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### Tender Details

Date : 16-Nov-2024 06:37 PM



#### Basic Details

Organisation Chain	Department of Health Research  Indian Council of Medical Research		
Tender Reference Number	ICMR-NITM/24-25/drug development HH 1		
Tender ID	2024_DoHR_778565_1		
Tender Type	Open Tender	Form of contract	Buy
Tender Category	Services	No. of Covers	2
Payment Mode	Offline	Is Multi Currency Allowed For BOQ	No
Is Multi Currency Allowed For Fee	No		

#### Payment Instruments

Offline	S.No	Instrument Type
	1	As Per Tender Document

#### Cover Details, No. Of Covers - 2

Cover No	Cover	Document Type	Description
1	Fee/PreQual/ Technical	.pdf	technical bid
2	Finance	.xls	financial bid

#### Tender Fee Details, [Total Fee in ₹ \* - 0.00]

Tender Fee in ₹	0.00		
Fee Payable To	NA	Fee Payable At	NA
Tender Fee Exemption Allowed	NA		

#### EMD Fee Details

EMD Amount in ₹	1,20,000	EMD Exemption Allowed	Yes
EMD Fee Type	percentage	EMD Percentage	3.0%
EMD Payable To	DIRECTOR, ICMR NITM	EMD Payable At	icmr nitm belagavi

#### Work /Item(s)

Title	The preparation of test drugs in the GMPcertified manufacturing units for clinical trial				
Work Description	The preparation of test drugs in the GMPcertified manufacturing units for clinical trial				
Pre Qualification Details	Please refer Tender documents.				
Tender Value in ₹	40,00,000	Product Category	Miscellaneous Services	Sub category	preparation of test drugs
Contract Type	Tender	Bid Validity(Days)	180	Period Of Work(Days)	180
Location	ICMR NITM Belagavi	Pincode	590010	Pre Bid Meeting Place	NA
Pre Bid Meeting Address	NA	Pre Bid Meeting Date	NA	Bid Opening Place	ICMR NITM Belagavi

#### Critical Dates

Publish Date	16-Nov-2024 06:50 PM	Bid Opening Date	09-Dec-2024 12:00 PM
Document Download / Sale Start Date	17-Nov-2024 09:00 AM	Document Download / Sale End Date	07-Dec-2024 06:20 PM
Clarification Start Date	17-Nov-2024 09:05 AM	Clarification End Date	22-Nov-2024 09:10 AM
Bid Submission Start Date	17-Nov-2024 09:15 AM	Bid Submission End Date	07-Dec-2024 06:20 PM

#### Tender Documents

NIT Document	S.No	Document Name	Description	Document Size (in KB)
	1	Tendernotice_1.pdf	Tender for The preparation of test drugs in the GMP certified manufacturing units for clinical trial	782.83

<b>Work Item Documents</b>	<b>S.No</b>	<b>Document Type</b>	<b>Document Name</b>	<b>Description</b>	<b>Document Size (in KB)</b>
	1	Tender Documents	CPPPtenderfinal1.pdf	The preparation of test drugs in the GMPcertified manufacturing units for clinical trial	782.83

<b><u>Tender Inviting Authority</u></b>	
<b>Name</b>	Administrative Officer, ICMR NITM
<b>Address</b>	ICMR NITM NEHARU NAGAR BELAGAVI

<b><u>Tender Creator Details</u></b>	
<b>Created By</b>	Harsha Hegde
<b>Designation</b>	Scientist E
<b>Created Date</b>	16-Nov-2024 06:32 PM



**icmr**  
INDIAN COUNCIL OF  
MEDICAL RESEARCH

**NITM**  
NATIONAL INSTITUTE OF  
TRADITIONAL MEDICINE

## NOTICE INVITING TENDER

For

The preparation of test drugs in the GMP ( Good manufacturing Practices)-certified manufacturing units

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### PROJECT TITLE

1. Efficacy and safety of ointment containing 5% essential oil from *Mammea suriga* (Buch.-Ham. ex Roxb.) Kosterm. flower buds in treatment of diabetic foot ulcers: A multicentric parallel group randomized controlled trial.

&

2. Multicentric, randomized, double-blind, parallel-group, controlled trial to evaluate efficacy and safety of gel containing *Plumbago zeylanica* root for mild to moderate osteoarthritis of knee.

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### **ICMR- National Institute of Traditional Medicine**

Department of Health Research, Ministry of Health and Family Welfare, Govt. of India  
Nehru Nagar, National Highway No. 4,  
Belagavi, Karnataka- 590010  
Tele: 08312439213  
[www.icmrnitm.res.in](http://www.icmrnitm.res.in)

**Confidential**

No part of this document can be reproduced in any form or by any means, disclosed or distributed to any person without the prior consent of ICMR-National Institute of Traditional medicine, Belagavi except to the extent required for submitting bid and no more.

**Disclaimer**

1. Though adequate care has been taken while preparing the Notice Inviting Tender, the Bidders shall satisfy themselves that the document is complete in all respects. Intimation of any discrepancy shall be given to this office immediately. If no intimation is received from any Bidder within twenty one (21) days from the date of notification of Notice/ Issue of the Notice, it shall be considered that the Notice is complete in all respects.
2. ICMR-National Institute of Traditional Medicine, Belagavi reserves the right to modify, amend or supplement this Notice.
3. While this Notice has been prepared in good faith, neither ICMR-NITM nor their employees or advisors make any representation or warranty, express or implied, or accept any responsibility or liability, whatsoever, in respect of any statements or omissions herein, or the accuracy, completeness or reliability of information, and shall incur no liability under any law, statute, rules and regulations as to the accuracy, reliability or completeness of this Notice, even if any loss or damage is caused by any act or omission on their part.

Place: Belagavi

Date: 16-11-2024

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### 1. Bid Information Sheet

The time schedules for various tender-related events are follows:

Document Description	Tender document for "The preparation of test drugs in the GMP-certified manufacturing units for clinical trial"
Notice Inviting Bid No. & Date	Ref. No. ICMR-NITM/24-25/drug_development_HH dated 17-11-2024
Bid Submission Start Date	17-11-2024
<b>Last date &amp; Time of Submission of Bid</b>	07-12-2024
Bid Opening Date	08-12-2024
EMD	3% of estimated cost
ePBG	3% of contract value
Contract Period	6 (Six) calendar month
Bid Estimated Value	INR 40,00,000.00
Validity of Bid	180 days (One hundred and eighty days) from the date of opening of bid
Tender Inviting Authority	Administrative Officer
<b>Important Note:</b> Prospective Bidders are requested to remain updated for any notices/amendments/clarifications etc. to the Notice Inviting Bid through the websites <a href="https://eprocure.gov.in/epublish/app">https://eprocure.gov.in/epublish/app</a> and <a href="http://www.icmrnitm.res.in">www.icmrnitm.res.in</a> . No separate notification will be issued for such notices/amendments/clarifications etc. in print media or individually.	

ADMINISTRATIVE OFFICER  
(S/d)

