



Certificate of Analysis

Productname: Glucosum monohydricum

Inspection No: L02628/0524/536

Batchnumber: 23K13-T09-110370

Expiration date: 27.05.2028

Analysed according to: Ph.Eur.11.1

Customer: FAGRON a.s.

Sample Unit: 1 x 200 g

Batch Size: 30 x 250 g

Batch no. of vendor: 664900

	Requirement	Result	Unit	Standard remark
CHARACTERS				
Appearance	White or almost white, crystalline powder.	Conform		
Solubility	Conform	Conform		
IDENTIFICATION				
Identification A	+52,5 - +53,3	+53,0		Specific optic.rotation, anhydrous
Identification B	Conform	Conform		Chromatograms
Identification E	7,5 - 9,5	9,1	%	Water
TESTS				
Appearance of solution	Clear, <=BY7	Conform		10,0g/15ml of water
Conductivity	<=20	0,7	µS.cm-1	
Related substances	Conform	Conform		HPLC
Sum of impurities A + B	<=0,4	<0,4	%	
Impurity C	<=0,2	<0,2	%	
Impurity D	<=0,15	<0,15	%	
Unspecified impurities	<=0,10	<0,10	%	
Total impurities	<=0,5	<0,5	%	
Dextrin	Conform	Conform		
Soluble starch, sulfite	<=15	<15	ppm	
Water	7,5 - 9,5	9,1	%	
Microbiology	Conform	Conform		
TAMC	<=2 x 10 ³	<10	CFU/g	
TYMC	<=2 x 10 ²	<10	CFU/g	
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform		
Residual solvents	ICH Q3C	Conform		
Metallic residues	ICH Q3D	Conform		
ASSAY				
Glucose monohydrate	97,5 - 102,0	100,2	%	Anhydrous substance

Quality: Excipient

The substances is not intended for use in the manufacture of parental preparations.

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Performed by: QC Fagron a.s. (CZ)
Responsible: Mgr. Zdeňka Šinclová, QC
Ing. Martina Zemanová,
Date: 18.04.2024

Conclusion: **APPROVED**

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

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