



## Certificate of Analysis

**Productname:** Glucosum monohydricum

**Inspection No:** L02627/0524/536

**Batchnumber:** 23K13-T09-110369

**Expiration date:** 27.05.2028

**Analysed according to:** Ph.Eur.11.1

**Customer:** FAGRON a.s.

**Sample Unit:** 1 x 200 g

**Batch Size:** 100 x 1000 g

**Batch no. of vendor:** 664900

	Requirement	Result	Unit	Standard remark
<b>CHARACTERS</b>				
Appearance	White or almost white, crystalline powder.	Conform		
Solubility	Conform	Conform		
<b>IDENTIFICATION</b>				
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
<b>TESTS</b>				
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 <sup>3</sup>	<10	CFU/g	
TYMC	<=2 x 10 <sup>2</sup>	<10	CFU/g	
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform		
Residual solvents	ICH Q3C	Conform		
Metallic residues	ICH Q3D	Conform		
<b>ASSAY</b>				
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.

<b>Name</b>	Fagron a.s. (CZ) Kontrolní laboratoř č. 536	<b>Address</b>	Holícká 1098/31m, Olomouc 779 00	<b>Phone No.</b>	+420585222590
		<b>Post Code</b>		<b>Fax No.</b>	+420 585 226 521

**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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		<b>Post Code</b>	779 00	<b>Fax No.</b>	+420 585 226 521