

Certificate of Analysis

Product name: **Alumen**
Batch number / Weight: **24A31-B08-234322 / 100 G**
Analysed according to: **Ph.Eur.11.3**
Number of analysis / Inspection 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		
	or granular powder			
Identification A	White	Conform		
Identification B	White jelly	Conform		
Identification C	White	Conform		
Appearance of solution	Clear and colourless	Conform		
pH	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	
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 lab

Release:
Ewelina Gadzinowska
Qualified Person

12-03-2024

Expiration: 01-12-2025

Conclusion: APPROVED

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