

**ALUMINIO SULFATO POLVO 18 HIDRATO (EUR. PH.)**

PRODUCT CODE: 151266	CAS Nº: 7784-31-8	ANALYSIS Nº: 188/24
MANUFACTURER BATCH: 102488	CERTIFICATE ID: 42.970	
SUPPLIER BATCH: 233504	MANUFACTURING DATE: 12/09/2023	
METAPH BATCH: 0110724	EXPIRY DATE: 30/09/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	Colourless, lustrous crystals or crystalline masses	Colourless, lustrous crystalline masses (*)
Solubility	Soluble in cold water, freely soluble in hot water, practically insoluble in ethanol (96 %)	Complies
Identification A	Complies	Complies (*)
Identification B	Complies	Complies (*)
Appearance of solution	Not more opalescent than ref. sus. III and colourless	Complies (*)
pH	2.5 - 4.0	3.2
Alkali and alkaline-earth metals	=< 0.4 %	< 0.4 %
Ammonium	=< 500 ppm	10 ppm
Iron	=< 100 ppm	30 ppm
Assay	51.0 - 59.0 %	58.2 % (*)

**COMPLIES WITH**

European Pharmacopoeia 11.0

**REMARKS**

Aluminium Sulfate is subjected to the requirements of the ICH Q3D "Elemental Impurities" and the requirements of the EMA/CHMP/ICH/82260/2006 guideline.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

(\*) Data controlled by Metapharmaceutical Industrial SL

The product is not of animal origin and animal product is used in its production, so it is risk-free BSTE/TSE.

The product is not derived from GMO. No genetically modified organism is used in its production and no GMO product comes in contact with the product during any stage of production.

**STORAGE**

Store in a well-ventilated place. Keep container tightly closed.

Analysis date: 23/07/2024  
Signature: Cristina Borrell Olea (QA/QP)  
Conclusion: Complies

Manufacturer: 40000221