



# 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 : <b>MANNITAB SD2</b> (MANNITOL USP-NF)	Batch No. : <b>MB-19/MSD-013/06</b>
Party's Name : Inventia Health care	Sample Quantity : 300.00 gm.
Mfg. Date : JUNE - 2019	No. Of Packs : 01 X 300.00 gm.
Retest Date : MAY - 2021	Sampling Date : 04.06.2019
Material Code : 1500334	Analysis Date : 11.06.2019

Sr. No.	Test parameters	USP/NF	Results
1.	Description	White, crystalline powder or free - flowing granules.	White, crystalline powder
2.	Identification (By IR method)	The infrared spectrum of sample should be concordant with that Mannitol standard spectrum.	Complies
3.	Melting range	Between 165 °C and 170 °C	168.5°C
4.	Appearance of solution	The Sample solution is clear and colorless , its clarity is the same as that of water, or its opalescence is not more pronounced than that of the Reference suspension , and it is not more intensely colored than the Standard solution.	Complies
5.	Loss on drying (at 105°C for 4hr)	Not more than 0.5 % W/W	0.30 % W/W
6.	Nickel	Not more than 1 ug/g	< 1 ug/g
7.	Conductivity	Not more than 20 uS/cm.	11.2 uS/cm.
8.	Reducing Sugars (By Titration)	Not more than 0.1%, expressed as glucose, not more than 3.2 mL of 0.02 M Potassium permanganate VS is required to change the color of the solution . The green color turns to pink , and the color persists at least 10s	< 0.1 % 1.6 ml of 0.02 M potassium permanganate VS required to change green color to pink
9.	Related Substances	By liquid chromatography Should complies	
	Impurity A	NMT 2.0% w/w	< 2.0% w/w
	Impurity B & C	NMT 2.0 % w/w	Complies
	Unspecified Impurities	NMT 0.1 % w/w	Complies
	Total impurities	NMT 2.0 % w/w	Complies
10.	Assay (Content of C <sub>6</sub> H <sub>14</sub> O <sub>6</sub> )	Between 97 % - 102 % w/w (Calculated on the anhydrous basis)	99.5 % W/W
11.	Microbial limits		
	Total Aerobic microbial count	NMT 1000 CFU/g.	< 1000 CFU/g.
	Total Yeast & Moulds	NMT 100 CFU/g.	< 100 CFU/g.
	Escherichia coli	Should be absent	Absent
12.	Particle size	NMT 10% retains on 50 # ASTM NLT 90 % retains on 200 # ASTM.	1.20 % retains on 50 # 96.32 % retains on 200 #

Remark : The material "Confirms" as per above Specification.

Analyst

Head Quality Control





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## CERTIFICATE OF ANALYSIS

Material Name : <b>MANNITAB SD2</b> (MANNITOL USP-NF)	Batch No. : <b>MB-19/MSD-014/06</b>
Party's Name : Inventia Health care	Sample Quantity : 300.00 gm.
Mfg. Date : JUNE - 2019	No. Of packs : 01 X 300.00 gm.
Retest Date : MAY - 2021	Sampling Date : 06.06.2019
Material Code : 1500334	Analysis Date : 13.06.2019

