

Certificate of Analysis

Product name: **Arginini hydrochloridum apyr.**

Batch number / Weight: **23A12-B05-231028 / 25 G**

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

Number of analysis / Inspection Code **23A12-B05 / INS-23-0934**

Reference Code / No.: **V01167 / 22012074**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder / crystals	Conform		
Fermentation	According to Fermentation products Ph. Eur.	Conform		
Identification A	+21,0 - +23,5	Conform		
Identification B	Conform	Conform		
Identification E	Conform	Conform		
Appearance of solution	Clear / <=BY6	Conform		
Specific optical rotation	+21,0 - +23,5	+21,7		
Ninhydrin-positive substances	Conform	Conform		
Any ninhydrin-positive substance	<=0,2	<0,05	%	
Total	<=0,5	<0,05	%	
Sulphates	<=300	<300	ppm	
Ammonium at 570 nm	<=0,02	<0,02	%	
Iron	<=10	<10	ppm	
Loss on drying	<=0,5	0,03	%	
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 L-Arginine hydrochloride	98,5 - 101,0	99,55	%m/m	
Endotoxins	<=6,0	<6	IU / g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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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, EI Spol

Release:
Dominika Soltysik
Qualified Person

22-06-2023

Expiration: 27-01-2025

Conclusion: APPROVED

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