

Certificate of Analysis

Product name: Mannitolum apyrogen
Batch number / Weight: 23C16-B02-226877 / 5 KG
Analysed according to: Ph.Eur.11.1
Number of analysis / Inspection Code 23C16-B02 / INS-23-3007
Reference Code / No.: V01176 / E386Z

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder	Conform		
Identification C	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		
Conductivity	≤ 20	1,8	$\mu\text{S} / \text{cm}$	
Melting point	165 - 170	167,5	$^{\circ}\text{C}$	
Reducing sugars	$\leq 0,1$	$< 0,1$	%	
Related substances	Conform	Conform		
Impurity A	$\leq 2,0$	0,87	%	
Sum impurities B and C	$\leq 2,0$	0,11	%	
Unspecified impurities	$\leq 0,10$	$< 0,05$	%	
Total impurities	$\leq 2,0$	0,98	%	
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	98,80	%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	TSE/BSE-sta		Data producer
Endotoxins	$< 2,5$	$< 2,5$	IU/g	

fagron.pl

Fagron Sp. z o.o.
 ul. Armii Krajowej 3
 32-540 Trzebinia, Poland
 e-mail: biuro@fagron.pl

fagron.pl

Fagron sp. z o.o.
 ul. Pasternik 26, 31-354 Kraków, Poland
 tel.: +48 12 3343 512
 e-mail: biuro@fagron.pl

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 FAPL, EISpol, CBMiA

Release:
Dominika Soltysik
Qualified Person

29-05-2023

Expiration: 30-10-2025

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

fagron.pl

Fagron Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:biuro@fagron.pl