

CERTIFICATE OF ANALYSIS

Product : **MANNITOL (D-)**
 Product number : M0803
 Batch number : 010668
 Date of production : 09-03-2014
 Date of analysis : 31-03-2014
 Date of expiry : 31-03-2019

Packaging and storage : in a well-closed container, protected from light

	SPECIFICATION	RESULT	UNITS	REMARKS
Appearance	white crystalline powder, odourless, sweet taste	complies		
Identification:				
- A (specific optical rotation)	+137 – +145	+141	°	USP
- B (melting point)	165 – 170	167	°C	
- C (IR-spectrum)	conform	complies		
Appearance of solution	clear and colourless	complies		10% in H ₂ O
Conductivity	≤ 20	1.1	μS/cm	20% in H ₂ O
Reducing sugars	≥ 12.8	complies	ml/5g	0.05M Na ₂ S ₂ O ₃
Related substances	conform	0.9		HPLC
Chlorides	conform	< 1		
Sulphates	conform	< 1		
Sulphated ash	≤ 0.1	< 0.1	%	
Arsenic	≤ 1	complies	ppm	
Lead	≤ 0.5	complies	ppm	
Nickel	≤ 1.0	complies	ppm	
Loss on drying	≤ 0.5	0.1	%	
Assay	98.0 – 102.0	99.1	%	dried substance

This certificate of analysis is conform the results of the manufacturer.

Conclusion: approved

Released by:

drs. M. van Wissen, pharmacist
 Department of Quality Control Duchefa BV

Date: 10-09-2014

