

CERTIFICATE OF ANALYSIS
 No.: FCH7621 (20/2021/211378) - 2021
Ammonium Sulfate
 ACS11, USPNF 2021 Issue 3, FCC12

Parameter	Specification	Result of USP/NF
Colorless crystals or white, fine or coarse, crystalline powder. Has a cool, saline taste, and is somewhat hygroscopic. Freely soluble in water and in glycerin, and even more so in boiling water; sparingly soluble in alcohol. NF category: pH modifier (acidifying agent/alkalizing agent/buffering agent).		
Identification A)	Ammonium	complies
B)	Sulfate	complies
Assay	99.0 - 100.5 %	99.9 %
Insoluble Matter	NMT 1 mg (0.005 %)	<0.005 %
Residue on Ignition	NMT 0.005 %	<0.005 %
Phosphate	NMT 5 ppm	<5 ppm
Chloride	NMT 5 ppm	<5 ppm
Nitrate	NMT 10 ppm	<10 ppm
Iron	NMT 5 ppm	<5 ppm

Specific tests

TAMC	Max. 1000 CFU/g	<1000 CFU/g
TYMC	Max. 10 CFU/g	<10 CFU/g
pH (1 in 20)	5.0 - 6.0	5.3

Parameter	Specification	Result of ACS
Assay	≥99.0 % (NH ₄) ₂ SO ₄	99.9 %
pH (5% solution at 25°C)	5.0 - 6.0	5.3
Insoluble matter	Max. 0.005 %	<0.005 %
Residue after ignition	Max. 0.005 %	<0.005 %
Chloride	Max. 5 ppm	<5 ppm
Nitrate (NO ₃)	Max. 0.001 %	<0.001 %
Phosphate	Max. 5 ppm	<5 ppm
Heavy Metals (by ICP-OES)	Max. 5 ppm	<5 ppm
Iron	Max. 5 ppm	<5 ppm

Parameter	Specification	Result of FCC
Colorless or white crystals or granules that decompose at temperatures above 280°. One g is soluble in about 1.5 mL of water. It is insoluble in alcohol. The pH of a 0.1 M solution is between 4.5 and 6.0.		
Identity	Ammonium Sulfate	complies
Assay	99.0 - 100.5 %	99.9 %
Lead	NMT 3 mg/kg	<3 mg/kg
Residue on ignition	NMT 0.25 %	0.004 %
Selenium	NMT 0.003 %	<0.003 %

* Residual solvents

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Approved by Manager of Quality Control: Eliška Hájmalová

* None organic solvents aren't used in production, material fulfill the requirements of USP, PhEur and EMA/CHMP/ICH/82260/2006 for residual solvents.

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