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Tender Details

Date : 23-Apr-2024 04:51 PM

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Basic Details

Organisation Chain	Department of Pharmaceuticals||National Institute of Pharmaceutical Education and Research (NIPER) Guwahati		
Tender Reference Number	NIPERG/SNP/22/GLP Labs/2024-25/10		
Tender ID	2024_MCF_754195_1		
Tender Type	EOI	**Form of contract**	EOI
Tender Category	Services	**No. of Covers**	2
Payment Mode	Not Applicable	**Is Multi Currency Allowed For BOQ**	No
Is Multi Currency Allowed For Fee	No		

Cover Details, No. Of Covers - 2

Cover No	Cover	Document Type	Description
1	Fee/PreQual/Technical	.pdf	Technical Details for the EoI as per Annexure I
2	Finance	.xls	Financial Details for the EoI as per annexure II

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 ₹	0.00	**EMD Exemption Allowed**	NA
EMD Fee Type	NA	**EMD Percentage**	NA
EMD Payable To	NA	**EMD Payable At**	NA

Work /Item(s)

Title	Expression of Interest (EoI)				
Work Description	ENGAGEMENT OF GLP-ACCREDITED LABS OR REGISTERED ENTITIES TO PERFORM THE PRECLINICAL ANIMAL STUDIES FOR EYEDROP FORMULATION IN GLP CONDITIONS				
Pre Qualification Details	Please refer Tender documents.				
Tender Value in ₹	1	**Product Category**	Consultancy Services	**Sub category**	NA
Contract Type	Tender	**Bid Validity(Days)**	90	**Period Of Work(Days)**	365
Location	NIPER-Guwahati,SilaKatamur, Halugurisuk, Changsari	**Pincode**	781101	**Pre Bid Meeting Place**	NA
Pre Bid Meeting Address	NA	**Pre Bid Meeting Date**	NA	**Bid Opening Place**	NIPER-Guwahati

Critical Dates

Publish Date	23-Apr-2024 05:00 PM	**Bid Opening Date**	20-May-2024 03:30 PM
Document Download / Sale Start Date	23-Apr-2024 05:05 PM	**Document Download / Sale End Date**	20-May-2024 02:00 PM
Clarification Start Date	NA	**Clarification End Date**	NA
Bid Submission Start Date	23-Apr-2024 05:15 PM	**Bid Submission End Date**	20-May-2024 02:00 PM

Tender Documents

NIT Document

S.No	Document Name	Description	Document Size (in KB)
1	Tendernotice_1.pdf	ENGAGEMENT OF GLP-ACCREDITED LABS OR REGISTERED ENTITIES TO PERFORM THE PRECLINICAL ANIMAL STUDIES FOR EYEDROP FORMULATION IN GLP CONDITIONS	4105.55

Work Item Documents

S.No	Document Type	Document Name	Description	Document Size (in KB)
1	Tender Documents	GLP labs tender.pdf	ENGAGEMENT OF GLP-ACCREDITED LABS OR REGISTERED ENTITIES TO PERFORM THE PRECLINICAL ANIMAL STUDIES FOR EYEDROP FORMULATION IN GLP CONDITIONS	4105.55

Tender Inviting Authority

Name	Director, NIPER Guwahati
Address	NIPER Guwahati, SilaKatamur Halugurisuk, P.O. Changsari, Dist Kamrup, Assam, Pin 781101

Tender Creator Details	
Created By	Gitartha Goswami
Designation	Assistant Registrar
Created Date	23-Apr-2024 04:44 PM

NIPER GUWAHATI

EXPRESSION OF INTEREST

"TO ENGAGE GLP-ACCREDITED LABS OR REGISTERED ENTITIES TO PERFORM THE PRECLINICAL ANIMAL STUDIES FOR EYEDROP FORMULATION IN GLP CONDITIONS"

No.: NIPER-G/S&P/22/GLP-Labs/2024-25/ 10
Date: 23/04/2024

Product name: NIPER SURIA

NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH-GUWAHATI

Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India

SilaKatamur, Haluguri suk,Changsari, Kamrup, Assam-781101, India

Ph: 7099007822
Email: *purchase@niperguwahati.ac.in*

राष्ट्रीय औषधीय शिक्षा तथा अनुसंधान संस्थान गुवाहाटी
NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCHGUWAHATI
(Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Govt. of India)
SilaKatamur (Halugurisuk), P.O.: Changsari, Dist: Kamrup, Assam, Pin: 781101.

