

Certificate of Analysis

Product name: Sorbitolum

Batch number / Weight: 23H14-B09-236037 / 5 KG

Analysed according to: Ph.Eur.11.3

Number of analysis / Inspection Code 23H14-B09 / INS-23-6940

Reference Code / No.: V01176 / 584887

Tests	Requirement	Result	Unit	Standard remark
Appearance	(almost) white, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification D	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		
Conductivity	≤ 20	5,9	$\mu\text{S} / \text{cm}$	
Reducing sugars	$\leq 0,2$	$< 0,2$	%	
Related substance	Conform	Conform		
Any impurity	$\leq 2,0$	0,80	%	
Total impurities	$\leq 3,0$	1,64	%	
Water (Karl Fischer)	$\leq 1,5$	0,39	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	97,0 - 102,0	98,53	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Total yeasts and moulds (TYMC)	$\leq 10^2$	< 1	CFU/g	
Total aerobic microbial count (TA)	$\leq 10^3$	< 1	CFU/g	
Escherichia coli	Absence in 1g	Conform		
Salmonella	Negative / 10 gram	Conform		
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:

Agnieszka Pszczółka

Qualified Person

13-03-2024

Expiration: 01-03-2026

Conclusion: APPROVED

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