



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

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KSDP/PS/F-EPRO/Nifi-02/2023-24/177

10.01.2024

## **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 Nifedipine Prolonged release DC Granules-12.90%w/w-300 KG** from Suppliers / Organizations who have successfully completed similar works supplies as given elsewhere in the condition of contract.

|   |   |  |
|---|---|--|
| 1 | Name of work  | <b>Supply of Nifedipine Prolonged release DC Granules-12.90%w/w-300 KG</b>                                   |
| 2 | Earnest Money Deposit (EMD)   | <b>₹4350</b> (by online; refundable)   |
| 3 | Tender Submission Fee   | <b>₹1062</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 <a href="http://www.etenders.kerala.gov.in">www.etenders.kerala.gov.in</a> . |
| 7 | Last date and time of Receipt of Tender/ Bids   | <b>22.01.2024,10.00am</b>  |
| 8 | Date and Time of Opening of Tender (Technical Bid). Tender documents and tender schedule may be downloaded from the web site <a href="http://www.etenders.kerala.gov.in">www.etenders.kerala.gov.in</a> . | <b>23.01.2024,10.00am</b>  |

### **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: **NIFIDIPINE PROLONGED RELEASE DIRECT  
COMPRESSIBLE GRANULES 12.90% w/w\***

|                 |                 |              |                   |
|-----------------|-----------------|--------------|-------------------|
| SOP No:         | KSDP/SOP/SPEC01 | Spec. No:    | KSDP/R/SPEC01/260 |
| Effective date: | 21/02/23        | Revision No: | 00                |

| Sl.No. | TESTS                | SPECIFICATION  |
|--------|----------------------|--|
| 1.     | Description          | Yellow color free flowing granules.  |
| 2.     | Identification       | A. In the chromatogram obtained with the test solution the principal band, appearing as a compact light orange band against a yellow background, corresponds to that in the chromatogram obtained with reference solution.<br>B. When examined in the range 230nm to 350nm, a 0.001% w/v solution in methanol shows absorption maxima at about 289nm |
| 3.     | Bulk density         | 0.40 – 0.90g/ml  |
| 4.     | Moisture content     | Not more than 3.0%   |
| 5.     | Granulometry test    | Mesh 20: 0 - 25%<br>Mesh 40: 25 - 60%<br>Mesh 60: 60 - 85%<br>Mesh 100: 70 - 95%   |
| 6.     | Organic impurities   | Nifedipine nitrophenylpyridine analog: not more than 2.0%<br>Nifedipine nitrosophenylpyridine: not more than 0.5%  |
| 7.     | Microbial limit test |  |
|        | Aerobic Mesophiles   | <1000 cfu/g  |
|        | Yeast and fungus     | <100 cfu/g   |
|        | Escherichia coli     | Should be absent   |
|        | Salmonella           | Should be absent/10gm  |
|        | P. aureginosa        | Should be absent   |
|        | S. aureas            | Should be absent   |
| 8.     | Dissolution profile  | After 2 hours: not less than 25% and not more than 45% of the stated amount.<br>After 6 hours: not less than 65% cumulative of both the medium of the stated amount.   |

| Prepared by | Checked by | Reviewed By     | Approved By | MASTER COPY<br>UNCONTROLLED COPY |
|-------------|------------|-----------------|-------------|----------------------------------|
| Officer QA  | QC Head    | Production Head | QA Head     |                                  |
|             |            |                 |             |                                  |
| 15/02/23    | 15/02/23   | 16/02/23        | 21/02/23    |                                  |



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

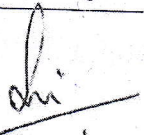
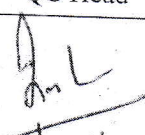

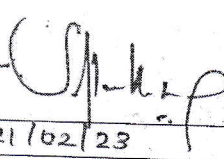
**Raw Material Specification**

|    |  |   |
|----|--|---|
| 9. | Assay :Each 100gm of DC granules contains:<br><b>Nifedipine</b><br><b>I.P.....12.90%</b> | Not less than 11.61% to not more than 14.19% of the labeled amount<br>Not less than 90.0%to not more 110.0% of the labeled amount |
|----|--|---|

Note: Details of the excipients should be specified.

\*In House Specification.



| Prepared by   | Checked by  | Reviewed By   | Approved By  | MASTER COPY |
|---|---|---|--|-------------|
| Officer QA  | QC Head   | Production Head   | QA Head  |             |
| <br>15/02/23 | <br>15/02/23 | <br>16/02/23 | <br>21/02/23 |             |