



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

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KSDP/PS/F-EPRO/Aceclo-02/2023-24/186

31.01.2024

Notice Re-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 Aceclofenac DC Granules-41.66%-4000 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 Aceclofenac DC Granules-41.66%-4000KG |
| 2 | Earnest Money Deposit (EMD) | ₹38025 <i>(by online; refundable)</i> |
| 3 | Tender Submission Fee | ₹ 5900 <i>(by online; non-refundable)</i> |
| 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 | 08.02.2024,10.00am |
| 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 . | 09.02.2024,10.00am |

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.

Sd/-

Managing Director



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

Raw Material Specification

Name of the Material: **ACECLOFENAC DC GRANULES 41.66% w/w***

| | | | |
|-----------------|-----------------|--------------|-------------------|
| SOP No: | KSDP/SOP/SPEC01 | Spec. No: | KSDP/R/SPEC01/273 |
| Effective date: | 02/06/2023 | Revision No: | 00 |

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| Sl.No. | TESTS | SPECIFICATION |
|--------|---|--|
| 1 | Description | White color free flowing granules |
| 2 | Identification | In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the principal peak in the chromatogram obtained with the reference solution. |
| 3 | Bulk Density | 0.40 - 0.90 g/mL |
| 4 | Moisture Content (By Moisture Analyzer) | Not more than 3.0 % |
| 5 | Related Substance | Impurity due to Diclofenac: Not more than 5.0% Any other secondary impurity: Not more than 1.0% Total impurities: Not more than 2.0 % |
| 6 | Granulometry | Mesh 20 : 0-25% Mesh 40 : 25-60% Mesh 60 : 60-85% Mesh 100 : 70-95% |
| 7 | Microbial limit test | Total bacterial count not more than 1000 CFU/g Total fungal count not more than 100 CFU/g Escherichia coli: Should be Absent/g Salmonella: Should be Absent/10g P. aureginosa: Should be Absent/g S. aureus: Should be Absent/g |

| Prepared by | Checked by | Reviewed by | Approved by | MASTER COPY UNCONTROLLED COPY |
|-------------|------------|-----------------|-------------|--|
| Officer QA | QC Head | Production Head | QA Head | |
| | | | | |
| 02/06/23 | 02/06/23 | 02/06/23 | 02/06/2023 | |



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Effective date: 02/06/2023

Revision No:

00

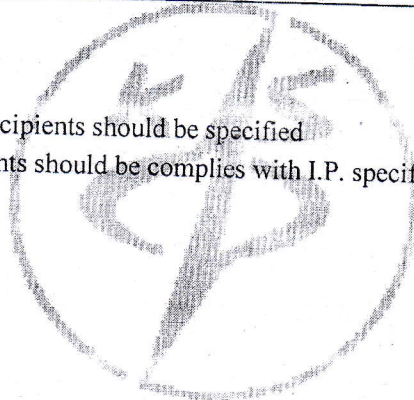
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| | | |
|---|---|---|
| 8 | Dissolution | Not less than 75% |
| 9 | Assay Each 100 gram of DC Granules contains: Aceclofenac I.P.41.66% | Not less than 90% to not more than 110% of the labeled amount Not less than 37.50% to not more than 45.80% of the labeled amount |

*In house Specification

Note:

- Details of the excipients should be specified
- API and excipients should be complies with I.P. specification



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|--------------|--------------|-----------------|--------------|--|
| Officer QA | QC Head | Production Head | QA Head | |
| 02/06/23 | 02/06/23 | 02/06/23 | 02/06/23 | |