

Certificate of Analysis

Productname: Sorbitolum apyrogen
Number of analysis/Inspection Code: 1 / KEUR-181070B
Batchnumber: 19K20-F01-367332
Reference code / No.: 1998 / E543F
Analysed according to: PHEUR10.0+

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	Conform	Conform	%	HPLC
Appearance of solution	Clear / colourless	Conform		10% <i>m/V</i>
Conductivity	<=20	4	μ S / cm	
Reducing sugars	<=0,2	<0,2	%	
Related substances	Conform	Conform		HPLC
Any impurity	<=2,0	0,6	%	
Total impurities	<=3,0	1,0	%	
Water (Karl Fischer)	<=1,5	0,2	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay D-Sorbitol	97,0 - 102,0	101,0	% <i>m/m</i>	Anhydrous
Endotoxins	<=2,5	<2,5	IU / g	LAL-test
Total viable aerobic count (TAMC)	<=10 ²	Conform	CFU / g	
Total yeasts and moulds (TYMC)	<=10 ²	Conform	CFU / g	
E. coli	Negative / gram	Conform		
Salmonella	Negative / gram	Conform		
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
 Wai Lung Chung
 Pharmacist - Qualified Person

03/11/20

Expiration: 09-2022

Conclusion: APPROVED

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