## **2. Definition**

- 2.1** "Notice Inviting Tender" means all Volumes and its Annexures and any other documents provided along with this Notice or issued during the course of the selection of bidder, seeking a set of solution(s), service(s), materials and/or any combination of them.
- 2.2** "Contract/Agreement/Contract Agreement/Master Service Agreement" means' The agreement to be signed between the successful bidder and ICMR – NITM, including all attachments, appendices, all documents incorporated by reference thereto together with any subsequent modifications, the Notice, the bid offer, the acceptance and all related correspondences, clarifications, presentations.
- 2.3** "Bidder" means any GMP Certified drug manufacturing site registered in India or having registered office in India submitting response, offering the solution(s), service(s) and/or materials as required in the Notice. The word Bidder when used in the pre-award period shall be synonymous with parties bidding against this Notice, and when used after award of the Contract shall mean the successful party (System Integrator (SI)) with whom the agreement is signed for rendering of services for implementation of this project.
- 2.4** "Proposal/Bid" means the Pre-Qualification, Technical and Commercial bids submitted for this project against this Notice.
- 2.5** "Authorized Signatory" shall indicate the authorized person/signatory who can discuss and correspond with the ICMR – NITM, with regard to the obligations under the contract.
- 2.6** "Bid Deadline" shall mean the last date and time for submission of Bid in response to this Notice as specified in information Sheet therein including all amendments there to;
- 2.7** "Chartered Accountant" shall mean a person practicing in India or a firm where all the partners practicing in India as a Chartered Accountant(s) within the meaning of the Chartered Accountants Act, 1949;
- 2.8** "Company" shall mean a body corporate incorporated in India under the companies Act, 1956 or the companies Act, 2013, as applicable;
- 2.9** "Contract" shall mean the Contract signed by the Parties and all the attached documents listed in the Notice, also including all amendments/clarifications thereof;
- 2.10** "ICMR" shall mean Indian Council of Medical Research (ICMR Hqrs. And ICMR Institutes) (An Autonomous Body under MOHFW)
- 2.11** "Selected Bidder or Successful Bidder" shall mean the eligible Bidder who has been selected based on this document issued by ICMR – NITM;
- 2.12** "Services" shall mean requirements defined in this Notice including all necessary and additional services associated thereto to be delivered by the bidder related to the Scope of Work.
- 2.13** "The Government" means the Government of India.
- 2.14** "Day" means calendar day;
- 2.15** "Week" means calendar week;
- 2.16** "Month" means calendar month;
- 2.17** "TBEC" means Technical Bid Evaluation Committee;
- 2.18** "SP" means Service Provider
- 2.19** "Corrupt practice" means: (i) the offering, giving, receiving, or soliciting, directly or indirectly, of anything of value to influence the action of any person connected with the selection process (for avoidance of doubt, offering of employment to or employing or engaging in any manner whatsoever, directly or indirectly, any official of the ICMR – NITM who is or has been associated in any manner, directly or indirectly with the selection process or the Letter of Intent or has dealt with matters concerning the Agreement or arising there from, before or after the execution thereof, at any time prior to the expiry of one year from the date such official resigns or retires from or otherwise ceases to be in the service of the ICMR – NITM, shall be deemed to constitute influencing the actions of a person connected with the selection process); or (ii) save as provided herein, engaging in any manner whatsoever, whether during the selection process or after the issue of the Letter of Agreement (LOA) or after the execution of the agreement, as the case maybe, any person in respect of any matter relating to the project or the LOA or the agreement, who at any time has been or is a legal, financial or technical consultant/adviser of the ICMR – NITM in relation to any matter concerning the project;
- 2.20** "Fraudulent practice" means a misrepresentation or omission off acts or disclosure of incomplete facts, in order to influence the selection process;
- 2.21** "Coercive practice" means property to influence any person's participation or action in the selection process;
- 2.22** "Undesirable practice" means: (i) establishing contact with any person connected with or employed or engaged by ICMR – NITM with the objective of canvassing, lobbying or in any manner influencing or attempting to influence the selection process; or (ii) having a conflict of interest; and
- 2.23** "Restrictive practice" means forming a cartel or arriving at any understanding or arrangement among bidders with



the objective of restricting or manipulating a full and fair competition in the selection process.  
**2.24** GMP means Good Manufacturing Practices.

### 3. Scope of Work

#### Part I – Scientific requirements

##### ICMR- National Institute of Traditional Medicine, Belagavi

**Requirement:** Preparation and supply of the following Test Drugs for topical application, with all the necessary approvals/ licensing for their clinical trials. The products listed and described in Sl. No. 2 & 3 are to be matched for their consistency and colour to each other. For this purpose, a suitable colouring agent, approved in the Schedule Q of Drugs and Cosmetics rules or colours approved in IS 4707 (1988).

#### 1. Ointment containing 5% essential oil:

The ointment to be prepared with the essential oil in an approved ointment base, formulated with approved ingredients or complying with ointment base specified in IP.

- 1.1. Quantity Required: 500 no. of packings each with 10 gm of ointment. 10 g ointment needs to be taken out by the subjects. Hence slightly higher quantity, maybe 10.5 g may be filled.
- 1.2. Packing: 10.5 g Collapsible tubes with lid.
- 1.3. The ointment so prepared should be stable and not show any bleeding or melting when stored at room temperature up to 40°C.

#### 2. Gel containing *Kashaya* of 50 g plant powder:

Gel formulation has to be prepared by mixing the *Kashaya* of 50 g of plant powder with the suitable, approved Gel base such as Carbomer 980 with suitable humectant added.

- 2.1. Quantity Required: 9000 number of packings with 5 g of Gel each. As 5 g Gel needs to be taken out by the subjects, a slightly higher quantity, maybe 5.5 g Gel may be filled into each packing.
- 2.2. Packing: 5.5 g Gel in wide-mouthed amber glass/PET bottles with lid OR in sachets.
- 2.3. Preliminary evaluation of gel for applicability on skin and consistency needs to be done. Evaluation needs to be done at one month, when stored at room temperature ( $28 \pm 2$  °C RH at 60 %), for any separation.

#### 3. Diclofenac Gel (1%) matching with Gel containing *Kashaya*

The Gel matching with that of containing *Kashaya* in its characteristics (appearance, consistency, color) to be prepared to facilitate blinding.

- 3.1. Quantity Required: 9000 number of packings with 5 g of Gel each. As 5 g Gel needs to be taken out by the subjects, slightly higher quantity, may be 5.5 g Gel may be filled in to each packing selected should be same for both products at Sl No 2 & 3.
- 3.2. Packing: 5.5 g Gel in wide mouthed amber glass/PET bottles with lid OR in sachets.
- 3.3. The packing should match with that of above (2) Gel containing *Kashaya* of plant powder

**Note :** If the supplier has any other options for packing the products at Sl No. 2 & 3 delivering the specified quantity, they may be discussed and agreed upon between supplier and ICMR-NITM.

#### Product Requirements:

- Proprietary Ayurvedic Medicine license to be obtained for the products 1 & 2. The names of the Essential Oil and Plant Powder with their classical references will be provided by ICMR-NITM.

**Note:** Product at SL No 3 containing Diclofenac will be a product licensed under D & C rules and is a non-prescription product. The supplier of products listed at SL No 1 & 2 may coordinate appropriately for supply of products at SL no 3 with a licenced manufacturer including matching the consistency and colour.

- The packings to be affixed with a label with mutually agreed text, provided by ICMR-NITM.
- The labelled packings to be supplied to ICMR-NITM packed in outer box of 25 each.

- Batch production records, analysis of all RM reports to be prepared and kept with the firm. The samples of these final products to be analysed for their QC report (like Congealing point, Viscosity or consistency by Renolds Viscometer at the specified RPM measured at 30°C, Content of the Oil, Acid value, peroxide value, and Microbial Quality etc. as applicable) and certificate of analysis to be provided. ICMR-NITM will provide method of testing of each of the product by TLC/ HPTLC, which shall be performed by the supplier or getting tested by approved testing facility and to provide the report of the TLC/HPTLC profiles with the certificate of analysis.
- Retention samples of the batch for 1 & 2 to be kept at room temperature for 3 months and COA of the batch after 3 month also to be provided.

#### **General Requirements:**

- Firm to provide copy of their GMP certification and the product has to be developed in a GMP Certified production unit.
- Required Raw Materials (Essential Oil and the Plant powder) will be provided by ICMR-NITM.
- Stability (For 1 & 2): The firm to do stability studies for 3 Months at RT and accelerated conditions and provide the data. Firm can discuss the stability study protocol with ICMR-NITM.
- The results of all the standardization & evaluation are to be provided to the ICMR-NITM.
- The required approvals/ certifications/ licensing for the test products (1 & 2) need to be obtained by the firm.

#### **Part II - Other Terms and Conditions**

1. The contract period shall be six months, commencing from the date of giving contract order and concluding after six calender months.
2. The successful bidder shall be responsible for the preparation of specified quantities of test drugs as per the scientific specifications provided by the institute.
3. All manufacturing sites for the preparation of specified quantities of test drugs must be GMP-certified.
4. The successful bidder shall ensure that all drugs/ API and ingredients used must be of good quality and approved certifications.
5. All manufacturing processes must comply with Good Manufacturing Practices (GMP) standards.
6. The supplier should provide properly packed and labelled products
7. **Timeframe: The supply of prepared and packed test drugs to be supplied within four months from the date of providing the raw materials. However, delivery schedules could be discussed and agreed upon between the two parties.**
8. The successful bidder must comply with all applicable laws and regulations, including those related to GMP, labor, and environmental standards.
9. The successful bidder must obtain all necessary permits and licenses.

