 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.	One Bottle of 150 tablets OR Box with 15 blister strips of 10 tablets each	5280 Bottles OR 5280 boxes of 15 blister strips of 10 tablets each
2	Investigation placebo tablet	The Investigation placebo product consists of tablets which must be identical in shape, size, color, appearance, touch, smell and taste to the drug. The placebo 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.	One Bottle of 150 tablets OR Box with 15 blister strips of 10 tablets each	5280 Bottles OR 5280 boxes of 15 blister strips of 10 tablets each

PROTOCOL, TESTING AND STORAGE

The supplier has to share all testing protocols and procedures being followed for the analysis of drug and will have to share Certificate of Analysis of each batch with the purchaser

The product must be Stored at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F) [See USP Controlled Room Temperature] in a dry place and protect from light. Dispense in tight, light-resistant container and the same must be ensured during transit of shipments to site.

ANNEXURE-III

DECLARATION & UNDERTAKING

(On Non-Judicial Stamp Paper of Rs 500/-)

I Name……S/o……..Age… Prop. /Partner/Director/Power of attorney holder / Authorized dealer of firm M/s……situated at (Complete address of Mfg. unit)……bearing drug license on Form 25, 28, 10, etc bearing Number…… &……respectively, issued on dated……..valid/Renewed up to…do hereby declare on oath as follows:-

1. That none of the quoted Drugs and Medicines manufactured/imported by us since the grant of the above drug license have been found as of spurious or adulterated quality and no case in this regard is pending in any court.

2. That the quoted product is manufactured/imported by us, and none has been declared as "Not of standard quality" during last two years.

3. That we have following Commitment of quantity in our plant at the above address

S.No.	Quoted item Code No. & Name of Drugs	Monthly Capacity in all shifts in nos.	Annual Production Capacity	Monthly supply Commitment to RMSCL in nos.	Supply Commitment quantity during rate contract period (not be less than estimated bid quantity)	Estimated Bid Quantity as per	GSTIN Number & Name of State where GSTIN registered
1.							
2.							

4. That concern/company/firm does not stand blacklisted/banned/debarred on any ground by Bid Inviting Authority or Government of …….State (Name of the state in which the manufacturing facility is located) or its departments on the date of bid submission.

5. The concern/company/firm does not stand blacklisted/banned/debarred on the ground of conviction by court of law or the products being found spurious or adulterated by any other State /Central Government or it"s any agencies (central Drugs procurement agencies). But my firm is blacklisted/banned/debarred on a different ground by a procurement agency, the details of which are given below----------(Write „NIL" if no such matter exists)

6. That our Firm/Company and its Proprietor/Partner/Directors/ Power of attorney holders have not been convicted for contravention of any provisions of Drugs & Cosmetic Act 1940 and rules made there under since grant of license.

7. That we have been granted product permission by the State Licensing Authority for manufacture of quoted products as per the details given below:-

S. No.	Code No.	Name of the Product	Date of product permission obtained from the Licensing Authority	Whether Endorsement is in Generic or Trade Name	Issuing Licensing Authority	Own manufacturing / Loan Licensee (Please mention)	Drug manufacturing/Import License Number for quoted items

S. No.	Code No.	Name of the Product	Date of product permission obtained from the Licensing Authority	Whether Endorsement is in Generic or Trade Name	Issuing Licensing Authority	Own manufacturing / Loan Licensee (Please mention)	Drug manufacturing/Import License Number for quoted items
1.							
2.							

