

Certificate of Analysis No. 1145/15 - E

Product D-(+)-Mannose  
Batch Number: 150930  
Formula: C<sub>6</sub>H<sub>12</sub>O<sub>6</sub>  
Molecular Weight 180.16  
CAS Registry Number [3458-28-4]

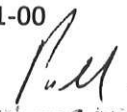

Test	Required by Analytical Specification No. M01-00	Found (result)
Description	White crystalline powder	Complies
Melting Point (Kofler, 4 °C/min)	not less than 126 °C	126 - 130 °C
Specific Optical Rotation $[\alpha]_D^{20}$	+14.1 ±0.5° (c=4, H <sub>2</sub> O, 24 h)	+14,33 °
Assay (HPLC)	Equal to or more than 99 %	99,69 %
IR Spectrum	Complies with the structure	Complies
5% Solution in Water	clear, colourless	Complies
Chloride	not more than 0.005 %	Complies
Sulphate	not more than 0.005 %	Complies
Loss on Drying	not more than 0.20 %	0.07 %
Sulphated Ash	not more than 0.10 %	0.0 %
Arsenic (AAS)	not more than 0.00001 %	Complies
Lead (AAS)	not more than 0.0005 %	Complies
Cadmium (AAS)	not more than 0.0005 %	Complies
Copper (AAS)	not more than 0.0005 %	Complies
Iron (AAS)	not more than 0.0005 %	Complies
Zinc (AAS)	not more than 0.0005 %	Complies
Endotoxin (LAL)	Not more than 1.2 EU/g	0,11
Heavy metals assay of less than	3 by ICP-MS	

Total aerobic micro-organisms count	Number of colonies (cfu) in 1g	Limit in 1g
Total aerobic microbial count (TAMC)	< 10	10 <sup>2</sup>
Total yeasts and moulds count (TYMC)	< 10	10 <sup>2</sup>

Specific micro-organisms	Number of colonies (cfu) in 1g	Limit in 1g
Escherichia coli	Not found/1 g	0/1 g
Salmonella abony	Not found/10g	0/10g

**CONCLUSION**

The sample complies with the test of the total aerobic micro-organisms count, test on selected specific micro-organisms and fulfils the requirements to the microbiological quality of the non-sterile dosage forms according to Ph.Eur.8., harmonised method for substances for pharmaceutical use.

RESULT:	<b>Product complies with the Analytical Specification No. M01-00</b>	
Date of production	September 30, 2015	 <b>EKOFIDAS engineering, spol. s r.o.</b> IČ: 24307084 DIČ: CZ24307084 
Date of expiration	3 years in standard conditions	
Date of analysis	Oktober 15, 2015	
Bulk Density	0,26 g /ml	
Quality Control Unit	Ing. Miloš Šorf	

Certificate of Analysis No. 0552/15 - E

Product D-(+)-Mannose  
Batch Number: 150428  
Formula: C<sub>6</sub>H<sub>12</sub>O<sub>6</sub>  
Molecular Weight 180.16  
CAS Registry Number [3458-28-4]

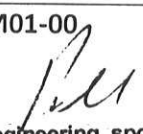

Test	Required by Analytical Specification No. M01-00	Found (result)
Description	White crystalline powder	Complies
Melting Point (Kofler, 4 °C/min)	not less than 126 °C	126 - 130 °C
Specific Optical Rotation $[\alpha]_D^{20}$	+14.1 ±0.5° (c=4, H <sub>2</sub> O, 24 h)	+14,25 °
Assay (HPLC)	Equal to or more than 99 %	99,67 %
IR Spectrum	Complies with the structure	Complies
5% Solution in Water	clear, colourless	Complies
Chloride	not more than 0.005 %	Complies
Sulphate	not more than 0.005 %	Complies
Loss on Drying	not more than 0.20 %	0.03 %
Sulphated Ash	not more than 0.10 %	0.0 %
Arsenic (AAS)	not more than 0.00001 %	Complies
Lead (AAS)	not more than 0.0005 %	Complies
Cadmium (AAS)	not more than 0.0005 %	Complies
Copper (AAS)	not more than 0.0005 %	Complies
Iron (AAS)	not more than 0.0005 %	Complies
Zinc (AAS)	not more than 0.0005 %	Complies
Endotoxin (LAL)	Not more than 1.2 EU/g	0,14
Heavy metals assay of less than	3 by ICP-MS	

Total aerobic micro-organisms count	Number of colonies (cfu) in 1g	Limit in 1g
Total aerobic microbial count (TAMC)	< 10	10 <sup>2</sup>
Total yeasts and moulds count (TYMC)	< 10	10 <sup>2</sup>

Specific micro-organisms	Number of colonies (cfu) in 1g	Limit in 1g
Escherichia coli	Not found/1 g	0/1 g
Salmonella abony	Not found/10g	0/10g

**CONCLUSION**

The sample complies with the test of the total aerobic micro-organisms count, test on selected specific micro-organisms and fulfils the requirements to the microbiological quality of the non-sterile dosage forms according to Ph.Eur.8., harmonised method for substances for pharmaceutical use.

RESULT:	<b>Product complies with the Analytical Specification No. M01-00</b>	
Date of production	April 28, 2015	 <b>EKOFIDAS engineering, spol. s r.o.</b> IČ: 24307084 DIČ: CZ24307084 
Date of expiration	3 years in standard conditions	
Date of analysis	May 27, 2015	
Bulk Density	0,26 g /ml	
Quality Control Unit	Ing. Miloš Šorf	