-Sd/-

Administrative Officer  
ICMR-NITM, Belagavi

#### **4. BID INFORMATION AND INSTRUCTIONS TO BIDDERS**

##### **4.1 Clarification:**

The bidders should ensure that their queries regarding the tender reach ICMR – NITM on or before 6-12-2024 @ 6.00 PM. Bidders may also email their queries to [stores.nitm@icmr.gov.in](mailto:stores.nitm@icmr.gov.in)

##### **4.2 Responses to Queries and Issue of Corrigendum:**

- 4.2.1** ICMR – NITM will endeavor to respond promptly to all queries. However, ICMR – NITM makes no representation or warranty regarding the completeness or accuracy of any response made in good faith.
- 4.2.2** At any time prior to the last date for receipt of bids, ICMR – NITM may, for any reason, whether at its own initiative or in response to a clarification requested by a prospective Bidder, modify the tender Document by a corrigendum.
- 4.2.3** The Corrigendum (if any) & and clarifications to the queries from all bidders will be posted on ICMR NITM website.
- 4.2.4** Any such corrigendum shall be deemed to be incorporated into this tender.
- 4.2.5** In order to afford prospective Bidders reasonable time in which to take the corrigendum into account in preparing their bids, NITM may, at its discretion, extend the last date for the receipt of Bids

##### **4.3 BID format**

- 4.3.1** The entire bid proposal shall be strictly as per the format specified in this Invitation for bids and any deviation may result in the rejection of the bid proposal. The tender documents are to be submitted through offline mode/hard copy to the below-mentioned address:

**The Director,  
ICMR-National Institute of Traditional Medicine  
NH 04, Nehru Nagar,  
Belagavi – 590010**

- 4.3.2** The following documents are to be submitted through offline mode/hard copy to the above mentioned address.

- 4.3.2.1** Format of Covering Letter (Format 1)
- 4.3.2.2** Format for Performance Bank Guarantee (Format 2)
- 4.3.2.3** Eligibility Criteria (Format 3)
- 4.3.2.4** Format for Technical Bid (Format 4)
- 4.3.2.5** Format for Covering Letter for Financial Bid (Format 5)
- 4.3.2.6** Format for Financial Bid (Format 6)
- 4.3.2.7** Format for Draft Contract Agreement (Format 7)
- 4.3.2.8** Annual Turnover (Format 8)
- 4.3.2.9** Format for Statutory Auditor's Certificate for Furnishing Net worth Details (Format 9)
- 4.3.2.10** Manufacturers'/Producers/Parent companies Authorization Form, if applicable (Format 10)
- 4.3.2.11** Declaration that the company has not been blacklisted in last three years (Format 11)
- 4.3.2.12** Format for BID security Declaration (Format 12)

##### **4.4 Earnest Money Deposit (EMD):**

- 4.4.1** Bidders are required to submit an Earnest Money Deposit (EMD) amounting to 3% of the total bid value. Exemptions from EMD submission are applicable for eligible MSEs and startups, as per government rules, upon submission of valid certification. The EMD amount must be submitted in the original form of demand draft along with the bid latest by the last date of bid submission .
- 4.4.2** The earnest money given by all the tenderers except the lowest tenderer will be refunded at the earliest immediately after the expiry of stipulated bid validity period or immediately after acceptance of the successful bidder, whichever is earlier. EMD of the successful Bidder will be returned after receipt of Performance Guarantee.
- 4.4.3** EMD should be in favour of

**The Director,  
ICMR-National Institute of Traditional Medicine  
NH 04, Nehru Nagar,  
Belagavi – 590010**

#### **4.5 The bid document should outline:**

- 4.5.1** Brief company profile, GMP certification, services offered, accreditation, participation in EQAS etc.
- 4.5.2** A detailed proposed project management plan for undertaking the work/implementation of services as detailed in the Scope of Work.
- 4.5.3** Number and Competence of resources proposed to be allocated for the project which individual(s) will undertake the work, including why they are suitable to do so, and a short CV
- 4.5.4** All manufacturing processes must comply with Good Manufacturing Practices (GMP) standards.
- 4.5.5** Subsequent to the assessment of submitted interests by a technical expert committee (TEC), the GMP-certified manufacturing units may be subjected to evaluation audits as relevant and determined.

#### **4.6 Validity of Bids**

The validity of the bids shall be 180 days from the date of opening of bids.

#### **4.7 Bidding Process:**

- 4.7.1** The bidders should submit their proposal offline in the provided format, with comprehensive details. The bidders satisfying the technical requirements of GMP-certified manufacturing units, as asked by ICMR-NITM and accepting the terms and conditions of this document shall be short-listed and may be called for a presentation
- 4.7.2** The shortlisted bidders will be security vetted. Bidders who fail to clear the security vetting will be disqualified from further selection.
- 4.7.3** The shortlisted bidders will be technically scrutinized thoroughly by the expert team of the ICMR-NITM. **2 days time will be allowed for Technical Clarifications during technical evaluation. Shortfall documents and reply to clarifications can be submitted through email. On failure to submission of any required technical documents**, the tender will be disqualified from further process i.e. for financial bid.
- 4.7.4** The successful bidder in both technical and financial will have to enter a non-disclosure agreement with ICMR-NITM, which include additional terms and conditions on information sharing and confidentiality, which may not be mentioned in the bid document and instructions on inviting the tender
- 4.7.5** Even though a bidder may satisfy the above requirements, the bidder may be liable to disqualification if the bidder has:
  - 4.7.5.1** Made misleading or false representation or deliberately suppressed the information or not submitted sufficient information in the forms, statements and enclosures required in the pre-qualification documents
  - 4.7.5.2** Record of poor performance such as abandoning work, not properly completing the contract, or financial failures /weaknesses etc.
- 4.7.6** ICMR-NITM reserves the right to change above bidding process.

#### **4.8 Instructions to Bidders**

- 4.8.1** The bidders may download the tender document from CPPP portal. No physical copy of the bid document would be made available.
- 4.8.2** Bidders are advised to study all instructions, forms, terms, requirements and other information in the tender document carefully. Submission of the bid shall be deemed to have been done after careful study and examination of the tender document with full understanding of its implications.
- 4.8.3** The response to this tender should be full and complete in all respects. Failure to furnish all information required by the tender document or submission of a proposal not substantially responsive to the tender document in every respect will be at the Bidder's risk and may result in rejection of its tender Proposal.
- 4.8.4** **Exemptions for Micro and Small Enterprises (MSEs) and startups will be provided in accordance with applicable government rules and regulations. Eligible MSEs and startups are required to submit relevant certifications to qualify for these exemptions**
- 4.8.5** The bidder is responsible for all costs incurred in connection with the participation in this process, including, but not limited to, costs incurred in conduct of informative and other diligence activities, participation in meetings/presentations, and preparation of bid along with providing any additional information required by ICMR-NITM to facilitate the evaluation process.

- 4.8.6 ICMR-NITM will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the bidding process.
- 4.8.7 This tender does not commit ICMR-NITM to award a contract or to engage in negotiations. Further, no reimbursable cost may be incurred in anticipation of award or for preparing this bid.
- 4.8.8 All materials submitted by the bidder will become the property of ICMR-NITM and may be returned completely at its sole discretion.
- 4.8.9 ICMR-NITM may terminate the tender process at any time and without assigning any reason. The institute makes no commitments, express or implied that this process will result in a business transaction with anyone.
- 4.8.10 The cost of bidding and submission of bid documents is entirely the responsibility of bidders, regardless of the conduct or outcome of the process.
- 4.8.11 **Language of bids:** The bid and supporting documents shall be submitted in English.
- 4.8.12 **Format and signing of bid:** Each page of the bid document should be numbered as 'page n of total x pages. Each page of the bid document must be signed and duly stamped by an authorized person of the bidding firm. Each bid will be submitted in the legal name of the bidder.
- 4.8.13 **Last Date and Time for acceptance of Bids:** Duly completed bids along with all supporting documents should be submitted offline to the address mentioned in clause no. 4.2 by latest by 06-12-2024 @ 6:00 PM. Incomplete bids shall summarily be rejected.
- 4.8.14 **Response to the Notice:** The bidder must submit the following documents with the bid in response to the Notice Inviting Bid:
  - 4.8.14.1 Point-wise compliance of each clause enumerated in the Notice.
  - 4.8.14.2 Eligibility Criteria checklist and related document
  - 4.8.14.3 Technical bid.
  - 4.8.14.4 Financial Bid
  - 4.8.14.5 Signed Copy of the Notice.
  - 4.8.14.6 Scanned copy bid security Declaration

Any Bid incomplete or not submitted in the given format or not duly paginated and signed by the authorized signatory of the Bidder shall be summarily rejected. Any deviation with the tender document should be clearly stated with the reasons thereof, as per technical deviation format given.

#### 4.9 Method of submission

The response to tender Document should be in Two cover bid systems and its details are given below:

- 4.9.1 **Technical Bid Cover** – Technical bid containing the details as per Format – 3 & 4 and other annexures should be submitted offline to the address mentioned in clause no. 4.2 under Technical bid cover.
- 4.9.2 **Financial Cover** –Financial bid should be submitted offline to the address mentioned in clause no. 4.2 under Financial bid cover. Format of the price bid given in Format – 5 & 6 is for reference.
- 4.9.3 Both the technical bid cover and the financial bid cover must be submitted separately and enclosed within the single covering letter, as per Format 1.

