

### 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

| (MANNITOL USP-NF) Party's Name : Inventia Health care |  |   | atch No.   | : MB-19/MSD-013/0   |
|---|--|---|--|---|
|   |  |   | Sample Quantity : 300.00 gm.  No. Of Packs : 01 X 300.00 gm. |   |
|   |  |   |  |   |
| Mate  | erial Code : 1500334   |   | Analysis Date  |   |
| Sr.<br>No.  | Test parameters  | USP/NF  | GALS LTD. M.B.<br>CALS LTD. M.B                              | : 11.06.2019<br>Results   |
| 1.  | Description  | White, crystalline powder flowing granules.   | or free -  | White, crystalline powde  |
| 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 MS<br>GARS<br>GARS<br>GARS<br>GARS<br>GARS<br>GARS  | 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  UGARS & PHARMACEUTIC  |
| 5.  | Loss on drying<br>(at 105°C for 4hr)                                 | Not more than 0.5 % W/W   | V TD. M.B.   | 0.30 % W/W  |
| 6.  | Nickel ACEUTICALS LTD.   | Not more than 1 ug/g  |  | < 1 ug/g  |
| 7.  | Conductivity   | Not more than 20 uS/cm.   |  |   |
| 8.<br>3.445<br>3.445<br>3.445                         | 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                  |  | 11.2 uS/cm. < 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  |  | UGARS & PHARMAGEUTICA<br>UGARS & PHARMAGEUTICA<br>UGARS & PHARMAGEUTICA                               |
| GARS<br>GARS<br>GARS<br>GARS                          | Impurity A   | NMT 2.0% w/w  | CALS LYD, M.B.   | < 2.0% w/w  |
|   | Impurity B & C   | NMT 2.0 % w/w   | CALS LTD. M.D.   | Complies  |
|   | Unspecified Impurities   | NMT 0.1 % w/w   |  | Complies  |
| ARS   | Total impurities   | NMT 2.0 % w/w   | CALS LTD. M.B.   | Complies  |
| 10.   | Assay<br>(Content of C <sub>6</sub> H <sub>14</sub> O <sub>6</sub> ) | Between 97 % - 102 % w/w<br>(Calculated on the anhydrou   |  | 99.5 % W/W  |
| 11.   | Microbial limits   | A LINEARS & PHARMACEUTIC  | ALS LTD. M.B.  | UGARS & PHARMACEUTIC  |

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

NMT 1000 CFU/g.

NMT 100 CFU/g.

Should be absent

NMT 10% retains on 50 # ASTM

NLT 90 % retains on 200 # ASTM.

Analyst

12

Total Aerobic microbial

Total Yeast & Moulds

Escherichia coli

Particle size

count

Hear Quality Control

< 1000 CFU/g.

< 100 CFU/g.

1.20 % retains on 50 #

96.32 % retains on 200 #

Absent



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#### CERTIFICATE OF ANALYSIS

| Material Name: MANNITAB SD2 (MANNITOL USP-NF) | Batch No. : MB-19/MSD-014/06   |
|---|--------------------------------|
| 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 : 06.06.2019     |
| Material Code: 1500334                        | Analysis Date : 13.06.2019     |

| Sr.<br>No.                                   | Test parameters  | USP/NF  | Results  |
|--|--|---|--|
| GARS   | Description  | White, crystalline powder or free - flowing granules.   | White, crystalline powder  |
| 2.   | Identification<br>(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. GARS GARS GARS GARS                       | 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  GARS PHARMACEUTICS  HARMACEUTICS  HARMACEUTICS                               |
| 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. S<br>GARS<br>GARS<br>GARS<br>GARS<br>GARS | 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  | UGARS & PHARMACEUTICA<br>UGARS & PHARMACEUTICA<br>UGARS & PHARMACEUTICA                |
| GARS   | 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   |
| BARS   | Total impurities   | NMT 2.0 % w/w   | Complies   |
| 10.  | Assay<br>(Content of C <sub>6</sub> H <sub>14</sub> O <sub>6</sub> ) | Between 97 % - 102 % w/w<br>(Calculated on the anhydrous basis)   | 98.6 % W/W   |
| 11.  | Microbial limits   | A B.SUGARS & PHARMACEUTICALS LTD. M.B.:   | UGARS & PHARMACEUTICA  |
| GARS<br>GARS<br>GARS<br>GARS<br>GARS         | 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<br>NLT 90 % retains on 200 # ASTM.   | 1.00 % retains on 50 #<br>95.80 % retains on 200 #                                     |

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

Analyst

Head Quality Control



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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.<br>No.   | Test parameters  | USP/NF  | Results  |
|--|--|---|--|
| CLRS<br>GARS   | Description  | White, crystalline powder or free - flowing granules.   | White, crystalline powder  |
| 2.   | Identification<br>(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   |
| C4.S<br>CARS<br>GARS<br>GARS<br>GARS<br>GARS<br>GARS | 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.   |
| SARS<br>GARS<br>GARS<br>GARS<br>GARS                 | 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  | UGARS & PHARMACEUTICA UGARS & PHARMACEUTICA UGARS & PHARMACEUTICA                      |
| ARS  | 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   |
| ARS  | Total impurities   | NMT 2.0 % w/w   | Complies   |
| 10.  | Assay<br>(Content of C <sub>6</sub> H <sub>14</sub> O <sub>6</sub> ) | Between 97 % - 102 % w/w<br>(Calculated on the anhydrous basis)   | 98.8 % W/W   |
| 11.  | Microbial limits   | LESUGARS & PHARMACEUTICALS LTD. M.B.S.  | UUARS & PHARMACEUTICA  |
| ARS<br>ARS<br>ARS<br>ARS                             | 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<br>NLT 90 % retains on 200 # ASTM.   | 1.40% retains on 50 #<br>96.00 % retains on 200 #                                      |

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

Analyst