

Certificate of Analysis

Product name: Sorbitolum apyrogen
Batch number / Weight: 22B07-B02-218363 / 5 KG
Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	(almost) white, crystalline powder	Conform		
Identification A	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		
Conductivity	≤ 20	2,2	$\mu\text{S} / \text{cm}$	
Reducing sugars	$\leq 0,2$	$< 0,2$	%	
Related substance	Conform	Conform		
Any impurity	$\leq 2,0$	max.0,51		
Total impurities	$\leq 3,0$	0,84	%	
Water (Karl Fischer)	$\leq 1,5$	0,27	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	97,0 - 102,0	98,82	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Total yeasts and moulds (TYMC)	$\leq 10^2$	Conform	CFU/g	
Total aerobic microbial count (TA)	$\leq 10^3$	Conform	CFU/g	
Escherichia coli	Absence in 1g	Conform		
Salmonella	Negative / 10 gram	Conform		
Endotoxins	$< 2,5$	$< 2,5$	IU/g	

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

27-05-2022

Expiration: 17-02-2024

Conclusion: APPROVED

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