**Important Note:** *The bidders shall not deviate from the naming and the numbering formats mentioned above, in any manner. Any deviation shall invite summary rejection of the bid.*

#### 4.10 Performance Guarantee

- 4.10.1 The successful Tenderer shall, within 7 days from the date of receipt of communication of acceptance of quotes from NITM shall intimate his acceptance of the order. An Integrity Pact shall be submitted by the successful Tenderer.
- 4.10.2 The successful bidder shall be required to submit a **Performance Guarantee equivalent to 3% of the contract value** in the form of Bank Guarantee, Demand Draft issued by any Commercial Bank in India. Time allowed for submission of Performance Guarantee shall be 15 days from the date of issue of letter of acceptance. This period can be further extended at the written request of the contractor by Competent Authority for a maximum period ranging from 1 to 15 days with late fee @0.1% per day of Performance Guarantee amount.
- 4.10.3 The performance Guarantee will remain valid for 60 days beyond the date of completion of all contractual obligations of the supplier.

- 4.10.4** The Performance security will be forfeited and credited to the Procuring Entity's account in the event of a breach of contract by the contractor.
- 4.10.5** The Performance Security will be refunded to the supplier without interest after the supplier duly performs and completes the contract in all respects.
- 4.10.6** If the successful tenderer, fails to furnish the prescribed performance guarantee on or before stipulated dates of commencement, shall without prejudice to any other right or remedy, be at liberty to suspend the bidder for one year from the date issue of suspension order.

#### **4.11 Evaluation**

- 4.11.1** The Overall objective of this evaluation process is the preparation of test drugs in the GMP-certified manufacturing units for clinical trial
- 4.11.2** The competitive bids shall be evaluated in the following stages:
- 4.11.2.1 Stage 1 – Technical Evaluation (Technical Bid):** Bidders must satisfy the Eligibility criteria as mentioned in the table 5.1. The technical proposal of the bidders will then be evaluated by a Technical Bid Evaluation Committee. Only the financial bids of the bidders who passed the technical evaluation will be opened.
- 4.11.2.2 Stage 2 – Financial/Commercial Bid**

**Table 4.1**

<b>S. No.</b>	<b>Eligibility Criteria</b>	<b>Proof Required</b>
1	The bidder should be registered in India under the Company Act, 1956 or have registered office in India for last 3 years.	Copy of Certificate of Incorporation/Registration,
2	The bidder/ unit have all the required relevant permissions and approvals for the production of drugs.	Provide the copies of all the permissions and approvals for the same.
3	Annual Gross Turnover  Gross annual turnover of the bidder firm during the last three Financial years 2020-21, 2021-22 and 2022-23 should be at least INR 20 Lakhs	Audited financial Statements (reflecting overall turnover) /annual report containing financial statement for the last three financial years  A certificate duly certified by the statutory auditor/CA of the bidder clearly mentioning the Gross annual turnover of the bidder.  As per Format-9
4	The Bidder should have valid GST Registration, Income Tax returns, and PAN card.	Copy of GST Registration , Income Tax returns for last 3 financial years (till 2022-23), Statutory Audit report from CA for last 3 FY (till 20-21), copy of PAN card
5	As on date of submission of the bid, the bidder should not be blacklisted by any Government entity in India and that there is no legal incapacity preventing the Bidder to enter into a contract.	Certificate duly signed signatory As per Format- 11
6	Letter of authorization from OEM/Parent organization (if applicable).	Format-10 if applicable
7	Bid Security Declaration	Bid Security Declaration as per Format 12
8	Bidder should have minimum 3 years' experience in production of Drugs in GMP certified manufacturing unit in India. If so, the details of such productions/ services to be furnished.	Copies of work orders/MoUs/Agreements

9.	List of relevant SOPs	Necessary documents
10	List of relevant equipment	Necessary documents
11	Proof of calibration for equipment should be provided	Necessary documents
12	CV of the Director/ In-charge/ Technical Head of the GMP-certified Manufacturing Unit	Necessary documents
13	<b>Latest MSME certificate in relevant category</b> (if applicable)	Necessary certificates



## 5. Special Conditions of Contract (SCC)

### 5.1 Instruction to Bidders

- 5.1.1 Bidder shall create a process document for carrying out the drug development in GMP-certified manufacturing units and submit the same to ICMR-NITM within 7 days of the award of the contract. This document shall clearly define all the processes to be undertaken by the bidder and standard operating procedures (SOP), the processes involved to meet all the requirements in the scope of work and SLA..
- 5.1.2 **As per applicable government rules, registered Micro and Small Enterprises (MSEs) and eligible startups are granted exemptions on submission of valid certifications. These exemptions include relaxation in requirements such as experience, turnover, and EMD (Earnest Money Deposit) where applicable."**
- 5.1.3 Bidder will provide the sufficient resources to fulfill service level requirements and availability as defined in this document.
- 5.1.4 Bidder shall have to keep the call records updated with applicable call resolution time details, exclusion etc., for all trial site locations in Excel on monthly basis.
- 5.1.5 Escalation matrix shall be given for the staff and other activities so that backup supports be available.
- 5.1.6 The selected Company shall not, without ICMR-NITM's prior written consent, disclose the contract, or any provision thereof, of any specification, plan sample of information furnished by or on behalf of ICMR-NITM in connection therewith, to any person other than a person employed by the SP in the performance of the contract. Disclosure to any such employed person shall be made in confidence and shall extend only as far as may be necessary for purposes of such performance.
- 5.1.7 All empaneled companies automatically agree with ICMR-NITM for honoring all aspect of fair-trade practices in executing the work orders placed by ICMR-NITM.
- 5.1.8 ICMR-NITM will process the bid as per procedures mentioned in tender document. It however, reserves the right to reject any bid without assigning any reason. ICMR-NITM would not be under obligation to give any clarifications to those agencies whose bid have been rejected.
- 5.1.9 ICMR-NITM reserves the right to modify and amend any of the tender condition/criterion depending upon Project priorities vis-à-vis urgent commitments. ICMR-NITM also reserves the right to cancel this bid without assigning any reason therefore.
- 5.1.10 **OPTION CLAUSE:** The buyer can increase or decrease the contract quantity or contract duration up to 25 percent at the time of issue of the contract. However, once the contract is issued, contract quantity or contract duration can only be increased up to 25 percent. Bidders are bound to accept the revised quantity or duration

### 5.2 Fraud and Corrupt Practices

The Bidders and their respective officers, employees, agents and advisers shall observe the highest standard of ethics during the Selection Process. Notwithstanding anything to the contrary contained in this Notice, the ICMR-NITM shall reject the proposal without being liable in any manner whatsoever to the Bidder, if it determines that the Bidder has, directly or indirectly or through an agent, engaged in corrupt practice, fraudulent practice, coercive practice, undesirable practice or restrictive practice (collectively the "Prohibited Practices") in the Selection Process. In such an event, the ICMR-NITM shall, without prejudice to its any other rights or remedies, forfeit and appropriate the Performance Security, as the case may be, as mutually agreed genuine pre-estimated compensation and damages payable to the Authority for, inter alia, time, cost and effort of the authority, in regard to the Notice, including consideration and evaluation of such bidder's proposal.

### 5.3 Conflict of Interest

The bidder shall disclose to ICMR-NITM in writing, all actual and potential conflicts of interest that exist, arise or may arise (either for the Bidder or the core bidder's team) in the course of performing the Service(s) as soon as practical after it becomes aware of that conflict.

### 5.4 Consequences of Termination

- 5.4.1** In the event of termination of the Contract due to any cause whatsoever, [whether consequent to the stipulated term of the Contract or otherwise], ICMR-NITM shall be entitled to impose any such obligations and conditions and issue any clarifications as may be necessary to ensure an efficient transition and effective business continuity of the service(s) which the vendor shall be obliged to comply with and take all available steps to minimize loss resulting from that termination/breach, and further allow the next successor Vendor to take over the obligations of the erstwhile Vendor in relation to the execution/ continued execution of the scope of the Contract.
- 5.4.2** After signing of the agreement, ICMR NITM reserves the right to modify/terminate the contract in case of technical/regulatory reasons.
- 5.4.3** The termination hereof shall not affect any accrued right or liability if either Party nor affect the operation of the provisions of the Contract that are expressly or by implication intended to come into or continue in force on or after such termination.
- 5.4.4** If the bidder issues notice of termination based on the fact that there is change to its legal entity status or solvency or due to any Scheme of Merger or Demerger, then the Bidder is duty bound to identify the alternate mutually acceptable implementing Agency in order to ensure continuity of the obligations as per the SOW. If this is not possible before the effective date of the termination as notified, ICMR-NITM can exercise any of the rights as stated under subclause 5.4.2 hereinabove.