8. That we have over three years" experience in the manufacture of the quoted product, or the quoted imported product has over 3 years market standing.
9. That we have approved qualified staff, machines & equipment along with the capacity to manufacture the above category of drugs, and our unit have been issued WHO-GMP/ GMP * by Licensing Authority vide letter No…….dated…….valid up to……..
10. That we hereby confirm that we have deposited all the VAT/Sale Tax/ GST & filling returns as applicable as on……..With the department. central excise / State commercial department is due on M/s……as on……..
11. That I will supply the Drug and Medicines per the designs given in Bid clause no 14 and as per the instructions given in this regard.
12. That I/We have carefully read all the conditions of e- Bid in Ref. no. XX and accept all conditions of Bid, including amendments if any. In case of typographical error found in submitted documents/affidavits, in this case, we accept all the Terms and conditions of bid documents.
13. I/We agree that the Bid Inviting Authority forfeiting the Bid security Deposit and or Performance Security and blacklisting /Debarring/Banning me/ us for 5 years or as deemed fit if, any information furnished by us proved to be false/fabricated at the time of inspection and not complying the conditions as per Schedule M of the said Act or at any time during the Bid process.
14. I/we possess the necessary professional, technical, financial, and managerial resources and competence required by the Bidding Document issued by the Procuring Entity. I/we have fulfilled my/our obligation to pay such of the taxes payable to the Union and the State Government or any local authority as specified in the Bidding Document; I/we is not insolvent, in receivership, bankrupt, or being wound up. not have my/our affairs administered by a court or a judicial officer, not have my/our business activities suspended and not the subject of legal proceedings for any of the foregoing reasons;
15. I/we do not have, and our directors and officers not have been convicted of any criminal offense related to my/our professional conduct or the making of false statements or misrepresentations as to my/our qualifications to enter into a procurement contract within three years preceding the commencement of this procurement process, or not have been otherwise disqualified according to debarment proceedings;
16. l/we do not have a conflict of interest as specified in the Act, Rules, and the Bidding Document, which materially affects fair competition.
17. Our complete address for communication

    ……
    ……
    ……
    ……Pin…….

    E-mail address: - ……...
    Phone No. /Mobile No……

(Name of Deponent & Signature)
Designation

Verification

I……..S/o……(Designation)……
Affirm on oath that the contents/information from para 1 to 17 as mentioned above, are true & correct to the best of my knowledge and nothing is hidden. I also declare on oath, that if any information furnished by me as above is found wrong, false, forged, or fabricated; the Corporation will be at liberty to cancel the Bid for which I shall be solely responsible and the firm may be Debarred/Banned/blacklisted/prosecuted for the same.

(Name of Deponent & Signature)
Witness :- (Name, Address & Signature) 1
2

*The GMP/WHO-GMP certificate must not be older than one year from the last date of Bid submission in case validity is not mentioned in the certificate.

ANNEXURE-IV

MANUFACTURERS' AUTHORIZATION FORM

No. _____ Date: _____

To,
The Executive Director,
Translational Health Science and Technology Institute,
3rd Mile Stone, Faridabad-Gurugram Expressway, Faridabad – 121001
Phone: +91-129-2876433

Dear Sir:

We _____ who are established and reputable manufacturers of having factories/works at (address) do hereby authorize M/s (Name and address of Agent) to submit a bid, negotiate and receive the order from you against your tender inquiry mentioned vide Tender ID No…….

No company or firm or individual other than M/s_____ is authorized to bid, and conclude the contract in regard to tender.

We hereby extend our full guarantee and warranty as per the terms and conditions of the General Conditions of Contract and of the Special Conditions of Contract for the supply of Clinical IP drugs to be supplied by the above firm and all the acts performed by M/s…….. in respect of supply of IP drug will be construed as performed by us.

Yours faithfully,

(Name)

(Name of manufacturers)

Note: This letter of authority should be on the letterhead of the manufacturer and should be signed by a person competent and having the power of attorney to bind the manufacturer. It should be included by the Bidder in its techno-commercial unpriced bid.

BID FORM

To,
The Executive Director,
Translational Health Science and Technology Institute,
3rd Mile Stone, Faridabad-Gurugram Expressway, Faridabad – 121001
Phone: +91-129-2876433

Dear Sir/Madam,

After reading the bid document carefully, we hereby declare that we accept all the terms and condition of the bid document and would like to submit our bid for supply of _____ (Description of Goods).

