

Certificate of Analysis

Product name: **Glucosum monohydricum apyr.**

Batch number / Weight: **22C01-B05-218379 / 5 KG**

Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) White, crystalline powder	Conform		
Identification A	+52,5 - +53,3	Conform		Specific optical rotation
Identification B	Conform			HPLC
Identification E	7,5 - 9,5	Conform	%	
Appearance of solution	Clear /<=BY7	Conform		
Conductivity	<=20	7	µS / cm	
Related substances	Conform	Conform		
Sum of impurities A and B	<=0,4	<0,4	%	
Impurity C	<=0,2	<0,2	%	
Impurity D	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	<0,5	%	
Dextrins	Conform	Conform		
Soluble starch, sulfite	<=15	<15	ppm	
Water (Karl Fischer)	7,5 - 9,5	8,58	%	
Assay Glucose monohydrate	97,5 -102,0	99,5	%m/m	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:

Agnieszka Pszczółka

Qualified Person

27-05-2022

Expiration: 31-12-2024

Conclusion: APPROVED

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