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

factory & office
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10.03.2022

EXPRESSION OF INTEREST

NOTICE INVITING EoI.

TENDER REF NO: KSDP/PRJ/STL/EOI/14/21-22/128

Expression of Interest (EOI) is invited from reputed registered Firms/Companies/Agencies/consortiumhaving inline experience and can provide Technical assistance for the formulation development of sterile liquid products and onsite qualification and validation.The Firms/Companies/Agencies/consortium who qualify prequalification can apply online/offline.

Shortlisted firms/companies/agencies/consortiums will be allowed to participate.

Interested parties are requested to submit their EOI in the prescribed format along with all supporting documents/ credentials.

For detailed information; please visit our website "www. etenders.kerala.gov.in orwww.ksdp.co.in."
For further clarification kindly contact: - +91 9846978803 (Production Manager)
Email: - ksdpprojects@gmail.com

1	Name of work	EoI for formulation development of sterile liquid products using the latest technology
2	Tender Submission Fee + GST 18%	***Rs. 5000 + Rs. 900 = Rs. 5900/-***
3	Period of completion	As per EOI
4	Tender documents	Can be downloaded from the site ***www.etenders.kerala.gov.in.***
5	PreBid meeting Date & Venue (Online and Offline)	**10:00 am at KSDP,Alappuzha , 18 /03/2022**

6	Online meeting link	**Platform:- Google meet** **Link:- https://meet.google.com/zqp-jqgx-aei**
7	Last date and time of Receipt of Tender/ Bids	**25.03.2022, 11:00 am.**
8	Date and Time of Opening of Tender. Tender documents and tender schedule may be downloaded from the website ***www.etenders.kerala.gov.in.***	**26.03.2022, 11:30 am.**

Mode of submission:

a) Online through ***www.etenders.kerala.gov.in***

A bid submission fee shall be submitted online during the time of bid submission.

Tenders/ bids received online without the fee will not be considered and shall be summarily rejected.

Further details on e-tender process can be had from the NIC, Thiruvananthapuram or Office of the Managing Director, KSDP Ltd, Kalavoor, Alappuzha during working hours.

The KSDP Ltd will not be responsible for any error like missing of schedule data while downloading by the Bidder.

Bidders who was already paid tender submission fee for the same EOI for tender Id:- shall be exempted from tender submission fee. To claim exemption such bidders shall upload previous payment transaction document.

b) Through sealed tender

Tenderer shall submit only one Sealed Tender which consists of tender fee and technical documents in the cover bidder should mentioned EOI name and number & should be sent to the office of the Managing Director, Kerala State Drugs and Pharmaceuticals Ltd., Kalavoor P.O, Alappuzha, Kerala

Technical documents consist all supporting documents and details asked for pre-qualification and EOI Document. The Tender fee and EMD should be submitted in the form of DD or should submit the UTR number of online payment. The amount can be transferred to thebelow mentioned bank account:

Account name: **Kerala State Drugs & Pharmaceuticals Ltd.**

Account No:57035284490,

Name and branch of bank: State Bank of India, Pathirapally,Alappuzha

IFSC Code: SBIN0070317

Bidders who was already paid tender submission fee for the same EOI for tender Id:2021_ksdp_457641_1, 2021_ksdp_457641_2,2021_ksdp_457641_3,2021_ksdp_457641_4 shall be exempted from tender submission fee. To claim exemption such bidders shall upload previous payment transaction document.

Bids shall be opened on specified date and time at the address mentioned above. Any tender received after the due time will be rejected If the tender opening date happens to be on a holiday or nonworking day due to any other valid reason, the tender opening process will be done on the next working day at same time and place.

The KSDP Ltd will not be responsible for any error like missing of schedule data while downloading by the Bidder.

Sd/-

Managing Director

CHECKLIST		
	Yes/No	**If Yes, Document submitted or not**
Registration certificate/Certificate of incorporation/License.		
GST certificate		
Experience details showing the client list with contact details of the person concerned and their feedback on similar work carried out by the firm.		
Details of projects done in the last 5 years with documentation proof.		
Organogram of the firm along with the turnover details pertaining to consultancy service offered by the firm for the last five years.		
List of people who will be potentially engaged to cover the work listed along with their qualification and experience (Team lead and team members details).		
Proposal on the plan along with the timelines envisaged for each major activity (Roadmap to execution).		
Certificate of incorporation of details of works undertaken in facility qualification, water system, process integration, validation of equipment /area etc, sterilisation disinfection procedures, in process checks, Microbial limit test etc.		
List of products developed in each category during the last 10 years with document proof.		
10 years of experience in formulation development of Sterile dosage forms 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).		
Qualification of Manufacturing Equipments (Minimum 3 projects).		
Experience in area validation of the clean rooms (Minimum 3 projects).		
Qualification of HVAC and Compressed Air (Minimum 3 projects).		
Qualification and Validation of Water System (Minimum 3 projects).		