Sr. No.	Test parameters	USP/NF	Results
1.	Description	White, crystalline powder or free - flowing granules.	White, crystalline powder
2.	Identification (By IR method)	The infrared spectrum of sample should be concordant with that Mannitol standard spectrum.	Complies
3.	Melting range	Between 165 °C and 170 °C	169.2 °C
4.	Appearance of solution	The Sample solution is clear and colorless , its clarity is the same as that of water, or its opalescence is not more pronounced than that of the Reference suspension , and it is not more intensely colored than the Standard solution.	Complies
5.	Loss on drying (at 105 °C for 4hr)	Not more than 0.5 % W/W	0.26 % W/W
6.	Nickel	Not more than 1 ug/g	< 1 ug/g
7.	Conductivity	Not more than 20 uS/cm.	10.20 uS/cm.
8.	Reducing Sugars (By Titration)	Not more than 0.1%, expressed as glucose, not more than 3.2 mL of 0.02 M Potassium permanganate VS is required to change the color of the solution . The green color turns to pink , and the color persists at least 10s	< 0.1 % 1.4 ml of 0.02 M potassium permanganate required to change green color to pink
9.	Related Substances	By liquid chromatography Should complies	
	Impurity A	NMT 2.0% w/w	< 2.0% w/w
	Impurity B & C	NMT 2.0 % w/w	Complies
	Unspecified Impurities	NMT 0.1 % w/w	Complies
	Total impurities	NMT 2.0 % w/w	Complies
10.	Assay (Content of C <sub>6</sub> H <sub>14</sub> O <sub>6</sub> )	Between 97 % - 102 % w/w (Calculated on the anhydrous basis)	98.6 % W/W
11.	Microbial limits		
	Total Aerobic microbial count	NMT 1000 CFU/g.	< 1000 CFU/g.
	Total Yeast & Moulds	NMT 100 CFU/g.	< 100 CFU/g.
	Escherichia coli	Should be absent	Absent
12.	Particle size	NMT 10% retains on 50 # ASTM NLT 90 % retains on 200 # ASTM.	1.00 % retains on 50 # 95.80 % retains on 200 #

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## CERTIFICATE OF ANALYSIS

Material Name : MANNITAB SD2 (MANNITOL USP-NF)	Batch No. : MB-19/MSD-015/06
Party's Name : Inventia Health care	Sample Quantity : 300.00 gm.
Mfg. Date : JUNE - 2019	No. Of packs : 01 X 300.00 gm.
Retest Date : MAY - 2021	Sampling Date : 08.06.2019
Material Code : 1500334	Analysis Date : 15.06.2019

Sr. No.	Test parameters	USP/NF	Results
1.	Description	White, crystalline powder or free - flowing granules.	White, crystalline powder
2.	Identification (By IR method)	The infrared spectrum of sample should be concordant with that Mannitol standard spectrum.	Complies
3.	Melting range	Between 165 °C and 170 °C	168.4 °C
4.	Appearance of solution	The Sample solution is clear and colorless , its clarity is the same as that of water, or its opalescence is not more pronounced than that of the Reference suspension , and it is not more intensely colored than the Standard solution.	Complies
5.	Loss on drying (at 105°C for 4hr)	Not more than 0.5 % W/W	0.30 % W/W
6.	Nickel	Not more than 1 ug/g	< 1 ug/g
7.	Conductivity	Not more than 20 uS/cm.	10.20 uS/cm.
8.	Reducing Sugars (By Titration)	Not more than 0.1%, expressed as glucose, not more than 3.2 mL of 0.02 M Potassium permanganate VS is required to change the color of the solution . The green color turns to pink , and the color persists at least 10s	< 0.1 % 1.8 ml of 0.02 M potassium permanganate required to change green color to pink
9.	Related Substances	By liquid chromatography Should complies	
	Impurity A	NMT 2.0% w/w	< 2.0% w/w
	Impurity B & C	NMT 2.0 % w/w	Complies
	Unspecified Impurities	NMT 0.1 % w/w	Complies
	Total impurities	NMT 2.0 % w/w	Complies
10.	Assay (Content of C <sub>6</sub> H <sub>14</sub> O <sub>6</sub> )	Between 97 % - 102 % w/w (Calculated on the anhydrous basis)	98.8 % W/W
11.	Microbial limits		
	Total Aerobic microbial count	NMT 1000 CFU/g.	< 1000 CFU/g.
	Total Yeast & Moulds	NMT 100 CFU/g.	< 100 CFU/g.
	Escherichia coli	Should be absent	Absent
12.	Particle size	NMT 10% retains on 50 # ASTM NLT 90 % retains on 200 # ASTM.	1.40% retains on 50 # 96.00 % retains on 200 #

Remark : The material "Confirms" as per above Specification.

Analyst

Head Quality Control