

Certificate of Analysis

Product name: Argininum apyrogen
Batch number / Weight: 22G19-B03-226356 / 500 G
Analysed according to: Ph.Eur.10.8
Number of analysis / Inspection Code 22G19-B03 / INS-22-7504
Reference Code / No.: V01167 / 21093573

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	+27,5		
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	0,25	%	
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	98,5 - 101,0	100,05	%	
Endotoxins	<=6	<6	IU / g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

fagron.pl

Fagron Sp. z o.o.
 ul. Armii Krajowej 3
 32-540 Trzebinia, Poland
 e-mail: biuro@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, ElSpol

Release:

Agnieszka Pszczółka

Qualified Person

21-12-2022

Expiration: 27-09-2024

Conclusion: APPROVED

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

fagron.pl

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