Experience in Execution of the approved IQ, OQ & PQ Protocols (Minimum 3 projects).		
Experience in Equipment and Area cleaning Validation (Minimum 3 projects).		
Experience in Media fill simulation studies (Minimum 3 projects).		
Implementation of Sterilization, Disinfection and Sanitation procedure in sterile manufacturing units (Minimum 3 projects).		
Microbial Validation / Testing Protocols for the sterile dosage forms (Minimum 3 projects).		
Analytical Validation/ Testing Protocols for the sterile dosage forms (Minimum 3 projects).		
Experience in layout design and review of implementation (Minimum 3 projects)\.		
Balance sheet/ P & L statement of last 5 years.		
If last year not available, kindly enclose a turnover statement certified by CA.		
Latest IT return details.		
Financial statement of consultancy for the last 5 years.		

GENERAL TERMS AND CONDITION

Kerala State Drugs & Pharmaceuticals Limited, Kalavoor, Alappuzha, Kerala, is the only fully Public Sector Undertaking of Government of Kerala, engaged in the manufacturing of pharmaceutical products like capsules, tablets, injectables both in the range of Betalactam and Non-Betalactam Products. Being the main supplier KSDP is assisting the policy of Government of Kerala to provide quality medicines at affordable prices to the people particularly in the lower economic strata. In addition KSDP is supplying medicines to other states such as ,Telangana, Tamilnadu, Karnataka , Andhra Pradesh etc and to Janaushdhi .The company is also having a state-of-the-art NABL ACCREDITED LABORATORY.

As KSDP is putting up a plant for sterile liquid products, we are inviting EOI from technically qualified agenciesforthe below works.

a. Development of suitable stable formulation for the parenteral and ophthalmic lines.

b. Generate sufficient data to complete the stability studies as per ICH guidelines (Off site).

c. Technology transfer & scale up techniques for different dosage forms along with the plausible trouble shooting at site during the scale-up.

d. Perform the exhibit batches for the products developed followed by the commercial batch for each product.

e. Facility Qualification should include the Qualification of Manufacturing equipment, HVAC, and compressed Air.

f. Qualification and validation of the water system

g. Process integration including execution of the approved IQ, OQ & PQ protocols/ operation, calibration of process equipment and process validation.

h. Equipment cleaning validation, area validation, area cleaning validation, media fill simulation studies Sterilization, disinfection and sanitization procedures needs to be implemented.

i. Implementation of In-process checks

j. Preparation of Product Microbial Limit Test (MLT), BET, Bio-Burden, & Sterility Method Validation Protocols.

k. Preparation of Analytical Method Validation/ Verification Protocols.

We are requested to give your company profile, a brief description of projects handled. The technical portion of the bid should include company profile, a brief description of projects handled, technical and non technical staff details and other documents mentioned in EOI.

1. Goals of this Expression of Interest.

The objective of this EoI is to solicit proposals from the interested parties for participation in a bid process for selection of a firm for works stated above for the products enclosed and detailed under scope of contract.The Consultant will also be responsible for giving advice, directions and total assistance for the purpose of attaining project is commissioned into as per the cGMP standards and Schedule M of Drugs and Cosmetics Act 1940 for the Kerala State Drugs & Pharmaceuticals Limited and get all strategy approvals.

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

2. EOI ISSUING AUTHORITY

This Expression of Interest (EoI) is issued by the Managing Director, Kerala State Drugs & Chemicals Limited, Kalavoor, Alappuzha, intended to short-list 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.

3. 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.

4. 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.

5. SCOPE OF CONTRACT.

General

a. Formulation development

- Development of suitable stable formulation for the parenteral and ophthalmic lines.
- Generate sufficient data to complete the stability studies as per ICH guidelines (Off site).
- Technology transfer & scale up techniques for different dosage forms along with the plausible trouble shooting at site during the scale-up.
- Perform the exhibit batches for the products developed followed by the commercial batch for each product.

b. Qualification and validation of equipment and process

- Facility Qualification should include the Qualification of Manufacturing equipment, HVAC, and compressed Air.
- Qualification and validation of the water system.
- Process integration should include execution of the approved IQ, OQ & PQ protocols/ operation, calibration of process equipments and process validation.
- Equipment cleaning validation, area validation, area cleaning validation, media fill simulation studies Sterilization, disinfection and sanitization procedures needs to be implemented.
- Implementation of In-process checks.
- Preparation of Product Microbial Limit Test (MLT), BET, Bio-Burden, & Sterility Method Validation Protocols.
- Preparation of Analytical Method Validation/ Verification Protocols.

6. CONDITIONS UNDER WHICH THIS EOI IS ISSUED.

i. This EoI is not an offer and is issued with no commitment and is meant only to shortlist technically qualified parties 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.

ii. Parties who have the competence, capability and meet the eligibility criteria only need to apply.

iii. Financial bids will be called only from technically short listed parties.

iv. Timing and sequence of events resulting from this EoI shall ultimately be determined by the Managing Director.

v. 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.

vi. 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).

vii. 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.

viii. Each applicant shall submit only one proposal.

