kerala state drugs and pharmaceuticals ltd.
a government of kerala enterprise

factory & office
kalavoor - 688 522
alappuzha, india
Email : ksdpltd@gmail.com
Website : www.ksdp.co.in
phone : 0477-2258184
0477-2258828
fax : 0477 - 2258162

22.02.2024

EXPRESSION OF INTEREST (EoI).

NOTICE INVITING

EOI REF NO: KSDP/PRD/EOI/SVP-OPHT/2023-24/01

Expression of Interest (EOI) is invited for "The Product Development Of Small Volume Parentrals and sterile ophthalmic preparations". Interested persons/organisation are requested to submit EoI along with all supporting documents/ credentials.

EoI shall submit in sealed cover addressing to the Managing Director, Kerala State Drugs and Pharmaceuticals Ltd., Kalavoor P.O, Alappuzha -688522, Kerala

EOI Name & Number should be mentioned on the sealed cover.

For detailed information; please visit website "www.ksdp.co.in".

Last date of submission: 20.03.2024 5.00 PM

Opening date: 21.03.2024, 10.00 AM

For further clarification kindly contact: - +91 9846978803 (Production Manager)
Email: - ksdpproject@gmail.com

Sd/-

Managing Director

TENDER INVITING FOR THE PRODUCT DEVELOPMENT OF SMALL VOLUME PARENTRALS AND STERILE OPHTHALMIC PREPARATIONS

GENERAL TERMS AND CONDITIONS

Kerala State Drugs & Pharmaceuticals Ltd. (KSDPL) is a Government of Kerala Undertaking that has been manufacturing and supplying allopathic medicines for more than 40 years. We are a major medicine supplier of Kerala Medical Service Corporation Ltd, an institution of Government of Kerala, to procure medicines, equipment, etc.at affordable prices, for the health institutions under Government of Kerala. We also supply medicines to the governments of Andhra Pradesh, Telangana, Karnataka, Uttar Pradesh and Tamil Nadu through their respective nodal agencies for the medicine procurement.

Our product range includes Tablets, Capsules, Liquids, dry syrups and parenterals including beta lactam products. The manufacturing facility has cGMP certification for the products and the manufacturing process involves well-equipped sophisticated GMP compliant machineries with huge capacity. The company also have NABL accredited laboratory with GLC certification for the testing of medicines.

As KSDPL is putting up a new plant for sterile liquid products, we are inviting EOI from technically qualified persons/organisation for the below works.

a. Development of suitable stable formulation for the small volume parenteral preparations and sterile ophthalmic preparations.

b. Generate sufficient data to complete the stability studies as per ICH guidelines.

c. Technology transfer & scale up techniques for each product along with the plausible trouble shooting at site during the scale-up.

d. Perform three exhibit batches of each product.

e. Perform Process validation & its documentation, for the exhibit batches of each product.

f. Implementation of In-process checks to ensure the quality of the intermediate and finished products.

g. Should assign sufficient number of technically qualified persons to develop formula at KSDPL

h. Should be responsible to give advice, directions and total assistance to increase the productivity and to streamline the manufacturing process in the most effective way as per the cGMP standards

.

The technical portion of the bid should include profile, a brief description of projects handled and other documents mentioned in EOI.

- **<u>Goal of this Expression of Interest.</u>**

  The objective of this EOI is to solicit proposals from the interested parties for participation in a bid process for selection of technically qualified persons/organisation for works stated above for the products enclosed and detailed under scope of contract. The Consultant will be responsible for giving advice, directions and total assistance to increase the productivity and to streamline the manufacturing process in the most effective way as per the cGMP standards and Schedule M of Drugs and Cosmetics Act 1940.

  The EOI intends to bring out the details with respect to scope of services that are deemed necessary to share with the interested bidders.

- **<u>EOI ISSUING AUTHORITY</u>**

  This Expression of Interest (EoI) is issued by the Managing Director, Kerala State Drugs & Chemicals Limited, Kalavoor, Alappuzha, intended to shortlist potential bidders. The Managing Director's decision with regard to the short-listing of bidders through this EoI shall be final and reserves the right to reject any or all the bids without assigning any reason.

