

## Certificate of Analysis

**Product name:** **Glucosum monohydricum apyr.**

**Batch number / Weight:** **23B14-B01-233641 / 5 KG**

**Analysed according to:** **Ph.Eur.11.2**

**Number of analysis / Inspection Code** **23B14-B01 / INS-23-2711**

**Reference Code / No.:** **V01797 / S1K347101**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) White, crystalline powder	Conform		
Identification A	+52,5 - +53,3	Conform		
Specific optical rotation	+52,5 - +53,3	+52,99		
Identification B	Conform	Conform		
Identification E	7,5 - 9,5	Conform		
Identification D	Conform	Conform		
Appearance of solution	Clear /<=BY7	Conform		
Conductivity	<=20	2,1	µS / cm	
Related substances	Conform	Conform		
Sum of impurities A and B	<=0,4	0,04	%	
Impurity C	<=0,2	0,16	%	
Impurity D	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	0,05	%	
Total impurities	<=0,5	0,25	%	
Dextrins	Conform	Conform		
Soluble starch, sulfite	<=15	<15	ppm	
Water (Karl Fischer)	7,5 - 9,5	8,33	%	
Assay Glucose monohydrate	97,5 -102,0	99,3	%m/m	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Pyrogens	Conform	Conform		
Endotoxins	<=0,006	Conform	IU / mg	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

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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, ElSpol, Eurofins

Release:

Ewelina Gadzinowska

Qualified Person

21-11-2023

Expiration: 31-12-2025

Conclusion: APPROVED

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