



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

factory & office | phone : 0477-2258184
kalavoor - 688 522 | 0477-2258828
alappuzha, india
Email: ksdpltd@gmail.com | fax : 0477 - 2258162
Website : www.ksdp.co.in

KSDP/PS/F-EPRO/Nifi-01/2024-25/07

05.09.2024

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 Nifedipine Prolonged release DC Granules-12.90%w/w-350 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 Nifedipine Prolonged release DC Granules-12.90%w/w-350 KG
2	Earnest Money Deposit (EMD)	₹5057 (by online; refundable)
3	Tender Submission Fee	₹1298 (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	13.09.2024,10.00AM
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 .	16.09.2024,10.00AM

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: **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

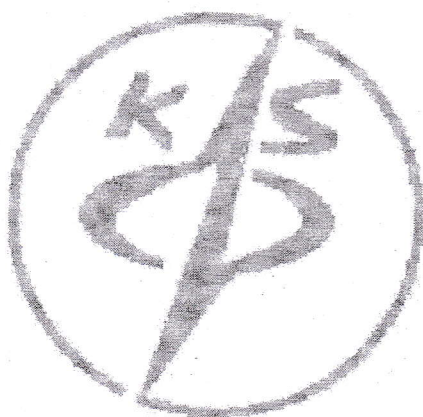
Sl.No.	TESTS	SPECIFICATION
1.	Description	Yellow color free flowing granules.
2.	Identification	A. In the chromatogram obtained with the test solution the principal band, appearing as a compact light orange band against a yellow background, corresponds to that in the chromatogram obtained with reference solution. 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% Mesh 40: 25 - 60% Mesh 60: 60 - 85% Mesh 100: 70 - 95%
6.	Organic impurities	Nifedipine nitrophenylpyridine analog: not more than 2.0% 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. After 6 hours: not less than 65% cumulative of both the medium of the stated amount.

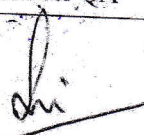
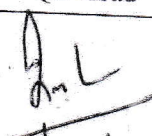

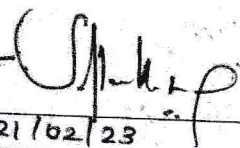
Prepared by	Checked by	Reviewed By	Approved By	MASTER COPY UNCONTROLLED COPY
Officer QA	QC Head	Production Head	QA Head	
15/02/23	15/02/23	16/02/23	21/02/23	

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

9.	Assay :Each 100gm of DC granules contains: Nifedipine I.P.....12.90%	Not less than 11.61% to not more than 14.19% of the labeled amount 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 UNCONTROLLED COPY
Officer QA	QC Head	Production Head	QA Head	
 15/02/23	 15/02/23	 16/02/23	 21/02/23	