



Scharlab S.L.

Tel. int.: +34-93-7151811

Email: scharlab@scharlab.com

CERTIFICATE OF ANALYSIS

Product: **D(-)-Mannitol**, extra pure, Pharmapur[®], Ph Eur, BP,
MA0149 USP

Batch 16961101
Quality release date 10/02/2016
Expiry date 2/2021

Analysis	Batch value	Specifications
assay (HPLC on dried sample)	99,00 %	97 - 102 %
identity (IR-spectrum)	passes test	passes test
appearance of solution (10 %, H ₂ O)	clear and colourless	clear and colourless
conductivity (25°C; 20%, in H ₂ O)	16,00 µS/cm	max . 20 µS/cm
specific rotation ([α] 20 / D, c=10, ammonium molybdate solution)	+ 137 ° - + 145 °	+ 137 ° - + 145 °
melting point	165 - 170 °C	165 - 170 °C
chlorides (as Cl)	< 0,0025 %	max. 0,007 %
acidity.....	passes test	passes test
sulfates (as SO ₄)	< 0,01 %	max. 0,01 %
arsenic (As)	< 0,0001 %	max. 0,0001 %
heavy metals (as Pb)	< 0,0005 %	max. 0,0005 %
nickel (Ni)	< 0,0001 %	max. 0,0001 %
related substances	passes test	passes test
reducing sugars (as glucose)	< 0,1%	max. 0,1%
loss on drying (105 ° C, 4h)	< 0,05 %	max. 0,5 %

Residual solvents are analysed

according to guideline

CPMP/ICH/283/95.