The Firms/Companies/Agencies/consortium meeting the following requirements are eligible to apply:

- Minimum 10 years' experience as consultancy firm/project management firm having undertaken the implementation of turnkey projects for IV fluids, injectable, and ophthalmic preparations (Sterile Dosage forms).
- Experience in preparing the lay out design, review and its implementation. Must have completed design and implementation of minimum 2 layouts for similar projects in the last 5 years.
- Should have min 10 years of experience in developing formulation for IV fluids, injectable, and ophthalmic preparations (Generic 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 batch post requisite validation (Process validation and integration).
- 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 6 months from the date of award of contract.
- The company should have an average Turnover of min 10 crore in the last 5 completed financial years.
- If it is a consortium, the EoI should clearly mention who is the leader of the consortium and produce valid consortium agreement with the partners and produce competence and experience of all the partners specified in the eligibility criteria.

The Firms/Companies/Agencies/consortium meeting the above requirements should apply with copies of following documents:

- Registration certificate/Certificate of incorporation/License.
- GST certificate
- Experience details showing the client list with contact details of the person concerned and their feedback on similar work carried out by the firm.
- Details of projects done in the last 5 years with documentation proof.
- Organogram of the firm along with the turnover details pertaining to consultancy service offered by the firm for the last five years.
- List of people who will be potentially engaged to cover the work listed along with their qualification and experience (Team lead and team members details).
- Proposal on the plan along with the timelines envisaged for each major activity (Roadmap to execution).
- Certificate of incorporation of details of works undertaken in facility qualification, water system, process integration, validation of equipment /area etc, sterilisation disinfection procedures, in process checks, Microbial limit test etc.
- List of products developed in each category during the last 10 years with document proof.
- 10 years of experience in formulation development of Sterile dosage forms 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).
- Qualification of Manufacturing Equipments (Minimum 3 projects)

- Experience in area validation of the clean rooms (Minimum 3 projects).
- Qualification of HVAC and Compressed Air (Minimum 3 projects).
- Qualification and Validation of Water System (Minimum 3 projects).
- Experience in Execution of the approved IQ, OQ & PQ Protocols (Minimum 3 projects)
- Experience in Equipment and Area cleaning Validation (Minimum 3 projects).
- Experience in Media fill simulation studies (Minimum 3 projects).
- Implementation of Sterilization, Disinfection and Sanitation procedure in sterile manufacturing units (Minimum 3 projects).
- Microbial Validation / Testing Protocols for the sterile dosage forms (Minimum 3 projects).
- Analytical Validation/ Testing Protocols for the sterile dosage forms (Minimum 3 projects).
- Experience in layout design and review of implementation (Minimum 3 projects).
- Balance sheet/ P & L statement of last 5 years.
- If last year not available, kindly enclose a turnover statement certified by CA.
- Latest IT return details.
- Financial statement of consultancy for the last 5 years.

Those Firms/Companies/Agencies/consortiumdesirous of engaging in this activity have to submit through online with their letter of submission showing the EoI on their letterhead, along with copies of the above statutory and other documents **on or before 25.03.2022, 11:00 am.**

Sd/-

Managing Director.

PRODUCT LIST	
SVP (vial)	
1	Amikacin Sulphate Injection 250mg/2ml
2	Dexamethasone Injection 4mg/ml-2ml vial
3	Enoxaparin Injection IP 40mg /0.4ml
4	Gentamicin Injection IP 40mg/ml -2ml
5	Pantoprazole Injection B P - 40mg-10ml
SVP (Ampoule)	
1	Atropine Sulphate Injection 0.6 mg/ml -1ml amp
2	Furosemide Injection 10mg/ml-2ml amp
3	Ondansetron injection-2mg/ml-2ml amp
4	Paracetamol injection-150mg/2ml-2ml amp
5	Phenytoin injection -50mg/ml-2ml amp
6	Ranitidine hydrochloride injection 50mg/2ml-2ml amp
7	Theophylline and etophylline injection 50.6+169.4mg-2ml amp
8	Thiamine injection -50mg/ml-1ml amp
9	Oxytocin injection 5 iu/ml -1ml
Ophthalmic Preparations	
1	Atropine eye drops BP-5ml
2	Carboxymethylcellulose eye drops 0.5% 10ml
3	Flurbiprofen eye drops 0.03% w/v- 5ml
4	Hydroxypropyl methylcellulose eye drops 0.3%-10ml
LVP	
1	METRONIDAZOLE INJ IP 100ml- 5mg/ml
2	DEXTROSE INJ IP (500ml) 5%
3	RINGER LACTATE INJ IP 500ML
4	SODIUM CHLORIDE & DEXTROSE INJ IP - 500ml-0.9% + 5% w/v
5	SODIUM CHLORIDE INJ IP - 500ml- 0.9% w/v