

## Certificate of Analysis

**Productname:** Galactosum D-  
**Number of analysis/Inspection Code:** 1 / KEUR-180624B  
**Batchnumber:** 19G12-B50  
**Reference code / No.:** 4161 / 0202619PF9  
**Analysed according to:** PH.EUR 9.8

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	0,9	ml	NaOH 0.01 M
Proteins	<=0,1	<0,1	mg / ml	
Related substances	Conform	Conform		
Impurity A+ B	<=1,0	0,6	%	
Unspecified impurities	<=0,3	<0,2	%	
Total impurities	<=2,0	0,6	%	
Barium	Conform	Conform		
Lead	<=0,5	<0,1	ppm	
Water (Karl Fischer)	<=1,0	0,1	%	
Sulphated ash	<=0,1	<0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Galactose	97,0 - 102,0	99,5	%m/m	Anhydrous
Total aerobic microbial count (TAMC)	<=100	Conform	CFU / g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:  
dr. M.J. Vincenten - van Maanen  
Pharmacist - Qualified Person

02/20/20

Expiration: 05-2022

Conclusion: APPROVED

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