- **Availability of the EOI documents.**
  The bidders are expected to examine all instructions, forms, terms, project requirements and other details in the EoI documents published in the website. Failure to furnish complete information as mentioned in the EoI documents or submission of a proposal not substantially responsive to the EoI documents in every respect will be at the bidder's risk and may result in rejection of the proposal.

- **Venue and deadline for submission of proposals.**
  Proposals, in its complete form in all respects as specified in the EoI, must be submitted as specified in Notice inviting Tender. Managing Director may, in exceptional circumstances and at discretion, extend the deadline for submission of proposals by issuing an addendum to be made available on the website and KSDP's website, in which case all rights and obligations of KSDP and the bidders previously subject to the original deadline will thereafter be subject to the deadline/changes as extended.

SCOPE OF CONTRACT.

- Development of suitable stable formulation for the small volume parenteral and sterile ophthalmic preparations.
- Generate sufficient data to complete the stability studies as per ICH guidelines.

- Technology transfer & scale up techniques for each product along with the plausible trouble shooting at site during the scale-up.
- Perform three exhibit batches of each product.
- Perform Process validation & its documentation, for the exhibit batches of each product.
- Implementation of In-process checks to ensure the quality of the intermediate and finished products.
- Should assign sufficient number of technically qualified persons to develop formula at KSDPL.
- Should be responsible to give advice, directions and total assistance to increase the productivity and to streamline the manufacturing process in the most effective way as per the cGMP standards.

CONDITIONS UNDER WHICH THIS EOI IS ISSUED.

- This EoI is not an offer and is issued with no commitment and is meant only to shortlist technically qualified persons/ organisation to undertake the work as mentioned. The Managing Director reserves the right to withdraw the EoI and change or vary any part thereof at any stage. The Managing Director also reserves the right to disqualify any bidder, should it be so necessary at any stage.
- Person/s who have the competence, capability and meet the eligibility criteria only need to apply.

- Financial bids will be called only from technically short listed parties. Request for Financial prospectus will be circulated to technically qualified person/s only.
    - Timing and sequence of events resulting from this EoI shall ultimately be determined by the Managing Director.
    - No oral conversations or agreements with any official, agent, or employee of KSDP shall affect or modify any terms of this EoI and any alleged oral agreement or arrangement made by a bidder with any department, agency, official or employee of KSDP shall be superseded by the definitive agreement that results from this EoI process. Oral communications by KSDP to bidders shall not be considered binding on KSDP, nor shall any written materials provided by any person other than Managing Director.
    - Neither the bidder nor any of the bidder's representatives shall have any claims whatsoever against KSDP or any of their respective officials, agents, or employees arising out of, or relating to this EoI or these procedures (other than those arising under a definitive service agreement with the bidder in accordance with the terms thereof).
    - Applicants who are found to canvass, influence or attempt to influence in any manner the qualification or selection process, including without limitation, by offering bribes or other illegal gratification, shall be disqualified from the process at any stage.

      Each applicant shall submit only one proposal.

The technically qualified persons/organisation meeting the following requirements are eligible to apply:

- Person/s should hold a degree in Pharmacy with minimum 10 years of experience in R&D or in manufacturing of small volume parenteral preparations and sterile ophthalmic products.
- Should have min 10 years of experience in developing formulation for injectable (SVP) and ophthalmic preparations (Sterile Dosage forms). Should provide the list of products developed for other clients in each category. Please enclose a client feedback letter certifying the formulation development activity. Products developed from the KSDP's list would be desirable.
- Experience in the successful technology transfer of minimum 5 products developed to commercial batches.
- Development of required documentation for the efficient operation and implementation of quality management systems.
- Experience in performing the stability studies of similar products and preparation of reports for the regulatory submission (minimum 5 numbers).
- Work should be completed within a period of 9 months from the date of award of contract.

The technically qualified persons/ organisations meeting the above requirements should apply with copies of following documents:

- Detailed profile.
- Copy of Pan Card.
- Details of experience showing the client list with contact details of the person concerned and their feedback on similar work carried out.
- List of people who will be potentially engaged to cover the work listed along with their qualification and experience (Team leader and team members' details).
- List of products developed in each category during the last 10 years with document proof.
- 10 years of experience in formulation development of parenteral preparation & sterile ophthalmic preparations along with the list.

- Experience in Technology transfer & scale up of sterile dosage forms (Minimum 3 projects).
- Experience in conducting stability studies and preparation of reports for the regulatory submission (Minimum 3 projects).

