

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	μS / cm	
Reducing sugars	<=0,2	<0,2	%	
Related substance	Conform	Conform		
Any impurity	<=2,0	max.0,51		
Total impurities	<=3,0	0,84	%	
Water (Karl Fischer)	<=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)	<=10 ²	Conform	CFU/g	
Total aerobic microbial count (TA)	<=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

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