

Certificate of Analysis

Product name:	Alumen			
Batch number / Weight:	24A31-B08-226708 / 1 KG			
Analysed according to:	Ph.Eur.11.3			
Number of analysis / Inspection	n Code 24A31-B08 / INS-24-1247			
Reference Code / No.:	V01749 / 127669			
Tests	Requirement	Result	Unit	Standard remark
Appearance	Colourless, transparent crystals or granular powde	Conform		
Identification A	White	Conform		
Identification B	White jelly	Conform		
Identification C	White	Conform		
Appearance of solution	Clear and colourless	Conform		
рН	3,0 - 3,5	3,01		
Ammonium	<= 0,2	<0,2	%	
Iron	<= 100	<100	ppm	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Aluminiumpotassium sulphate. 1	99,0 - 100,5	100,22	%m/m	

No contamination with TSE/BSE-risk materials

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

Conform

TSE/BSE-statement:

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 lab

Release: Ewelina Gadzinowska Qualified Person

14-03-2024

Expiration: 01-12-2025

Conclusion: APPROVED

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

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