We undertake to deliver the goods at THSTI premises in accordance with the terms of tender, if awarded the contract.

If our bid is accepted we will produce the performance security in the shape of bank guarantee as specified in SCC.

Yours Faithfully

Signature with date of authorized person
Name & Designation

ANNEXURE-V

Form of Performance Bank Guarantee/Bank Guarantee
(TO BE SUBMITTED FROM ANY INDIAN NATIONALIZED BANKS ONLY)

BG No.:…… Date…….

From **The Name of the Bank**	**To** **Translational Health Science Technology Institute, Faridabad**

In consideration of the Translational Health Science and Technology Institute, Faridabad (hereinafter called "The INSTITUTE") having offered to accept the terms and conditions of the proposed agreement between The Institute……and…… (hereinafter called "the Contractor(s)"for the work……. (hereinafter called "the said agreement'') having agreed to production of an irrevocable Bank guarantee for Rs…… (Rupees……only) as a security/guarantee form the contractor(s) for compliance of his obligations in accordance with the terms and conditions in the said agreement.

1. We …….. (hereinafter referred to as the ''Bank'') hereby undertake to (Indicate the name of the Bank) Pay to the Institute an amount not exceeding Rs…… (Rupees…… only) on demand.

2. We…(indicate the name of the Bank) ……. Do hereby undertake to pay the amounts due and payable under this Guarantee without any demur, merely on a demand from the Institute stating that the amount claimed is required to meet the recoveries due or likely to be due from the said contractor(s). Any such demand made on the Bank shall be conclusive as regards the amount due and payable by the Bank under this Guarantee. However, our liability under this Guarantee shall be restricted to an amount not exceeding Rs…… (Rupees……only).

3. We, The said Bank, further undertake to pay to the Institute any money so demanded notwithstanding any disputes raised by the contractor(s) in any suit or proceeding pending before any Court or Tribunal relating thereto, our liability under this present being absolute and unequivocal. The payment so made by us under this bond shall be a valid discharge of our liability for payment thereunder, and the contractor(s) shall have no claim against us for making such payment.

4. We (indicate the name of the Bank) …… further agree that the Guarantee herein contained shall remain in full force and effect during the period that would be taken for the performance of the said agreement, and it shall continue to be enforceable till all the dues of the Institute under or by virtue of the said agreement have been fully paid, and its claims satisfied or discharged, as per the terms and

conditions of the said agreement have been fully and properly carried out by the said contractor(s), and accordingly discharges this guarantee.

5. We……(Name of the bank)…… further agree with the Institute that the Institute shall have the fullest liberty without our consent, and without effecting in any manner our obligations hereunder, to vary any of the terms and conditions of the said agreement or to extend time of performance by the said contractor(s) from time to time or to postpone for any time or from time to time any of the powers exercisable by the Institute against the said contractor(s), and to forbear or enforce any of the terms and conditions relating to the said agreement, and we shall not be relieved from our liability by reason of any such variation or extension being granted to the said not be relieved from our liability by reason of any such variation or extension being granted to the said contractor(s) or for any forbearance, act of omission on the part of the Institute or any indulgence by the Institute to the said contractor(s) or by any such matter or thing whatsoever which under the law relating to sureties would, but for this provision, have effect of so relieving us.
6. This Guarantee will not be discharged due to the change in the constitution of the Bank or the contractor(s).
7. We ……(Name of the bank)……. lastly under take not to revoke the Guarantee except with the previous consent of the Institute in writing. This bank Guarantee on the Bank or its successors or permitted assigns.

8. We……(Indicate the name of the Bank)…… lastly undertake not to revoke this Guarantee except with (indicate the name of the Bank) the previous consent of the Institute extended on demand by the Institute. Notwithstanding anything mentioned above, our liability against this Guarantee is restricted to Rs…….(Rupees……..only), and unless a claim/demand is made on the bank in writing on or before ……all your rights under the Guarantee will be forfeited and we shall be relieved and discharged from all liabilities thereunder.

