

Certificate of Analysis

Product name: **Alumen**
Batch number / Weight: **24A31-B08-238005 / 1 KG**
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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