## **5.5 Penalty**

- 5.5.1** The Bidder shall perform its obligations under the agreement entered into with the ICMR- NITM, in a professional manner.
- 5.5.2** In the event of failure of executing the tasks as defined in above Chapter, penalty would be levied subject to a maximum of 10% of the payment for that period.
- 5.5.3** ICMR-NITM may recover such amount of penalty from any payment being released to the Bidder.
- 5.5.4** If any act or failure by the bidder under the agreement results in failure or inoperability of systems and if the ICMR-NITM has to take corrective actions to ensure functionality of its property, the ICMR-NITM reserves the right to impose penalty, which may be equal to the cost it incurs or the loss it suffers for such failures.
- 5.5.5** ICMR-NITM may impose penalty to the extent of delay caused due to non-performance and loss of time, if the delay was due to the actions directly attributable to the staff of Bidder.
- 5.5.6** The ICMR-NITM shall implement all penalty clauses after giving 15 days due notice to the bidder. If the Bidder fails to complete the due performance of the contract in accordance with the specification and conditions of the offer document, the ICMR-NITM reserves the right either to cancel the order or to recover a suitable amount as deemed reasonable as Penalty for nonperformance. ICMR-NITM also reserves the right to get the work done through alternate agency and recover the cost of such work from the Performance Bank Guarantee of Bidder with ICMR-NITM

## **5.6 Indemnification & Limitation of Liability**

Subject to Clause below, Bidder (the "Indemnifying Party") undertakes to indemnify, hold harmless the purchaser/ ICMR-NITM (the "Indemnified Party") from and against all claims, liabilities, losses, expenses (including reasonable attorneys' fees), fines, penalties, taxes or damages (Collectively "Loss") on account of bodily injury, death or damage to tangible personal property arising in favor of any person, corporation or other entity (including the Indemnified Party) attributable to the Indemnifying Party's negligence or willful default in performance or non-performance under this Agreement.

The indemnities shall be subject to the following conditions: The Indemnified Party as promptly as practicable informs the Indemnifying Party in writing of the claim or proceedings and provides all relevant evidence, documentary or otherwise.

- 5.6.1** The Indemnified Party shall, at the cost of the Indemnifying Party, give the Indemnified Party may, at its sole cost and expense, reasonably participate through its attorney's or otherwise, in such Defense.
- 5.6.2** If the Indemnifying Party does not assume full control over the Defense of a Claim as provided in this

Article, the Indemnified Party may participate in such Defense at its sole cost and expense, and the Indemnified Party may participate in such Defense of the claim in such manner as it may deem appropriate, and the cost and expense of the Indemnified Party will be included in Losses

- 5.6.3** The Indemnified Party shall not prejudice, pay or accept any proceedings or claim, or compromise and proceedings or claim, without the consent of the Indemnifying party.
- 5.6.4** All settlements of claims subject to indemnification under this clause with: Be entered into only with the consent of the indemnified Party, which consent will not be unreasonably withheld and include an unconditional release to the Indemnified Party from the claimant or plaintiff for all liability in respect of such claim; and Include any appropriate confidentiality agreement prohibiting disclosure of the terms of such settlement;
- 5.6.5** The Indemnified Party shall account to the indemnifying party for all awards, settlements, damages and costs (if any) finally awarded in-favor of the Indemnified Party which are to be paid to it in connection with any such claim or proceedings;
- 5.6.6** The Indemnified Party shall take steps that the Indemnifying Party may reasonably require to mitigate or reduce its loss as a result of such a claim or proceedings;
- 5.6.7** In the event that the Indemnifying Party is obligated to indemnify an Indemnified Party pursuant to this Article, the Indemnifying Party will upon payment of such indemnity in full, be subrogated to all rights and defenses of the indemnified Party with respect to the claims to which such indemnification relates; and If a Party makes a claim under the indemnity set out under Indemnification & Limitation of Liability in respect of any particular loss or losses, then that Party shall not be entitled to make any further claim in respect of that loss or losses (including any claim for damages).
  - 5.6.7.1** The liability of either Party (whether in contract, tort, negligence, strict liability in tort, by statute or otherwise) for any claim in any manner related to this Agreement, including the work, deliverables or Services covered by this Agreement, shall be the payment of direct damages only which shall in no event exceed one time the total contract value payable under this Agreement. The liability cap given under this Clause shall not be applicable to the indemnification obligations set out in Indemnification & Limitation of Liability.
  - 5.6.7.2** In no event shall either party be liable for any consequential, incidental, indirect, special or punitive damage, loss or expenses (including but not limited to business interruption, lost business, lost profits, or lost savings) nor for any third-party claim (other than those set forth in Indemnification & Limitation of Liability) even if it has been advised of their possible existence.
  - 5.6.7.3** The allocations of liability in this Indemnification & Limitation of Liability represent the agreed and bargained-for understanding of the parties and compensation for the Services reflects such allocations. Each Party has a duty to mitigate the damages and any amounts payable under an indemnity that would otherwise be recoverable from the other party pursuant to this Agreement by taking appropriate and commercially reasonable actions to reduce or limit the amount of such damages or amounts

## **5.7 Confidentiality, Data Security and Safety**

- 5.7.1** The Bidder shall comply with the requirements of the confidentiality, relevant security, safety and other requirements of the information as specifically stated in the Notice and follow the industry standards and National and International standards governing Clinical study related to confidentiality, safety and security (including those as stated in the Notice), insofar as it applies to the provision of the Services and information generated thereafter.
- 5.7.2** The parties to the Agreement shall use reasonable endeavors to report forthwith in writing to each other all identified attempts (whether successful or not) by unauthorized person (including unauthorized persons who are employees of any Party) wither to gain access to on interfere with the Purchaser as

the case may be or any of their nominee's data, facilities or Confidential information.

- 5.7.3 The Bidder shall upon reasonable request by ICMR-NITM as the case may be or their nominee(s) participate in regular meetings when management report and security matters are reviewed.
- 5.7.4 As per the provisions of this Agreement, the Bidder shall promptly report in writing to ICMR- NITM, any act or omission which they are aware that could have an adverse effect on the proper conduct of the Clinical Study.

## **5.8 Confidential Information and Data Ownership**

- 5.8.1 The "Confidential Information" means the confidential and proprietary information of Sponsor and includes (i) all information disclosed by or on behalf of ICMR-NITM, Site Institution, Investigator or other Institution's personnel assisting in the conduct and managing of the Trial, including without limitation, drug development, technical information relating to drug development all Pre-Existing Intellectual Property and the contents of the Protocol; and (ii) Study enrolment information, information pertaining to the status of the Study, communications to and from regulatory authorities, information relating to the regulatory status of the drug development, Data in physical or electronic Data form..
- 5.8.2 Each party understands and agrees that a party's may be injured by breach of any of the confidentiality provisions of this Agreement or breach of the exclusivity provisions of this Agreement, that money damages would not be a sufficient remedy for any such breach, and that a party (in the case of breaches of the confidentiality provisions) shall be entitled to seek injunctive relief as a remedy for any such breach and to enforce specifically the terms and provisions of this Agreement regarding same from the court of competent jurisdiction, this being in addition to any other remedy to which a party while seeking the benefit of this clause is entitled at law
- 5.8.3 The ultimate owner shall be the ICMR-NITM and if required ICMR-NITM take the necessary punitive action against the Bidder regarding any forbidden disclosure.
- 5.8.4 To the extent Bidder shares its confidential or proprietary information with the Purchaser for effective performance of the Services; the provisions of the above Clause shall apply Mutand is on the Purchaser or its nominated agencies.
- 5.8.5 Any handover of the confidential information needs to be maintained in a list, both by ICMR- NITM& bidder, containing at the very minimum, the name of provider, recipient, date of generation of the data, date of handing over of data, mode of information, purpose and signatures of both parties.

**5.9 Contract Period :** The contract is valid for a duration of six months, starting from date of giving contract subject to the terms outlined in this document."

