

Certificate of Analysis

Product name: **Argininum apyrogen**

Batch number / Weight: **23F15-B07-234265 / 500 G**

Analysed according to: **Ph.Eur.11.2**

Number of analysis / Inspection Code **23F15-B07 / INS-23-5403**

Reference Code / No.: **V01167 / 22063661**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colourless crystals	Conform		
Identification A	+25,5 - +28,5	Conform		
Identification C	Conform	Conform		
Appearance of solution	Clear / <=BY6	Conform		
Specific optical rotation	+25,5 - +28,5	+27,1		
Ninhydrin-positive substances	Conform	Conform	%	
Any ninhydrin-positive substance	<=0,2	<0,05	%	
Total	<=0,5	<0,05	%	
Chlorides	<=200	<200	ppm	
Sulphates	<=300	<300	ppm	
Ammonium at 570 nm	<=0,02	<0,02	%	
Iron	<=10	<10	ppm	
Loss on drying	<=0,5	0,26	%	
Sulphated ash	<=0,1	0,01	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay L-Arginine	98,5 - 101,0	100,08	%	
Endotoxins	<=6	<6	IU / g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

fagron.pl

Fagron Services Northern Europe Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail: fsne@fagron.pl

fagron.pl

Fagron sp. z o.o.
ul. Pasternik 26, 31-354 Kraków, Poland
tel.: +48 12 3343 512
e-mail: biuro@fagron.pl

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:

Agnieszka Pszczółka

Qualified Person

27-11-2023

Expiration: 16-06-2025

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

fagron.pl

Fagron Services Northern Europe Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:fsne@fagron.pl