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) MANNITAB F2	Batch No.	: **MB-17/MF2-011/07**
Party's Name	: Trans-Chem corporation	Sample Quantity	: 300.00 gm.
Mfg. Date	: JULY – 2017	No. Of Jar	: 01 X 300.00 gm.
Retest Date	: JUNE – 2019	Sampling Date	: 26.07.2017
		Analysis Date	: 01.08.2017

Sr. No.	Test parameters	I.P./B.P./Ph.Eur./USP 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	165^0-170^0 (BP/EP) 165^0-170^0 (USP)	168^0
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)	0.16 ml of 0.01 M NaOH 0.20 ml of 0.01 M HCl
7.	Specific optical rotation	Between $+23.0^0$ to $+25.0^0$ (IP)	$+23.58^0$
8.	Conductivity	Maximum 20 μScm^{-1} (BP/EP/USP)	18.20 μScm^{-1}
9.	Arsenic	NMT 2 ppm (IP)	Complies
10.	Chloride	NMT 50 ppm (IP)	Complies
11.	Sulphates	NMT 100 ppm (IP)	Complies
12.	Reducing Sugars	NLT 12.8 ml of 0.05M $Na_2S_2O_3$ (IP) NMT 0.1 % (BP/EP/USP)	15.4 ml 0.058 %
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)	0.070 % w/w
15.	Loss on drying	NMT 0.5 % w/w (IP/BP/EP/USP)	0.24 % 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	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
19	Assay (Content of $C_6H_{14}O_6$)	Between 98 % - 102 % w/w (IP) Between 97 % - 102 % w/w (BP/EP/USP)	99.79 % 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 1 gm	Absent
	E.Coli	Absent in 1 gm	Absent
21.	**Particle size (by laser)**		
	Residue on 250 micron	Not more than 5%	Complies
	Residue on 100 micron	Not more than 25%	Complies
	Residue on 20 micron	Not less than 55%	Complies

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

Note : For Pharma excipient use only.

Analyst

Head Quality Control

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Regd Off: : Lodha Bhuvan, P.B.No: 31, Malegaon - 423 203, Dist :Nashik (Maharashtra) India.

CERTIFICATE OF ANALYSIS

Material Name	: (MANNITOL) MANNITAB F2	Batch No.	: **MB-17/MF2-013/08**
Party's Name	: Trans-Chem corporation	Sample Quantity	: 300.00 gm.
Mfg. Date	: AUG. – 2017	No. Of Jar	: 01 X 300.00 gm.
Retest Date	: JULY – 2019	Sampling Date	: 12.08.2017
		Analysis Date	: 18.08.2017

Sr. No.	Test parameters	I.P./B.P./Ph.Eur./USP 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	165^0-170^0 (BP/EP) 165^0-170^0 (USP)	168.4^0
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)	0.14 ml of 0.01 M NaOH 0.16 ml of 0.01 M HCl
7.	Specific optical rotation	Between $+23.0^0$ to $+25.0^0$ (IP)	$+23.42^0$
8.	Conductivity	Maximum 20 μScm^{-1} (BP/EP/USP)	17.40 μScm^{-1}
9.	Arsenic	NMT 2 ppm (IP)	Complies
10.	Chloride	NMT 50 ppm (IP)	Complies
11.	Sulphates	NMT 100 ppm (IP)	Complies
12.	Reducing Sugars	NLT 12.8 ml of 0.05M $Na_2S_2O_3$ (IP) NMT 0.1 % (BP/EP/USP)	13.6 ml 0.050 %
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)	0.060 % w/w
15.	Loss on drying	NMT 0.5 % w/w (IP/BP/EP/USP)	0.26 % 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	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
19	Assay (Content of $C_6H_{14}O_6$)	Between 98 % - 102 % w/w (IP) Between 97 % - 102 % w/w (BP/EP/USP)	99.8 % 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 1 gm	Absent
	E.Coli	Absent in 1 gm	Absent
21.	**Particle size (by laser)**		
	Residue on 250 micron	Not more than 5%	Complies
	Residue on 100 micron	Not more than 25%	Complies
	Residue on 20 micron	Not less than 55%	Complies

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

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