

Certificate of Analysis

Product name: Glycinum
Batch number / Weight: 23G05-B12-231357 / 1 KG
Producer / Producer Batch Number: Yuki Gosei Kogyo Co., Ltd / 1000001700
Analysed according to: Ph.Eur.11
Number of analysis / Inspection Code 23G05-B12 / INS-23-6303
Reference Code / No.: V01938 / 1000001700

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	Conform	Conform		
Appearance of solution	Clear ≤Y7	Conform		
pH	5,9 - 6,4	6,22		
Related substances	Conform	Conform		
Impurity B	≤0,10	<0,05	%	
Impurity H and I	≤0,10	<0,05	%	
Impurity I	≤0,10	0,000	%	
Unspecified impurities	≤0,10	<0,05	%	
Total impurities	≤0,2	0,00	%	
Ninhydrin-positive substances	Conform	Conform		
Any ninhydrin-positive substance	≤0,10	<0,05	%	
Total	≤1,0	<0,05	%	
Ammonium at 570 nm	≤0,02	<0,02	%	
Chlorides	≤75	<75	ppm	
Loss on drying	≤0,5	0,16	%	
Sulphated ash	≤0,1	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	98,5 - 101,0	100,51	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Endotoxins	<6,0	<6,0	IU/g	

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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, El Spol

Release:
Ewelina Gadzinowska
Qualified Person

22-09-2023

Expiration: 15-04-2026

Conclusion: APPROVED

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