

Certificate of Analysis

Productname: Galactosum D-
Number of analysis/Inspection Code: 2 / KEUR-198573B
Batchnumber: 23H08-F01-385676
Reference code / No.: 4799 / DG-230216
Analysed according to: PH.EUR11.2

Tests	Requirement	Result	Unit	Standard remark
Appearance	Almost white, crystalline or finely granulated powder	Conform		
Identification A	Conform	Conform		IR-spectrum
Appearance of solution	Clear / <=B8	Conform		
Acidity or alkalinity	<=1,5	0,7	ml	NaOH 0.01 M
Proteins	<=0,1	0,0	mg / ml	
Related substances	Conform	Conform		
Impurity A+ B	<=1,0	<0,2	%	
Unspecified impurities	<=0,3	<0,2	%	
Total impurities	<=2,0	<0,2	%	
Water (Karl Fischer)	<=1,0	0,1	%	
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Galactose	97,0 - 102,0	99,0	%m/m	Anhydrous
Total aerobic microbial count (TAMC)	<=10 ²	Conform	CFU / g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Fagron Sp. z o.o. (PL).

Manufacturer / Country : Zhejiang Yixin Pharm. (Site) / CN
CEP :

Release:
Anthony Amoureux
Qualified Person

11-01-24

Expiration: 16-02-26

Conclusion: APPROVED

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