**5.10 Purchase preference to Micro and Small Enterprises (MSEs):** Purchase preference will be given to MSEs as defined in Public Procurement Policy for Micro and Small Enterprises (MSEs) Order, 2012 dated 23.03.2012 issued by Ministry of Micro, Small and Medium Enterprises and its subsequent Orders/Notifications issued by concerned Ministry. If the bidder wants to avail the Purchase preference, the bidder must be the manufacturer of the offered product in case of bid for supply of goods. Traders are excluded from the purview of Public Procurement Policy for Micro and Small Enterprises. In respect of bid for Services, the bidder must be the Service provider of the offered Service. Relevant documentary evidence in this regard shall be uploaded along with the bid in respect of the offered product or service. If L-1 is not an MSE and MSE Seller (s) has/have quoted price within L-1+ 15% of margin of purchase preference /price band defined in relevant policy, such Seller shall be given opportunity to match L-1 price and contract will be awarded for percentage of 25% of total value.

**5.11 Preference to Make In India products (For bids less than 200 Crore):** Preference shall be given to Class 1 local supplier as defined in public procurement (Preference to Make in India), Order 2017 as amended from time to time and its subsequent Orders/Notifications issued by concerned Nodal Ministry for specific Goods/Products. The minimum local content to qualify as a Class 1 local supplier is denoted in the bid document 50%. If the bidder wants to avail the Purchase preference, the bidder must upload a certificate from the OEM regarding the percentage of the

local content and the details of locations at which the local value addition is made along with their bid, failing which no purchase preference shall be granted. In case the bid value is more than Rs 10 Crore, the declaration relating to percentage of local content shall be certified by the statutory auditor or cost auditor, if the OEM is a company and by a practicing cost accountant or a chartered accountant for OEMs other than companies as per the Public Procurement (preference to Make-in -India) order 2017 dated 04.06.2020. Only Class-I and Class-II Local suppliers as per MII order dated 4.6.2020 will be eligible to bid. Non - Local suppliers as per MII order dated 04.06.2020 are not eligible to participate. In case Buyer has selected Purchase preference to Micro and Small Enterprises clause in the bid, the same will get precedence over this clause.

## **6. General Conditions of Contract (GCC)**

### **6.1 Terms and Conditions:**

**Rates:** The charges quoted should include the entire facilities required to render the services without any hidden charges. All costs in the bid should be expressed in Indian Rupees without any dependence on exchange rate, duty or tax structure.

- 6.1.1** No payment over and above the quoted charges will be made by ICMR-NITM as the Price is inclusive of applicable GST.
- 6.1.2** **Technical Inspection and performance Evaluation:** ICMR-NITM may carry out a visit to the Bidders premises to assess the level of services and facilities etc. & performance evaluation (evaluation audits (GCP/GCLP) as relevant and determined) of solutions offered during the process of Technical Evaluation or thereafter, if required.
- 6.1.3** **Payments:** Payments for Services will be released by ICMR-NITM after completion of work & getting the goods/ material / item with due certification of HOD and after deduction of applicable taxes.
- 6.1.4** In case of reduction in cost or in ward credit of GST, benefit shall accrue to ICMR-NITM.
- 6.1.5** **Publicity:** Any publicity by the vendor in which the name of ICMR-NITM is to be used should be done only with the explicit written permission of ICMR - NITM. If vendor fails to do so, it shall be considered a breach of contract.
- 6.1.6** The service provider is responsible to provide all the required services in timely manner.
- 6.1.7** All the instruments for preparation of drugs in GMP certified manufacturing unit should be properly calibrated. The proof of calibration with traceability shall be available with the service provider undertaking the job. Service provider shall stand responsible for any sort of delay caused by them in executing hours and no payment will be made on account of this.
- 6.1.8** The Service Provider shall be fully responsible for the acts of their representatives / consultants/ team members and shall fully indemnify the Buyer for any kind of losses or damages caused by its team members/ consultants. The Buyer shall not be responsible for any claim from any consultant / team member employed by the Service Provider. The Service Provider shall wholly and fully be responsible for any such claims.
- 6.1.9** Bidder should submit the compliance sheet documents.

### **6.2 Force Majeure:**

- 6.2.1** Notwithstanding the provisions of the Notice, the Bidder shall not liable for forfeiture of its performance security, liquidated damages or termination for default, if and to the extent that its failure to perform its obligations under the contract is the result of an event of Force Majeure.
- 6.2.2** For purposes of this Clause, "Force Majeure" means an event beyond the control of the Bidder and not involving the Bidder and not involving the Bidder's fault or negligence and not foreseeable. Such events may include, but are not restricted to, acts of the client, either in its sovereign or contractual capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions and freight embargoes, bandhs, political unrest.
- 6.2.3** If a Force Majeure situation arises, the Bidder shall notify the client of such conditions within 7 days and the cause thereof. Unless otherwise directed by the ICMR-NITM in writing, the Bidder shall continue to perform its obligations under the contract as far as reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event, the client may terminate this contract by giving a written notice of minimum 30 days to the Bidder, if as a result of Force Majeure, the Bidder being unable to perform a material portion of the services for a period of more than 60 days.
- 6.2.4** In case of any damage/ theft of ICMR-NITM resources, the sole responsibility to indemnify lies on the bidder.

- 6.2.5** In case of urgent situations failure bidders shall provide corrective support on Holidays/ out of working hours.

### **6.3 Governing Law and Disputes**

- 6.3.1** All disputes, differences, claims and demands arising under or pursuant to or touching upon this Notice and the Agreement that will be entered into between the Bidder and ICMR-NITM shall be referred to the sole arbitrator constituted by the Director of ICMR-NITM. The award of the sole arbitrator shall be final and binding on both the parties under the provisions of the Arbitration and conciliation Act, 1996 or any statutory modification/re-enactment thereof for the time being in force. Such arbitration shall be held at Dharwad.
- 6.3.2** The Bidder shall continue work under the Agreement during the arbitration proceedings unless otherwise directed in writing by ICMR-NITM or unless the matter is such that the work cannot possibly be continued until the decision of the Arbitrator or the umpire, as the case may be, is obtained.
- 6.3.3** The venue of the Arbitration shall be in Dharwad. Any disputes and Arbitral proceedings would be subject to the jurisdiction of Dharwad courts only.

## FORMAT-1

### Covering Letter

Date:

Reference No:

From: [Insert name and address of Bidding Company]

Tel #:

Email address#

To,

Director,

ICMR -National Institute of Traditional Medicine

Neharu Nagar, Belagavi

Pincode - 590010

Subject: Response to Notice Inviting Bid No ICMR-NITM/23-24/drug\_development\_HH dated 17-11-2024 for tender document for The preparation of test drugs in the GMP-certified manufacturing units for clinical trial"

Dear Sir,

1. We, the undersigned [insert name of the Bidder] having read, examined, and understood in detail the notice hereby submit a response to the tender document. We confirm we have not submitted more than one response. We are submitting the Bid at ICMR – National Institute of Traditional Medicine, Belagavi.
2. We give our unconditional acceptance to the Notice Inviting Tender dated 17-11-2024 issued by ICMR - NITM and, the same has been initiated by us and enclosed with the Bid.
3. We have enclosed the Bid Security Declaration
4. We have submitted our Bid strictly as per the Formats for Bid submission of this Bid document, without any deviation, or condition, and without mentioning any assumptions or notes in the said Formats. We are hereby submitting our Proposal, which includes Compliance with Eligibility Criteria, Technical bid, and Financial/Commercial Bid submitted offline on given address.
5. We hereby unconditionally agree and accept that the decision made by ICMR-National Institute of Traditional Medicine, Belagavi in respect of any matter regarding or arising out of the Notice Inviting Bid shall be binding on us. We hereby expressly waive and withdraw any claims in respect of this process.
6. Familiarity with Relevant Indian Law and regulations: We confirm that we have studied the provisions of the relevant Indian law and regulations as required to enable us to submit this response to tender document, in the event of our selection as Successful Bidder.
7. We are enclosing herewith our response to the tender document with formats duly signed as desired by you in the tender document for your consideration.
8. It is confirmed that our response to the tender document is consistent with all the requirements of submission as stated in the tender document and subsequent communications from ICMR-NITM.
9. The information submitted in our response to the tender document is correct to the best of our knowledge and understanding. We would be solely responsible for any errors or omissions in our response to the tender document.
10. We hereby declare that our company has not been debarred/blacklisted by any Central/State Govt. Ministry or



Department/Public Sector company/ Government autonomous body.

11. We confirm that all the terms and conditions of our Bid are valid up to [insert date in dd/mm/yyyy] for acceptance (i.e. period of One hundred and eighty (180) days from the date of opening of bids).

