

Certificate of Analysis

Productname: Mannitolum apyrogen
Number of analysis/Inspection Code: 1 / KEUR-179733B
Batchnumber: 19I13-F04-365825
Reference code / No.: 1998 / E159R
Analysed according to: PH.EUR9.8+

Tests	Requirement	Result	Unit	Standard remark
Appearance	Almost white crystals or powder	Conform		
Identification C	Conform	Conform		IR-spectrum
Appearance of solution	Clear / colourless	Conform		10% _{m/V}
Conductivity	<=20	4	μS / cm	
Melting point	165 - 170	167	°C	
Reducing sugars	<=0,1	Conform	%	
Related substances	Conform	Conform		HPLC
Impurity A	<=2,0	1,1	%	
Sum impurities B and C	<=2,0	0,1	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=2,0	1,1	%	
Loss on drying	<=0,5	0,0	%	4 h 105°C
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay D-Mannitol	97,0 - 102,0	100,6	% _{m/m}	Dried
Total aerobic microbial count (TAMC)	<=10 ²	Conform	CFU / g	
Total yeasts and moulds (TYMC)	<=10 ²	Conform	CFU / g	
E. coli	Negative / gram	Conform		
Salmonella	Negative / 10 gram	Conform		
Endotoxins	<0,0025	Conform	IU / mg	LAL-test
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
 dr. M.J. Vincenten - van Maanen
 Pharmacist - Qualified Person

01/20/20

Expiration: 03-2022

Conclusion: APPROVED

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