Authorised Signatories of the Bank with name and Seal

Name of the Officer:
Designation:
Code if any:
Date:
Place

Annexure VI

BID SECURITY UNDERTAKING

To,
The Executive Director,
Translational Health Science and Technology Institute,
3rd Mile Stone, Faridabad Gurgaon Expressway
Faridabad – 121001

Dear Sir

Having examined the bidding document the receipt of which is hereby duly acknowledged, we the undersigned offer to supply and deliver _____ (Description of Goods) in conformity with the said bidding documents for a sum or such other sums as may be ascertained from the bid.

We undertake if our bid is accepted, to deliver the goods in accordance with the delivery schedule specified.

We agree to abide by this bid for requisite period as fixed for bid opening as per the instructions to the bidders. Further it shall remain binding upon us and accepted at any time before the expiry of that period.

Until a formal contract is prepared and executed, this bid, together with your written acceptance thereof and your notification of award shall constitute a binding contract between us.

We understand that you are not bound to accept the lowest or any bid you may receive.

Dated this _____day of _____20_____

Signature_____in
the capacity of_____

Duly authorized to sign the bid for and on behalf of _____

Price Bid Format

PRICE SCHEDULE (FINANCIAL BID)

PRICE SCHEDULE FORMANUFACTURE, RANDOMISATION, STORAGE AND TRANSPORRT OF IP DRUG

1	2	3	4						5
S. No.	Brief Description of Goods (with make & model)	Quantity (Nos)	Price per unit (Rs.) Ex-factory / Ex-warehouse /Ex-showroom / Off-the shelf (a)	GST (if any) [%age & value] (b)	Transportation, loading/ unloading and incidental costs till consignee's site (c)	Insurance charges for a period including 3 months beyond the date of delivery (d)	Incidental services (including installation & commissioning, supervision, demonstration and training) at the consignee's site (e)	Unit price (at consignee site) basis (f) =a+b+c+d+e	Total price (at consignee site) (Rs.)
	Manufacture storage and Randomization and supply Digoxin IP drug tablets. (To be manufactured in three batches)	5280 Bottles of 150 tablets each OR 5280 boxes (15 blister strip of 10 tablets each) total 79200 blister strips of 10 tablets							

		each							
	Manufacture, storage and Randomization of Placebo drug tablets. (To be manufactured and three batches)	5280 Bottles of 150 tablets each OR 5280 boxes (15 blister strip of 10 tablets each) total 79200 blister strips of 10 tablets each							
2.	Shipment of Digoxin and Placebo to sites as mentioned	12 sites as per Clause 10							
3.	Collection, transport, and destruction of the used, unused, Expired drugs (1 & 2above) [OPTIONAL]								

Total value in Rupees: (in figures):- _____
In words: _____

Note: -

1. If there is a discrepancy between the unit price and total price THE UNIT PRICE shall prevail.

Name: _____
Business Address _____
Signature of Tenderer _____
Seal of Tenderer _____

Place:_____
Date:_____

Guidelines to bidders on CPPP e-Procurement Module

1. **Procedure for Registration by the Bidder**

1.1. Bidders are required to enroll on the e-Procurement module of the Central Public Procurement Portal (URL: https://eprocure.gov.in/eprocure/app) by clicking on the link "Click here to Enroll" on the CPP Portal.

1.2. As part of the enrolment process, the bidders will be required to choose a unique username and assign a password for their accounts.

1.3. Bidders are advised to register their valid email address and mobile numbers as part of the registration process. These would be used for any communication from the CPP Portal.

1.4. Upon enrolment, the bidders will be required to register their valid Digital Signature Certificate (Class II or Class III Certificates with signing key usage) issued by any Certifying Authority recognized by CCA India (e.g. Sify / TCS / nCode / eMudhra etc.), with their profile.