No. NIPER-G/S&P/22/GLP-Labs/2024-25/10 Date: 23/04/2024

Expression of Interest (EoI)

ENGAGEMENT OF GLP-ACCREDITED LABS OR REGISTERED ENTITIES TO PERFORM THE PRECLINICAL ANIMAL STUDIES FOR EYEDROP FORMULATION IN GLP CONDITIONS

National Institute of Pharmaceutical Education and Research (NIPER)-Guwahati is an Institute of National Importance set up by an Act of Parliament under the aegis of Dept. of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Govt. of India, to impart higher education and undertake advanced research in the field of Pharmaceutical Sciences and Technology. NIPER-G is establishing a GMP accredited Pilot Scale extraction facilities to develop herbal or phytopharmaceutical products from the medicinal plants of NE India with financial support from the Department of Biotechnology, Ministry of Science & Technology, Government of India.

NIPER-Guwahati intends to identify a suitable Good Lab practice Labs (GLP Labs) for conducting the Safety Assessment of Eyedrops in GLP Condition as per the OECD 405 (eye irritation), OECD 407 (repeated dose ocular toxicity study) and intents to call expressions of interest (EoI) from any GLP-accredited Labs or registered entities to perform the following preclinical animal studies in GLP conditions. The GLP-accredited Labs or registered entities may fill the application in two parts *i.e.* (a) Technical details and (b) Commercial details as per the formats enclosed in Annexure 1 and Annexure 2 in separate sealed envelopes.

DATE & TIME OF SUBMISSION: Tenders in sealed envelope is hereby invited by the undersigned, on behalf of Director, NIPER Guwahati from Potential, Experienced reputed vendors so as to reach in this office on or before **20th May 2024 (Monday) up to 2:00 pm** and only technical bids shall be opened on the same day at 3:30pm in Stores and Purchase Department, NIPER Guwahati. The signed documents should be submitted in a sealed cover, super scribed with **"EoI under Ref. No. NIPER-G/S&P/22/GLP-Labs/2024-25 dated 23/04/2024 for GLP LABS TO CONDUCT SAFETY ASSESSMENT OF EYEDROPS IN GLP CONDITION"** and addressed to the Director, National Institute of Pharmaceutical Education and Research (NIPER)-Guwahati, SilaKatamur, Halugurisuk, Changsari, Kamrup, Assam-781101, INDIA.

EXPRESSION OF INTEREST for the conduction of toxicology studies given below.

1. *In Vitro* Cytotoxicity study : OECD 129 with modification to suit of cell lines specific to eye epithelium

2. Acute Eye irritation study: OECD 405

3. Subacute (repeated) dose ocular toxicity study 21 days: general guidelines OECD 407

The animal studies must comply to GLP compliance and hence the study results of eyedrop formulation should be considered by CDSCO for granting clinical trial approvals.

Route of application is topical application into the eye

Formulation is Nanocapsule eyedrops

Reference:

OECD guideline for the testing of chemicals. Test Guideline No. 405, Acute eye irritation/corrosion. https://www.oecd-ilibrary.org/environment/test-no-405-acute-eye-irritation-corrosion_9789264185333-en; https://doi.org/10.1787/9789264185333-en; Accessed on 26th March 2024.

Essential Requirements:

1. The GLP-accredited Labs or registered entities registered under any Indian law and applying in response to this advertisement should have relevant experience in undertaking this kind of job and should be in this line for a period of at least five years.

2. The GLP-accredited Labs or registered entities should have a well-qualified and experienced efficient knowledgeable scientist in handling animal and *in vitro* cell culture studies and be capable of executing the responsibilities required for completing the job detailed through this document.

3. The CRO or registered entity who are participating, the firm or registered entity should have at least one staff should possess Doctorate and with a successful proven record.

4. Proven record of establishing the preclinical animal safety details of eyedrop formulation that should be considered by **Central Drugs Standard Control Organization (CDSCO)** for granting clinical trial approvals.

5. Should have proven record to impart

- the OECD 129 for *In Vitro* Cytotoxicity study, i.e., the OECD 129 with modification to suit of cell lines specific to eye epithelium
- the OECD 405 for Acute Eye irritation study
- the OECD 407 for Subacute (repeated) dose ocular toxicity study.

