

KSDP/PS/F-EPRO/Mannitol -01/2025-26/14

10.06.2025

#### 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 the **Supply of Mannitol IP -2500 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 Mannitol IP -2500 Kg
2	Earnest Money Deposit (EMD)	<b>₹9775</b> (by online; refundable)
3	Tender Submission Fee	<b>₹2360</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 www.etenders.kerala.gov.in.
7	Last date and time of Receipt of Tender/ Bids	18.06.2025, 1.00 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>19.06.2025, 1.00 PM</mark>

NOTE: The Tenderer reserves the right to apportion the tendered quantity among bidders participated (Refer Clause no: 15 in General condition).

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 Mat SOP No:	KSDP/SOP/SPEC01	Spec. No:	KSDP/R/SPEC01/305	
Effective date:	KODI / SOI / SI LOUI	Revision No:	00	Page 1 of 2

SI.No.	TESTS	SPECIFICATION		
1.	Description	A white crystalline powder or free-flowing granules.		
2.	Solubility	Freely soluble in water; slightly soluble in pyridine; very slightly soluble in ethanol (95%); insoluble in chloroform and in ether.		
3.	Identification			
A)	By IR	The spectrum obtained with sample shall be concordant with the spectrum obtained with mannitol IPRS or with the reference spectrum of mannitol.		
B)	Chemical reaction	A clear solution is obtained which remains clear on the further addition of sodium hydroxide solution.		
C)	Colour reaction	A pink colour is produced.		
D)	Melting range	$165^{\circ}$ to $170^{\circ}$ .		
4.	Appearance of solution	Solution A is clear and colourless.		
5.	Acidity or alkalinity	Not more than 0.2 mL of 0.01 M sodium hydroxide is required to change the colour of the solution to pink. Not more than 0.3 mL of 0.01 M hydrochloric acid is required to change the colour of the solution to		
		red.		
6.	Specific optical rotation	$+23.0^{\circ}$ to $+25.0^{\circ}$		
7,	Arsenic .	NMT 2 ppm.		
8.	Chlorides	NMT 50 ppm.		
9.	Sulphates	NMT 100 ppm.		
10.	Reducing sugars	Not less than 12.8 mL of 0.05 M sodium thiosulphate is required.		
11.	Sorbitol	Any spot corresponding to sorbitol in the		

Prepared by	Checked by	Reviewed by	Approved by	Authorized by	
QA Officer	QC Head	Dy. Manager Production	Production Head	QA Head	
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#### KERALA STATE DRUGS AND PHARMACEUTICALS LTD, KALAVOOR PO, ALAPPUZHA, KERALA-688522

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# **Raw Material Specification**

	erial:MANNITOL I.P.	Case No:	KSDP/R/	SPEC01/305
SOP No:	KSDP/SOP/SPEC01	Spec. No:		Page 2 of 2
Effective date:	19/7/24	Revision No:	00	rage 2 01 2

			chromatogram obtained with the test solution is not more intense than the spot in the
			chromatogram obtained with the reference
			solution.
-	12.	Sulphated ash	NMT 0.1 %, determined on 2.0 g.
-	13.	Loss on drying	NMT 0.5 %, determined on 1.0 g.
	14.	Bacterial endotoxins	Not more than 4 endotoxin unit per g for parenteral
	1		preparation having a concentration of 100g per
			litre or less of mannitol, and less than 2.5
(manufacture)			endotoxin unit per g for parenteral preparations
	-1.	1 20 22	having a concentration of more than 100g per litre
			of mannitol.
ł	15.	Assay	NLT 97.0 % and NMT 102.0 % calculated on the
			dried basis.
	16.	Microbial Enumeration Tests*	
		i. Total aerobic microbial count	$\leq 100 \text{ CFU/g}$
		(TAMC)	
		ii. Total Combined Yeasts and	$\leq$ 50CFU/g
		Molds count (TYMC)	

\*In house specification

The product complies to I.P. 2022 with respect to above tests.

Prepared by	Checked by	Reviewed by	Approved by	Authorized by
OA Officer	QC Head	Dy. Manager Production	Production Head	QA Head
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Rony 15/7/24	12/2/04	C 10/2/20	19/7/2/1	UNCONTROLLED