

Certificate of Analysis

Product name: **Mannitolum apyrogen**
Batch number / Weight: **21J11-B01-219199 / 5 KG**
Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder	Conform		
Identification C	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		
Conductivity	<=20	1,2	µS / cm	
Melting point	165 - 170	168,7	°C	
Reducing sugars	<=0,1	Conform	%	
Related substances	Conform	Conform		
Impurity A	<=2,0	0,82	%	
Sum impurities B and C	<=2,0	0,07	%	
Unspecified impurities	<=0,10	0,060	%	
Total impurities	<=2,0	0,95	%	
Loss on drying	<=0,5	0,03	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay D-Mannitol	97,0 - 102,0	99,17	%m/m	
Total aerobic microbial count (TA)	<=100	Conform	CFU / g	
Total yeasts and moulds (TYMC)	<=100	Conform	CFU/g	
E. coli	Negative / gram	Conform		
Salmonella	Negative / 10 gram	Conform		
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Endotoxins	<2,5	<2,5	IU/g	

Analysis performed by the authorized lab.

Release:

Agnieszka Pszczółka

Qualified Person

03-03-2022

Expiration: 07-12-2023

Conclusion: APPROVED

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