

MANNITAB PHARMA SPECIALITIES PVT. LTD.

Mfg. Site : Gat No. 61/5/2, Nilgavan, Tal. Malegaon - 423105, Dist. Nashik. Maharashtra (India)

Regd. Off. : Post Box No. 31, Lodha Bhuvan, Satana Road, Malegaon - 423203, Dist. Nashik.

CERTIFICATE OF ANALYSIS

Material Name : MANNITOL USP-NF/Ph.Eur./BP/IP (Spray Dried SD1)	Batch No. : MP-23/MSD1-001/01
Party's Name :	Dispatch Quantity : 25.000 Kg
Mfg. Date : JAN. - 2023	No. Of Packs : 01 X 25.000 Kg
Exp. Date : DEC. - 2027	Sampling Date : 05.01.2023
Mfg.Lic.No. : MH/104944	Analysis Date : 11.01.2023

Sr. No.	Test parameters	USP/Ph.Eur/BP/IP Specification	Results
1.	Description Appearance	A white, Crystalline powder (IP) White or almost white, crystals or powder (BP/Ph. Eur.) White, crystalline powder or free-flowing granules. (USP)	Complies
2.	Solubility	Freely soluble in water, slightly soluble in pyridine, very slightly soluble in Ethanol (95%), Insoluble in chloroform and in ether. (IP) Freely soluble in water, practically insoluble in ethanol (96%) (BP/Ph.Eur). Freely soluble in water, soluble in alkaline solutions, slightly soluble in pyridine, very slightly soluble in alcohol, practically insoluble in ether. (USP)	Complies
3.	Identification	Method A, B, C and D (IP) Method A, B, C and D (BP/EP) By IR method (USP)	Complies Complies Complies
4.	Melting point / range	165°-170° (BP/EP) 165°-170° (USP)	168.5°
5.	Appearance of solution	Solution A is clear & colorless(IP) The solution is clear & colorless (BP/EP/USP)	Complies Complies
6.	Acidity and alkalinity	NMT 0.2 ml of 0.01 M NaOH (IP) NMT 0.3 ml of 0.01 M HCl (IP)	0.12 ml of 0.01 M NaOH 0.14 ml of 0.01 M HCl
7.	Specific optical rotation	Between +23.0° to +25.0° (IP)	+ 23.52°
8.	Conductivity	Maximum 20 μScm^{-1} (BP/EP/USP)	3.65 μScm^{-1}
9.	Arsenic	NMT 2 ppm (IP)	< 2 ppm
10.	Chloride	NMT 50 ppm (IP)	< 50 ppm
11.	Sulphates	NMT 100 ppm (IP)	< 100 ppm
12.	Reducing Sugars	NLT 12.8 ml of 0.05M $\text{Na}_2\text{S}_2\text{O}_3$ (IP) NMT 0.1 % (NMT 3.2ml of 0.02 M potassium permanganate required to change green color to pink.) (BP/EP/USP)	17.9 ml < 0.1% 0.31 ml of 0.02 M potassium permanganate required to change green color to pink.
13.	Sorbitol (By TLC)	Any spot corresponding to sorbitol in the chromatogram obtained with test soln is not more intense than the spot in the chromatogram obtained with the ref. soln (IP)	Spot obtained from test soln is not more intense than obtained from ref. soln

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14.	Sulphated Ash	NMT 0.1%w/w (IP)	0.055 % w/w
15.	Loss on drying	NMT 0.5 % w/w (IP/BP/EP/USP)	0.20 % w/w
16.	Nickel	NMT 1 ppm (BP/EP/USP)	< 1 ppm
17.	Heavy metals	NMT 5 ppm (BP/EP)	< 5 ppm
18.	Related Substances	By liquid chromatography Should complies (BP/EP/USP)	
	Impurity A	NMT 2.0% w/w	0.25 % w/w
	Impurity B & C	NMT 2.0 % w/w	0.00 % w/w
	Unspecified Impurities	NMT 0.10 % w/w	0.00 % w/w
	Total impurities	NMT 2.0 % w/w	0.25 % w/w
19.	Assay by HPLC (Content of $C_6H_{14}O_6$) On dried basis	Between 98.0 % - 102 % w/w (IP) Between 97.0 % - 102 % w/w (BP/EP/USP)	99.51 % w/w
20.	Microbial limits (BP/EP/USP)		
	Total Aerobic microbial count	NMT 1000 CFU/g.	< 1000 CFU/g.
	Total Yeast & Moulds	NMT 100 CFU/g.	< 100 CFU/g.
	Salmonella	Absent in 10 gm	Absent
	E.Coli	Absent in 1 gm	Absent
21.	Particle size		
	Residue on 150 micron	NMT - 35%	13.60 %
	Residue on 100 micron	40 - 70%	53.20 %
	Residue on 75 micron	NLT - 70%	77.80 %

Remark : The material "Confirms" I.P./B.P./E.P/USP Specification.

Note : Use as Pharma excipient only.

bmaw
Analyst

F. Dahube
Q.A.Incharge