

KSDP/PS/F-EPRO/Mero-02/2023-24/202

01.02.2024

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 Meropenem IP(Sterile)-90 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 MeropenemIP(Sterile)-90 KG |
|---|---|--|
| 2 | Earnest Money Deposit (EMD) | ₹50310/- (by online; refundable) |
| 3 | Tender Submission Fee | ₹ 8968 /-(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 | 08.02.2024, 01.00 PM |
| 8 | Date and Time of Opening of Tender (Technical Bid). Tender documents and tender schedule may be downloaded from the web site www.etenders.kerala.gov.in. | <mark>09.02.2024, 01.00 PM</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 Material: MEROPENEM FOR INJECTION I.P. | | | | | | | | |
|--|-----------------|--------------|-------------------|--|--|--|--|--|
| SOP No: | KSDP/SOP/SPEC01 | Spec. No: | KSDP/R/SPEC01/207 | | | | | |
| Effective date: | 10/03/23 | Revision No: | 00 | | | | | |

| SI.No. | TESTS Description | SPECIFICATION | | | |
|--------|---|---|--|--|--|
| 1 | | A white to off- white crystalline powder, very hygroscopic. | | | |
| 2 | Identification | In the assay, the principal peak in the chromatogram | | | |
| | | obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution. | | | |
| 3 | pH | 7.3 to 8.3, determined in 5.0%w/v solution. | | | |
| 4 | Related substances (by HPLC) | Complies I.P. | | | |
| 5 | Content of sodium | 80 to 120% of the labelled amount of sodium. | | | |
| 6 | Bacterial endotoxins | Not more than 0.125 Endotoxin units per mg of meropenem. | | | |
| 7 | Loss on drying | 9.0% to 12.0%, determined on 1.0g by drying it in vacuum oven at 65°C for 6 hours. | | | |
| 8 | Sterility | Complies with the test for sterility. | | | |
| 9 | Bulk density* | 0.40 g/mL | | | |
| 10 | Constituted solution* Completeness & clarity of solution | The material should dissolve completely living no visible residue as undissolved matter. The constituted solution is not significantly less clear than an equal volume of purified water contained in a similar vessel and examined similarly | | | |
| 11 | Particulate matter* | Free from any types of visual particles. | | | |
| 12 | Assay (by HPLC) | Not less than 90.0% and not more than 120.0% of the stated amount of meropenem. | | | |

The product complies to I.P. 2022 with respect to above tests. *In House Specification.

| Prepared By | Checked By | Reviewed By | Approved By | |
|-------------|-----------------|-----------------|------------------------|-------------------|
| Officer QA | QC Head | Production Head | QA Head | MASTER COPY |
| 1003/23 | dal 10/03/93 | 10/3/23 | Jal- Valap 10103/23 | UNCONTROLLED COPY |

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