M. B. SUGARS & PHARMACEUTICALS LTD.

Mfg Site : Gat No.61/5, Nilgavan, Tal: Malegaon - 423 203, Dist :Nashik (Maharashtra) India.
Regd Off: : Lodha Bhuvan, P.B.No: 31, Malegaon - 423 203, Dist :Nashik (Maharashtra) India.

CERTIFICATE OF ANALYSIS

Material Name : MANNITOL IP/BP/Ph.Eur./USP-NF (MANNITAB F3)		Batch No.	: **MB-18/MF3-001/05**
Party's Name :		Sample Quantity	: 500.00 gm.
Mfg. Date	: MAY – 2018	No. Of Jar	: 01 X 500.00 gm.
Exp. Date	: APR. – 2020	Sampling Date	: 18.05.2018
		Analysis Date	: 24.05.2018

Sr. No.	Test parameters	Ph.Eur./USP Specification	Results
1.	Description Appearance	White or almost white, crystals or powder (EP) White, crystalline powder or free –flowing granules. (USP)	Complies
2.	Solubility	Freely soluble in water, practically insoluble in ethanol (96 %) (EP) 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 (EP) By IR method (USP)	Complies
4.	Melting point / range	165^0-170^0 (EP) 165^0-170^0 (USP)	167.2^0
5.	Appearance of solution	The solution is clear & colorless (EP/USP)	Complies
6.	Conductivity	Maximum 20 μScm^{-1} (EP/USP)	9.40 μScm^{-1}
7.	Reducing Sugars	NMT 0.1 % (EP/USP)	0.040 %
8.	Loss on drying	NMT 0.5 % w/w (EP/USP)	0.24 % w/w
9.	Nickel	NMT 1 ppm (EP/USP)	< 1 ppm
10.	Heavy metals	NMT 5 ppm (EP)	< 5 ppm
11.	Related Substances	By liquid chromatography Should complies (EP/USP)	
	Impurity A	NMT 2.0% w/w	Nil
	Impurity B & C	NMT 2.0 % w/w	Nil
	Unspecified Impurities	NMT 0.1 % w/w	Nil
	Total impurities	NMT 2.0 % w/w	Nil
12.	Assay (Content of $C_6H_{14}O_6$)	Between 97 % - 102 % w/w (EP/USP)	99.92 % w/w
13.	**Microbial limits (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 1 gm	Absent
	E.Coli	Absent in 1 gm	Absent
14.	**Particle size**		
	Residue on 500 micron	Not more than 2 %	Complies
	Residue on 315 micron	Not more than 10 %	Complies
	Residue on 40 micron	Not less than 70 %	Complies

Remark : The material "Confirms" as per Ph.Eur./USP Specification.
Note : For Pharma excipient use only.

Analyst

Head Quality Control