

#### KSDP/PS/F-EPRO/Cefo-sul-02/2023-24/193

25.01.2024

#### **Notice Inviting e-Tender**

The Managing Director, Kerala State Drugs & Pharmaceuticals Ltd, Kalavoor – PO, Alappuzha, Kerala 688 522 invites online bids in **two** cover system for **Supply of Sterile Cefoperazone Sodium and Sulbactum Sodium(2:1)-800 KG** from Suppliers / Organizations who have successfully completed similar works / supplies as given elsewhere in the condition of contract.

| 1 | Name of work  | Supply of Sterile Cefoperazone Sodium and<br>Sulbactum Sodium(2:1)-800 KG                    |
|---|---|--|
| 2 | Earnest Money Deposit (EMD)   | <b>₹100800</b> (by online; refundable)   |
| 3 | Tender Submission Fee   | <b>₹17936</b> (by online; non-refundable)  |
| 4 | Period of completion  | 30days   |
| 5 | Classification of Bidder  | From reputed suppliers/organisations with at least 3 years consistent standing in the field. |
| 6 | Tender documents  | Can be downloaded from the site www.etenders.kerala.gov.in.                                  |
| 7 | Last date and time of Receipt of Tender/ Bids   | <mark>06.02.2024,10.00am</mark>  |
| 8 | Date and Time of Opening of Tender<br>(Technical Bid). Tender documents and<br>tender schedule may be downloaded from<br>the web site www.etenders.kerala.gov.in. | <mark>07.02.2024,10.00am</mark>  |

# NOTE: The Tenderer reserves the right to apportion the tendered quantity among bidders participated

The bid submission fee shall be remitted online during the time of bid submission.

Those bidders possessing valid "**Udyog Aadhar**" can avail EMD & Tender Cost exception by uploading relevant document.

All bid/tender documents are to be submitted online only and in the designated cover(s)/envelope(s) on the e-Tenders website. Technical bid and financial bid shall be submitted in online covers. Tenders/ bids will be accepted only through online mode on the website and no manual submission of the same will be entertained. Late tenders will not be accepted. The scanned copies of registration certificate and EMD exemption certificate (if any) and other documents as specified in the general condition shall be submitted online. More details on Tender documents/bid submission fee are mentioned in the Tender Document. The technical bids/Financial bids shall be opened online on specified date and time. 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. 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.



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### KERALA STATE DRUGS AND PHARMACEUTICALS LTD, KALAVOOR PO, ALAPPUZHA, KERALA-688522

## **Raw Material Specification**

| Name of the Mat | Name of the Material: STERILE CEFOPERAZONE SODIUM AND SULBACTAM SODIUM (2:1) * |              |                   |  |  |
|-----------------|--|--------------|-------------------|--|--|
| SOP No:         | KSDP/SOP/SPEC01  | Spec. No:    | KSDP/R/SPEC01/266 |  |  |
| Effective date: | 14/03/2023   | Revision No: | 00                |  |  |

| SI.No. | TESTS   | SPECIFICATION   |
|--------|---|---|
| 1.     | Description.  | A white or off- white powder.   |
| 2.     | Identification.<br>a) By HPLC   | The retention time of the two major peaks in the<br>chromatogram of the assay preparation respectively<br>corresponds to that exhibited in the chromatogram of the<br>standard preparation. |
|        | b) By Chemical  | It meets the requirements of the tests for sodium.  |
| 3.     | pH  | Between 3.50 and 6.50.  |
| 4.     | Clarity and Color of the solution.  | Should be clear and not more than 0.10 AU at 430 nm.  |
| 5.     | Water.  | Not more than 4.0%.   |
| 6.     | <ul> <li>Related substance (By HPLC).</li> <li>a) Cefoperazone Impurity A<br/>(On Cefoperazone Basis)</li> <li>b) Cefaperazone Impurity C<br/>(On Cefaperazone Basis)</li> <li>c) Any other Impurity<br/>(On the basis of the sum of two<br/>principle peak areas in the<br/>chromatogram of reference<br/>solution)</li> </ul> | Not more than 2.00%<br>Not more than 0.60%  |

| Prepared By | Checked By | Reviewed By     | Approved By           |                   |
|-------------|------------|-----------------|-----------------------|-------------------|
| Officer QA  | QC Head    | Production Head | QA Head               | MASTER COPY       |
| 11/03/23    | 11/03/03   | 13/03/23        | - (Julie)<br>14/03/23 | UNCONTROLLED COPY |

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# **Raw Material Specification**

|     | <ul> <li>d) Total impurity<br/>(On the basis of the sum of two<br/>principle peak areas in the<br/>chromatogram of reference<br/>solution)</li> </ul> | Not more than 3.00%  |
|-----|---|--|
| 7.  | Bacterial Endotoxins.   | Not more than 0.050 EU/mg.   |
| 8.  | Sterility.  | Complies with the test of sterility.   |
| 9.  | Assay.  | Not less than 90% and not more than 110% of the stated amount of Cefoperazone and Sulbactam. |
| 11. | Visual particulate matter.  | Should be free from any visible particles.   |
| 12. | Bulk density.   | Not less than 0.45g/mL.  |

\*In House Specification.

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| Prepared By  | Checked By | Reviewed By     | Approved By         |                   |
|--------------|------------|-----------------|---------------------|-------------------|
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