

Certificate of Analysis

Product name: Mannitolum apyrogen

Batch number / Weight: 23I20-B10-233824 / 5 KG

Analysed according to: Ph.Eur.11.2

Number of analysis / Inspection Code 23I20-B10 / INS-23-8021

Reference Code / No.: V01176 / 690262

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder	Conform		
Identification C	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		
Conductivity	≤ 20	1,1	$\mu\text{S} / \text{cm}$	
Melting point	165 - 170	168,8	$^{\circ}\text{C}$	
Reducing sugars	$\leq 0,1$	$< 0,1$	%	
Related substances	Conform	Conform		
Impurity A	$\leq 2,0$	0,72	%	
Sum impurities B and C	$\leq 2,0$	0,12	%	
Unspecified impurities	$\leq 0,10$	0,055	%	
Total impurities	$\leq 2,0$	0,95	%	
Loss on drying	$\leq 0,5$	0,00	%	
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	99,25	%m/m	
Total aerobic microbial count (TA)	≤ 100	< 1	CFU / g	
Total yeasts and moulds (TYMC)	≤ 100	< 1	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	

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL, EI Spol, CBMiA

Release:

Ewelina Gadzinowska

Qualified Person

29-11-2023

Expiration: 07-07-2026

Conclusion: APPROVED

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