Those technically qualified persons/organisation desirous of engaging in this activity have to submit the above statutory and other documents in sealed cover addressing, The Managing Director, Kerala state Drugs & Pharmaceuticals Ltd,Kalavoor,Alappuzha,Kerala-688522 **on or before 20.03.2024, 05.00pm**

Sd/-

Managing Director

LIST OF SMALL VOLUME PARENTRALS & STERILE OPHTHALMIC PREPARATIONS			
	SVP		
	VIAL		
SL No	Drug Name	Strength	Unit
1	HEPARIN SODIUM INJ IP	5000 IU/ml	5 ml Vial
2	LIGNOCAINE HCL INJ IP (FOR IM USE)	2% w/v	10 ml Vial
3	KETAMINE INJ IP	50 mg/ml	10 ml Vial
4	LIGNOCAINE HCL INJ IP (FOR IV USE-PRESERVATIVE FREE)	2% w/v	30 ml Vial
5	LIGNOCAINE HCL INJ IP	4% w/v	30ml vial
	AMPOULE		
1	PARACETAMOL INJ	150 mg/2 ml	2 ml Amp
2	FRUSEMIDE INJ IP	10 mg/ml	2 ml Amp
3	TRANEXAMIC ACID INJ IP	500 mg/5 ml	5 ml Amp
4	POTASSIUM CHLORIDE INJ IP	15% w/v	10 ml Amp
5	NORADRENALINE STERILE CONCENTRATE IP	0.20%	2 ml Amp
6	FLUPHENAZINE DECANOATE INJ IP	25 mg	1 ml Amp
7	CHLORPHENIRAMINE MALEATE INJ IP	10 mg/ml	1 ml Amp
8	LABETALOL INJ IP	5 mg/ml	4 ml Amp
9	DICLOFENAC SODIUM INJ IP	25 mg/ml	3 ml Amp
10	DEXMEDITOMEDINE INJ USP	200 mcg/2 ml	2 ml Amp
11	BUPIVACAINE HYDROCHLORIDE IN DEXTROSE INJ USP	0.50%	4 ml Amp
12	MAGNESIUM SULPHATE INJ IP	500 mg/ml	2 ml Amp
13	N-ACETYL CYSTEINE INJ	1g	5 ml Amp
14	GLYCOPYRROLATE INJ IP	0.2 mg/ml	1 ml Amp
15	KETOROLAC TROMETHAMINE INJ IP	30 mg/ml	1 ml Amp
16	NEOSTIGMINE METHYL SULPHATE INJ IP	0.5 mg/ml	1 ml Amp
17	ADENOSINE INJ IP	3 mg/ml	2 ml Amp
18	HALOPERIDOL INJ IP	5 mg/ml	1 ml Amp
	EYE DROPS		
1	CIPROFLOXACIN EYE/EAR DROPS IP	0.3% w/v	5 ml
2	DORZOLAMIDE + TIMOLOL EYE DROPS IP	2 % + 0.5 %	5 ml
3	DORZOLAMIDE EYE DROPS IP	2% w/v	5 ml
4	BIMATOPROST EYE DROPS	0.03%	3 ml
5	TROPICAMIDE + PHENYLEPHRINE OPHTHALMIC SOLUTION	0.8% + 5%	5 ml
6	PROPARACAINE HCL OPHTHALMIC SOLUTION	0.50%	5 ml
7	MOXIFLOXACIN EYE DROPS IP	0.5% w/v	5 ml
8	TOBRAMYCIN EYE/EAR DROPS	0.3% w/v	5 ml
9	BRIMONIDINE EYE DROPS IP	0.20%	5 ml

10	FLURBIPROFEN EYE DROPS IP	0.03% w/v	5 ml
11	HOMATROPINE EYE DROPS IP	2% w/v	5 ml
12	TIMOLOL MALEATE EYE DROPS IP	0.5% w/v	5 ml
13	OFLOXACIN EAR/EYE DROPS	0.30%	10 ml
14	PILOCARPINE NITRATE EYE DROPS IP	2% w/v	5 ml
15	GENTAMICIN EYE DROPS IP	0.3% w/v	5 ml
16	ATROPINE EYE DROPS BP/USP	1%	5 ml

****