12. Contact Person / Details of a representative to be contacted by ICMR - NITM are furnished as under Name:

Designation:

Phone Nos:

Company:

Mobile:

Address:

Email address:

13. We have neither made any statement nor provided any information in this Bid, which to the best of our knowledge, is materially inaccurate or misleading. Further, all the confirmation, declaration and representation made in our Bid are true and accurate. In case this is found to be incorrect after our selection as successful bidder, we agree that the same would be treated as a Seller's event of default.

Dated the            day of, 20...

Thanking you, Yours faithfully,

(Name, Designation and Signature of Authorized Person)

## **FORMAT- 2**

**FORMAT FOR PERFORMANCE BANK GUARANTEE**  
(To be on Rs 100/- non-judicial stamp paper)

In consideration of the ----- [Insert name of the Bidder] (hereinafter referred to as selected Bidder') submitting the response

to Bid inter alia for The preparation of test drugs in the GMP-certified manufacturing units for clinical trial". to the Bid dated \_\_\_\_\_ issued by ICMR- National Institute of Traditional Medicine, Belagavi (hereinafter referred to as ICMR-NITM) and ICMR-NITM considering such response to the Bid of .....[insert the name of the selected Successful Bidder] (which expression shall unless repugnant to the context or meaning thereof include its executors, administrators, successors and assignees) and selecting Successful Bidder/Trader and issuing Letter of award No..... to (Insert Name of selected Successful Bidder) as per terms of Bid and the same having been accepted by the selected Successful Bidder, M/s. -----, if applicable]. As per the terms of the tender, the [insert name, branch code & address of bank] hereby agrees unequivocally, irrevocably and unconditionally to pay to ICMR-NITM at [Insert Name of the Place from the address of ICMR NITM] forthwith on demand in writing from ICMR-NITM or any Officer authorized by it in this behalf, any amount up to and not exceeding Rupees----- [Total Value] only, on behalf of M/s [Insert name of the selected Successful Bidder]

This guarantee shall be valid and binding on this Bank up to and including..... and shall not be terminable by notice or any change in the constitution of the Bank or the term of contract or by any other reasons whatsoever and our liability hereunder shall not be impaired or discharged by any extension of time or variations or alternations made, given, or agreed with or without our knowledge or consent, by or between parties to the respective agreement.

Our liability under this Guarantee is restricted to Rs. ....  
.....only).

Our Guarantee shall remain in force until..... ICMR-NITM shall be entitled to invoke this Guarantee till .....

The Guarantor Bank hereby agrees and acknowledges that ICMR - NITM shall have a right to invoke this BANK GUARANTEE in part or in full, as it may deem fit.

The Guarantor Bank hereby expressly agrees that it shall not require any proof in addition to the written demand by ICMR-NITM, made in any format, raised at the above-mentioned address of the Guarantor Bank, to make the said payment to ICMR-NITM.

The Guarantor Bank shall make payment hereunder on first demand without restriction or conditions and notwithstanding any objection by [Insert name of the selected Successful Bidder] and/or any other person. The Guarantor Bank shall not require ICMR -NITM to justify the invocation of this BANK GUARANTEE, nor shall the Guarantor Bank have any recourse against ICMR-NITM in respect of any payment made hereunder.

This BANK GUARANTEE shall be interpreted in accordance with the laws of India and the courts at Belagavi shall have exclusive jurisdiction.

The Guarantor Bank represents that this BANK GUARANTEE has been established in such form and with such content that it is fully enforceable in accordance with its terms as against the Guarantor Bank in the manner provided herein.

This BANK GUARANTEE shall not be affected in any manner by reason of merger, amalgamation, restructuring or any other change in the constitution of the Guarantor Bank.

This BANK GUARANTEE shall be a primary obligation of the Guarantor Bank and accordingly ICMR-NITM shall not be obliged before enforcing this BANK GUARANTEE to take any action in any court or arbitral proceedings against the selected Successful Bidder, to make any claim against or any demand on the selected Successful Bidder or to give any notice to the selected Successful Bidder or to enforce any security held by ICMR - NITM or to exercise, levy or enforce any distress, diligence or other process against the selected Successful Bidder

Notwithstanding anything contained hereinabove, our liability under this Guarantee is restricted to Rs.  
(Rs. only) and it shall remain in force until .....

We are liable to pay the guaranteed amount or any part thereof under this Bank Guarantee only if ICMR-NITM serves upon us a written claim or demand.

Signature                  Name                  Power of Attorney No.

For

[Insert Name of the Bank]

Banker's Stamp and Full Address. Dated this                  day of                  , 20                  Witness:

1. .... Signature  
Name and Address

2. .... Signature  
Name and Address

Note:

1.                  The Performance Bank Guarantee shall be executed by any of the Nationalized Bank.

**Format 3**

**COMPLIANCE SHEET FOR ELIGIBILITY CRITERIA**

S. No.	Basic Requirement	Provided	Ref & Page No
1.	Particulars of the Bidders ( <b>As per Annexure I</b> )	Yes/No	
2.	The bidder should be registered in India under the Company Act, 1956 or have registered office in India for last 3 years.	Yes/No	
3.	The bidder/ unit have all the required relevant permissions and approvals for the production of drugs. Provide the copies of all the permissions and approvals for the same.	Yes/No	
3.	GMP certification of manufacturing Unit (Mandatory)	Yes/No	
4.	List of relevant SOPs	Yes/No	
5.	List of relevant equipments	Yes/No	
6.	Proof of calibration for equipment should be provided	Yes/No	
7.	CV of the Director/ In-charge/ Technical Head of the GMP-certified Manufacturing Unit	Yes/No	
8.	Annual Gross Turnover Gross annual turnover of the GMP-certified Manufacturing Unit during the last three financial years 2020-21, 2021-22 and 2022-23. The gross turnover should be at least INR 20 Lakhs	Yes/No	
9.	The Bidder should have valid GST Registration, Income Tax returns and PAN card.	Yes/No	
10.	As on the date of submission of the bid, the Bidder should not be blacklisted by any Government entity in India and that there is no legal incapacity preventing the Bidder to enter into a contract.	Yes/No	
11.	Letter of authorization from OEM/Parent organization (if applicable).	Yes/No	
12.	Bidder should have minimum 3 years' experience in production of Drugs in GMP certified manufacturing unit in India. If so, the details of such productions/ services to be furnished.	Yes/No	
13	Tender Acceptance Letter ( <b>As per Annexure III</b> )	Yes/No	

**Format 4**  
**Format for Technical Bid**

<b>S. No.</b>	<b>Criteria</b>	<b>Details</b>
1.	Company Profile with experience and capability	
2.	Execution plan as per scope of work	

**Kindly enclose the documents as desired above and mention the details and number of documents in each column in the table given above.**

**FORMAT- 5**  
**FINANCIAL PROPOSAL**  
**Covering Letter**  
**(On Bidder's letter head)**

[Date and Reference]

**To,**  
The Director,  
National Institute of Traditional Medicine,  
Nehru Nagar, Old RMRC Layout,  
Belagavi – 590010.

Sub: Response to Notice Inviting Tender for The preparation of test drugs in the GMP-certified manufacturing units for clinical trial” at ICMR-NITM vide Ref No.-----

Dear Sir,  
I/ We, (Applicant's name) have sent the Financial Proposal for selection of my / our company for The preparation of test drugs in the GMP-certified manufacturing units for clinical trial as a bidder.

I/ We agree that this offer shall remain valid for a period of 180 (One hundred and eighty) days from the date of opening of Bid or such further period as may be mutually agreed upon.

Yours faithfully,  
(Signature, name and designation of the Authorized Signatory)

Note: The Financial/Commercial Proposal is to be submitted strictly as per forms given in the Notice.

### FORMAT- 6

Subject: - Response to Notice Inviting Bid No. Ref. No. ICMR-NITM/23-24/drug\_development\_HH dated..... for  
**The preparation of test drugs in the GMP-certified manufacturing units for clinical trial”** at ICMR-NITM, Belagavi

SI No.	Name of test	Amount
1	Ointment containing 5% essential oil:	
2	Gel containing <i>Kashaya</i> of 50 g plant powder	
3	Diclofenac Gel (1%) matching with Gel containing <i>Kashaya</i>	

**Note:**

1. Total cost shall be quoted as a fixed amount in Indian Rupees only. Conditional proposal shall be summarily rejected.
2. In the event of arithmetic calculation mistake, the individual price in words shall be considered for calculation.
3. All figures are to be rounded off to the nearest Rupee only. Any figures given in paisa will not be considered.
4. The L-1 bidder will be decided on the basis on total cost . No cost will be paid which is not mentioned in the price bid.

