

Certificate of Analysis

Product name: Mannitolum apyrogen
Batch number / Weight: 21I02-B05-216344 / 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	$\mu\text{S} / \text{cm}$	
Melting point	165 - 170	168,7	$^{\circ}\text{C}$	
Reducing sugars	$\leq 0,1$	Conform	%	
Related substances	Conform	Conform		
Impurity A	$\leq 2,0$	0,82	%	
Sum impurities B and C	$\leq 2,0$	0,07	%	
Unspecified impurities	$\leq 0,10$	0,060	%	
Total impurities	$\leq 2,0$	0,95	%	
Loss on drying	$\leq 0,5$	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		
Endotoxins	$< 0,0025$	Conform	IU / mg	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:

Ewelina Gadzinowska

Qualified Person

20-12-2021

Expiration: 07-12-2023

Conclusion: APPROVED

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