Note: Documentary evidence to substantiate the information related above point no 1 to 6 needs to be attached, for shortlisting the Potential bidder.

The basis of selection is based on the credentials, capabilities, Infrastructure facilities, available with the Bidder and past proven record supported by experienced capable staff etc.

INSTRUCTIONS FOR PREPARING AND SUBMMISSION OF BIDS

The Bidder can submit their bids on their own Letter Heads. As the Bidding system is Two step Evaluation, the Bidders are required to submit their bids separately for technical information containing documents related to establishing the Credentials for assessment of technical capabilities indicated under Annexure 1 below with entity details. This information may please be provided in a separate sealed cover No 1 superscribing "TECHNICAL BID".

The financial related information as per Annexure 2 needs to be filled and kept in a separate sealed cover superscribing "FINANCIAL BID". The financial bids of technically qualified bidders only will be opened.

Both separate sealed technical bid (Cover no 1) and sealed financial bid (Cover no 2) may be kept in an outer cover indicating the EoI reference no. and details and date of opening as indicated in this document under "Date and Time of submission".

Tenure of engagement: Initially for a period of one year, that may be extended based on the need and performance the identified bidder.

The Identified bidder needs to sign an agreement related to Intellectual property rights with the Institute.

The Director reserves the right to withdraw above EoI at any stage without assigning any reason. Director further reserves the right to relax any of the conditions, in the best Interest of the Institute.

Stores & Purchase Officer

ANNEXURE 1

(To be kept in separate sealed cover no. 1 indicating "TECHNICAL BID")

Technical Details for the EoI engagement of GLP-accredited labs or registered entities to perform the preclinical animal studies for eyedrop formulation in GLP conditions.

1. Name of the Registered entity/CRO: (in case if applicant is CRO, furnish the details of concerning authority with designation, furnish the details of company registration, Pan details and enclose the GST filing for minimum three years)

2. (a) Date of Incorporation

3. (a) Adress for correspondence

4. (b) Names and designation of authorised contact persons

5. (c) Mobile and Land line numbers of above officials

6. (d) Email id of the entity and the Authorised Persons.

7. Profile and achievements of the entity in the past and present supported by printed documents like printed brochures etc.

8. An Undertaking that in the event of their entity gets the contract they will accept the same and fulfil all contractual obligations and will not leave the assignment in between.

9. **Essential qualification**

a) Experience and credentials of entity

S. no.	Name of the organisation/Designation	from	To	Total experience

b) Detail of the organisation served as a registered entity or as CRO:

c) Furnish the detail(s) of the organisation obtained GLP certification as a registered entity or CRO consultant (Proofs should attached).

Note: (a) Those who qualifies technically as per the essential requirement in the EoI, Financial envelope will be opened for the Registered Entity /CRO only. The Short listed entity quoting the lowest amount per month would be considered for the award of work (b) If Registered entity/CRO fails to submit or furnish the details as per the essential requirement supported by documentary evidence will be technically rejected and their corresponding financial bids will not be considered for further evaluation

ANNEXURE 2

(To be kept in separate sealed cover no. 2 indicating "FINANCIAL BID")

Financial Details for the EoI of GLP-accredited labs or registered entities to perform the preclinical animal studies for eyedrop formulation in GLP conditions

1. Name of the applicant/CRO/registered entity:

2. Amount should be indicated as a total package deal.

   (*Statutory taxes as applicable would be loaded extra and paid to the entity and same may not be included in the quote*)

   50% Payment will be made after successful completion of agreed assignment and furnishing report along with a Bill in triplicate for certification by User department. The Balance 50% payment will be released immediately after acceptance of the Report by M/S CDSCO against submission of bill claiming the Balance payment.

3. Most of the meetings will be preferred online only. As per the decision by the competent authority or up on request by any of the faculty of NIPERG, consultant/registered entity or any representative of CRO must attend physical meetings as when required. In such events the expenditure connected with travel by Air through Short distance will be reimbursed against submission of Proof of travel and incurring expenditure. Guest house and food felicities will be taken care by the Institute.

4. If any component is missing for fulfilling contractual obligations the same may be quote as optional apart from the monthly charges.