1.5. Only one valid DSC should be registered by a bidder. Please note that the bidders are responsible to ensure that they do not lend their DSC's to others which may lead to misuse.

1.6. Bidder then logs in to the site through the secured log-in by entering their user ID / password and the password of the DSC / e-Token.

2. **Searching for Tender Documents**

2.1. There are various search options built in the CPP Portal, to facilitate bidders to search active tenders by several parameters. These parameters could include Tender ID, organization name, location, date, value, etc. There is also an option of advanced search for tenders, wherein the bidders may combine a number of search parameters such as organization name, form of contract, location, date, other keywords etc. to search for a tender published on the CPP Portal.

2.2. Once the bidders have selected the tenders they are interested in, they may download the required documents / tender schedules. These tenders can be moved to the respective 'My Tenders' folder. This would enable the CPP Portal to intimate the bidders through SMS / e-mail in case there is any corrigendum issued to the tender document.

2.3. The bidder should make a note of the unique Tender ID assigned to each tender, in case they want to obtain any clarification / help from the Helpdesk.

3. **Procedure for preparation and submission of bids**

3.1. The documents should be page numbered and contain the list of contents with page numbers. The deficiency in documentation may result in the rejection of the Bid.

3.2. Bidder should take into account any corrigendum published (if any) on the tender document before submitting their bids.

3.3. The documents should be page numbered and contain the list of contents with page numbers. The deficiency in documentation may result in the rejection of the Bid.

3.4. Bidder should take into account any corrigendum published (if any) on the tender document before submitting their bids.

3.5. Bidders are advised to go through the Tender advertisement and the Tender document carefully to understand the documents required to be submitted as part of the bid. Please note the number of covers in which the bid documents have to be submitted, the number of documents - including the names and content of each of the document that need to be submitted. Any deviations from these may lead to rejection of the bid.

3.6. Bidder, in advance, should get ready the bid documents to be submitted as indicated in the tender document / schedule and generally, they can be in PDF formats. Bid documents may be scanned with 100 dpi.

3.7. To avoid the time and effort required in uploading the same set of standard documents which are required to be submitted as a part of every bid, a provision of uploading such standard documents (e.g. PAN card copy, annual reports, auditor certificates etc.) has been provided to the bidders. Bidders can use "My Space" area available to them to upload such documents. These documents may be directly submitted from the "My Space" area while submitting a bid, and need not be uploaded again and again. This will lead to a reduction in the time required for bid submission process.

3.8. As part of the bid, bidder should provide all the documents as follows:-

- Bidder should log into the site well in advance for bid submission so that he/she upload the bid in time i.e. on or before the bid submission time. Bidder will be responsible for any delay due to other issues.
- The bidder has to digitally sign and upload the required bid documents one by one as indicated in the tender document.
- The serve time (which is displayed on the bidders' dashboard) will be considered as the standard time for referencing the deadlines for submission of the bids by the bidders, opening of bids etc. The bidders should follow this time during bid submission.
- All the documents being submitted by the bidders would be encrypted to ensure the secrecy of the data. The data entered cannot be viewed by unauthorized persons until the time of bid opening. The confidentiality of the bids is maintained using the secured Socket Layer 128 bit encryption technology. Data storage encryption of sensitive fields is done.
- The uploaded tender documents become readable only after the tender opening by the authorized bid openers.

- Upon the successful and timely submission of bids, the portal will give a successful bid submission message & a bid summary will be displayed with the bid no. and the date & time of submission of the bid with all other relevant details.
- The bid summary has to be printed and kept as an acknowledgement of the submission of the bid. This acknowledgement may be used as an entry pass for any bid opening meetings

4. Assistance to Bidders

Any queries relating to the NIT document and the terms and conditions contained therein should be addressed to the Store Purchase Officer, Translational Health Science and Technology Institute.

Any queries relating to the process of online bid submission or queries relating to CPP Portal in general may be directed to the 24x7 CPP Portal Helpdesk. The contact number for the helpdesk is 1800 3070 2232.