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KSDP/PS/F-EPRO/Glimepr-01/2024-25/05

16.04.2024

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 Glimepiride DC Granules 0.74%-10000 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 Glimepiride DC Granules 0.74%-10000 KG
2	Earnest Money Deposit (EMD)	₹48500(by online; refundable)
3	Tender Submission Fee	₹8614(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	27.04.2024,12.00PM
	Date and Time of Opening of Tender	
8	(Technical Bid). Tender documents and tender schedule may be downloaded from the web site www.etenders.kerala.gov.in.	29.04.2024,12.00PM

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.



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

Raw Material Specification

Name of the Material: GLIMEPIRIDE DIRECT COMPRESSIBLE GRANULES 0.74% w/w* SOP No: KSDP/SOP/SPEC01 국3 o 과 리바워S Effective date: Spec. No: KSDP/R/SPEC01/262 Revision No:

SI.No	TESTS				
1	Description	SPECIFICATION			
		Light red color free flowing granules.			
4.	Identification	In the assay principal peak in the 1			
		test solution corresponds to the principal peak in the chromatogram obtained with the obtained with the reference solution			
		obtained with the reference solution.			
3.	Bulk density	0.40 - 0.90g/ml			
4.	Moisture content	Not more than 3.0%			
5.	Related substances	Glimepiride impurity B: not more than 2.5%			
		Any other secondary peak: not more than 0.5% Total impurities (evolution 1)			
	1	Total impurities (excluding Climina 1)			
		Total impurities (excluding Glimepiride impurity B): not more that 1.0%			
6.		Total impurities (including impurity D)			
6.	Granulometry test	Total impurities(including impurity B): not more than 3.5% Mesh 20: 0 - 25%			
		Mesh 40: 25 - 60%			
		Mesh 60: 60 - 85%			
7.	Microbial limit test	Mesh 100: 70 - 95%			
<i>''</i>	Total base : 1				
	Total bacterial count	<1000 cfu/g			
-	Total fungal count	<100 cfu/g			
* ***	Escherichia coli	Should be absent/g			
	Salmonella	Should be absent/10g			
-	P. aureginosa	Should be absent/g			
3.	S. aureas	Should be absent/g			
	Dissolution profile	Not less than 80% of the stated			
	Assay :Each 100gm of	Not less than 0.67% to not more than 0.81% of the labeled amount			
	DC granules contains:	amount amount 10.81% of the labeled			
- 1	Glimepiride I.P	Not less than 90.0% to not more than 110.0% of the labeled amount			
		amount amount 110.0% of the labeled			
e: Deta	ils of the excipients should				

*In House Specification.

Prepared by	Checked by	Reviewed By	An., 15	
Officer QA	QC Head	Production Head	Approved By	MASTER COPY UNCONTROLLED COP
23 02 23	3 02 23	*	QA Head	