Authorized  
Signatory Name,  
Designation  
Name of the Company & Address

## FORMAT- 7

### **Draft Contract Agreement (To be executed on Rs 100/- Stamp Paper/s)**

This Agreement is made at Belagavi on the \_\_ day of \_\_\_\_\_ 2024 Between ICMR-National Institute of Traditional Medicine, Belagavi hereinafter called "the Purchaser" of the one part and (Name of Successful Bidder) \_\_\_\_\_ of \_\_\_\_\_ (Address of Successful Bidder) hereinafter called "the Supplier" of the other part.

Whereas the Purchaser is desirous that certain Works should be executed, viz The preparation of test drugs in the GMP-certified manufacturing units for clinical trial" at ICMR- National Institute of Traditional Medicine, Belagavi and trial sites where the clinical trial will be conducted (as described on these bidding documents) hereinafter called "the Works" and has accepted a bid by the Supplier for the execution and completion of such works and the remedying of defects therein. NOW THIS AGREEMENT WITNESSETH as follows:

1. In this Agreement words and expression shall have the same meanings as are respectively assigned to them in the Conditions of Contract hereinafter referred to.
2. The following documents shall be deemed to form and be read / construed as part of this Agreement, viz:
  - Letter of Award and Acceptance
  - Bid Information Sheet
  - Bid information and Instructions to Bidders
  - Bid Evaluation
  - Special Conditions of Contract (SCC)
  - General Conditions of Contract (GCC)
  - Formats for submission of Bid
3. In consideration of the payments to be made by the Purchaser to the Supplier as hereinafter mentioned, the Supplier hereby covenants with the Purchaser to execute and complete the works by \* \_\_\_\_\_ and remedy any defects therein in conformity in all respects with the provisions of the Contract.
4. The Purchaser hereby covenants to pay the Supplier in consideration of the execution and completion of the works and the remedying of defects therein, the Contract Price of \*\*Rs \_\_\_\_\_ being the sum stated in the letter of award subject to such additions thereto or deductions there from as may be made under the provisions of the Contract at the times and in the manner prescribed by the Contract.
5. Jurisdiction of Court: The Courts at Dharwad shall have the exclusive jurisdiction to try all disputes arising out this agreement between the parties with cause of action arising at Belagavi.



Other disputes with cause of action arising at the respective Institutes/trial sites shall be within the concerned Courts / Tribunals of respective city where the sites are situated.

IN WITNESS WHEREOF the parties hereto have caused their respective Common Seals to be hereunto affixed / (or have hereunto set their respective hands and seals) the day and year first above written.

For and on behalf of the Supplier  
authorized official

Signature of the

For and on behalf of the Purchaser Signature of the  
authorized official

Name of the official  
Stamp/Seal of the Supplier

Name of the official  
Stamp/Seal of the Purchaser

SIGNED, SEALED AND DELIVERED

By the said \_\_\_\_\_  
Name \_\_\_\_\_ on behalf of  
the Supplier in the presence of:  
Witness \_\_\_\_\_  
Name \_\_\_\_\_  
Address \_\_\_\_\_

By the said \_\_\_\_\_  
Name \_\_\_\_\_ on behalf of  
the Supplier in the presence of:  
Witness \_\_\_\_\_  
Name \_\_\_\_\_  
Address \_\_\_\_\_

Note:

\*\* Blanks to be filled by the Purchaser at the time of finalization of the Form of Agreement.

**Format 8**  
**Annual Turnover**

It is hereby certified that the Gross turnover of M/s. \_\_\_\_\_ (name of the firm ) for the last three years is as given below:

Annual Gross turnover for the last 3 Financial Years in Indian Rupees (in crore)			
Year (2020-21)	Year (2021-22)	Year (2022-23)	

(Signature of Statutory Auditor/CA) Name of  
Statutory Auditor/CA:  
Name of Statutory Auditor/CA Firm:  
Seal

**Format 9**  
**Format for Statutory Auditor's Certificate for Furnishing Net worth Details**

We hereby certify that Positive Net Worth of M/s. \_\_\_\_\_(name of the bidder) as on 31<sup>st</sup> March, 2023 is positive and is as given below: Net worth as on 31<sup>st</sup> March, 2023 in Indian Rupees (in Lakhs)

	Net worth as on 31 <sup>st</sup> March, 2023 in Indian Rupees (in Lakhs)
Particular	
Paid up Share Capital	
Free Reserve	
Total	

(Signature of Statutory Auditor)

Name of Statutory Auditor: Name of

Statutory Auditor Firm: Seal

**Format 10**  
**Parent Company Authorization Form (If applicable)**

No. & Date:

To:

The Director

ICMR – National Institute of Traditional Medicine,

Nehru Nagar, Old RMRC Layout,

Belagavi – 590010.

OEM Authorization Letter Dear

Sir:

Ref: Your Tender Ref: [\*] dated [\*]

We are established and reputable Company/Organization in providing \_\_\_\_\_ services having Office at (address of the office) do hereby authorize M/s \_\_\_\_\_ (Name and address of Agent) to submit a Bid, and sign the contract with you against the above Bid Invitation.

We hereby extend our full guarantee and warranty for the Solution, Products and services offered by the above firm against this Bid Invitation.

We hereby declare that we are not insolvent, in receivership, bankrupt or being wound up, our affairs are not being administered by a court or a judicial officer, our business activities have not been suspended and we are not the subject of legal proceedings for any of the foregoing.

We also undertake to provide any or all of the following materials, notifications, and information pertaining to the Products manufactured or distributed by the Supplier:

- a. Such Products as the ICMR-NITM may opt to purchase from the Supplier/Service Provider, provided, that this option shall not relieve the Supplier of any warranty obligations under the Contract; and
- b. In the event of termination of production of such Products:
  - i. Advance notification to the ICMR-NITM of the pending termination, in sufficient time to permit the ICMR to procure needed requirements; and
  - ii. Following such termination, furnishing at no cost to the ICMR-NITM, operations manuals and specifications of the Products, if requested.

We duly authorize the said firm to act on our behalf in fulfilling all installations, Technical support and maintenance obligations required by the contract.

Yours faithfully, (Name)

(Name of Producers)

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. The Bidder in its Bid should include it.

**Format 11**  
**Declaration that the Company has not been blacklisted in the last three years**

(To be submitted on the Letterhead of the responding SI)

{Place}

{Date}

To,

Ref: No: ----- dated -----

Subject: Self Declaration of not been blacklisted in response to the Tender for at ICMR-NITM.

Dear Sir,

We confirm that our company, M/s.\_\_\_\_\_, is not blacklisted in any manner whatsoever by any of the State/UT and/or Central Government in India in last three years on any ground including but not limited to indulgence in corrupt practice, fraudulent practice, coercive practice, undesirable practice or restrictive practice.

Further it is confirmed that there is no legal incapacity that will bar the Bidder from entering into a Contract or Agreement or to undertake the specified Scope of Work

Place:

Date:

Bidder's Company Seal:

Authorized Signatory's Signature:

Authorized Signatory's Name and Designation:

Note: The Bidder shall necessarily provide a copy of 'Power of Attorney' authorizing the signatory for signing the Bid on behalf of the Bidder in its Bid.

**FORMAT 12**

**BID SECURING DECLARATION**

(to be given by Bidders in Company letter head by Authorized Signatory)

Date: [insert date (as day, month and year)]

Notice Inviting Tender No.: [insert number of No]

To

The Director

ICMR – National Institute of Traditional Medicine,

Nehru Nagar, Old RMRC Layout,

Belagavi - 590010

We, the undersigned, declare that:

We hereby agree that, our firm will be disqualified from bidding in any contract with NITM, Belagavi for a period of One Year starting from the date that we receive a notification from NITM, under the bid conditions, which are as follows:

(a) have withdrawn/modified/amended, impairs or derogates from the tender conditions during the period of bid validity specified in the tender document; or

(b) having been notified of the acceptance of our Bid by NITM, Belagavi during the period of bid validity,

i. fail or refuse to execute the Contract Form, if required,

ii. fail or refuse to furnish the performance security, in accordance with the tender terms and Conditions mentioned in the tender document,

(c) have breached a provision of the Code of Integrity specified in the tender document;

We understand this Bid-Securing Declaration shall expire if we are not the successful Bidder, upon the earlier of

i. our receipt of your notification to us of the name of the successful Bidder; or

ii. thirty days after the expiration of our Bid.

Sign: [insert signature of person whose name and capacity are shown]

In the capacity of: \_\_\_\_\_

[insert legal capacity of person signing the Bid-Securing Declaration]

Name: \_\_\_\_\_

[insert complete name of person signing the Bid-Securing Declaration]

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

[insert complete name of Bidder] Dated on day of [insert date of signing]

Corporate Seal