

Powdered Aloe

Aloe Pulverata

アロエ末

Powdered Aloe is the powder of Aloe.

Description Powdered Aloe occurs as a dark brown to yellowish dark brown powder. It has a characteristic odor and an extremely bitter taste.

Under a microscope, Powdered Aloe, immersed in olive oil or liquid paraffin, reveals greenish yellow to reddish brown, angular or rather irregular fragments.

Identification (1) Dissolve 0.5 g of Powdered Aloe in 50 mL of water by warming. After cooling, add 0.5 g of siliceous earth, and filter. Perform the following tests with the filtrate as the sample solution.

(i) Dissolve 0.2 g of sodium tetraborate decahydrate in 5 mL of the sample solution by warming in a water bath. Drop a few drops of this solution into 30 mL of water, and shake: a green fluorescence is produced.

(ii) Shake 2 mL of the sample solution with 2 mL of nitric acid: a yellow-brown color which changes gradually to green is produced. Then warm this colored solution in a water bath: the color of the solution changes to red-brown.

(2) To 0.2 g of Powdered Aloe add 10 mL of methanol, shake for 5 minutes, filter, and use the filtrate as the sample solution. Separately, dissolve 1 mg of barbaloin for thin-layer chromatography in 1 mL of methanol, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Develop the plate with a mixture of chloroform, ethanol (95) and water (30:15:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 365 nm): one spot among several spots from the sample solution and a red spot from the standard solution show the same in color tone and R_f value.

Purity (1) Resin—Warm 0.5 of Powdered Aloe with 10 mL of diethyl ether on a water bath, and filter. Wash the residue and the filter paper with 3 mL of diethyl ether. Combine the filtrate and the washing, and evaporate the diethyl ether: the mass of the residue does not exceed 5.0 mg.

(2) Ethanol-insoluble substances—Boil 1.0 g of Powdered Aloe with 50 mL of ethanol (95) on a water bath for 30 minutes under a reflux condenser. Filter the warm mixture through a tared glass filter (G4), and wash the residue on the filter with ethanol (95) until the last washing becomes colorless. Dry the residue at 105°C for 5 hours, and weigh: the mass of the residue does not exceed 0.10 g.

Loss on drying Not more than 12.0% (6 hours).

Total ash Not more than 2.0%.

Extract content Water-soluble extract: not less than 40.0%.

Containers and storage Containers—Tight containers.

Alum Solution

ミョウバン水

Alum Solution contains not less than 0.27 w/v% and not more than 0.33 w/v% of aluminum potassium sulfate [AlK(SO₄)₂·12H₂O: 474.39].

Method of preparation

Aluminum Potassium Sulfate	3 g
Mentha Water	50 mL
Water or Purified Water	a sufficient quantity
To make 1000 mL	

Dissolve and mix the above ingredients.

Description Alum Solution is a clear, colorless liquid. It has the odor of the mentha oil and an astringent taste.

Identification (1) To 5 mL of Alum Solution add 3 mL of ammonium chloride TS and 1 mL of ammonia TS: a white, gelatinous precipitate is produced, which changes to red upon the addition of 5 drops of alizarin red S TS (aluminum sulfate).

(2) Place 100 mL of Alum Solution in an evaporating dish, evaporate on a water bath to dryness, and dissolve the residue in 5 mL of water: the solution responds to the Qualitative Tests for potassium salt.

(3) Alum Solution responds to the Qualitative Tests (1) and (2) for sulfate.

Assay Pipet 50 mL of Alum Solution, add exactly 30 mL of 0.02 mol/L disodium dihydrogen ethylenediamine tetraacetate VS, and further add 20 mL of acetic acid-ammonium acetate buffer solution, pH 4.8. Boil for 5 minutes, cool, add 55 mL of ethanol (95), and titrate with 0.02 mol/L zinc acetate VS (indicator: 2 mL of dithizone TS), until the color of the solution changes from light dark green to light red. Perform a blank determination.

Each mL of 0.02 mol/L disodium dihydrogen ethylenediamine tetraacetate VS
= 9.488 mg of AlK(SO₄)₂·12H₂O

Containers and storage Containers—Tight containers.

Aluminum Monostearate

モノステアリン酸アルミニウム

Aluminum Monostearate is mainly aluminum compounds of stearic acid (C₁₈H₃₆O₂) and palmitic acid (C₁₆H₃₂O₂).

Aluminum Monostearate, when dried, contains not less than 7.2% and not more than 8.9% of aluminum (Al: 26.98).

Description Aluminum Monostearate occurs as a white to yellowish white powder. It is odorless or has a faint, characteristic odor.

It is practically insoluble in water, in ethanol (95) and in diethyl ether.

Identification (1) Heat 3 g of Aluminum Monostearate with 30 mL of hydrochloric acid in a water bath with occasional shaking for 10 minutes. After cooling, shake the mixture vigorously with 50 mL of water and 30 mL of diethyl ether for 3 minutes, and allow to stand. To the separated aqueous layer add sodium hydroxide TS until the solution becomes slightly turbid, and filter: the filtrate responds to the Qualitative Tests for aluminum salt.

(2) Wash the diethyl ether layer separated in (1) with two 20-mL portions of water, and evaporate the diethyl ether layer on a water bath: the residue melts at above 54°C (Method 2).

Acid value for fatty acid 193 – 210. Weigh accurately about 1 g of fatty acid obtained in the Identification (2), transfer a 250-mL glass-stoppered flask, add 100 mL of a mixture of diethyl ether and ethanol (95) (2:1), warm to dissolve, add several drops of phenolphthalein TS, and proceed as directed under the Acid Value.

Purity (1) Free fatty acid—Mix 1.0 g of Aluminum Monostearate with about 50 mL of a mixture of neutralized ethanol and diethyl ether (1:1), filter through dry filter paper, wash the vessel and the filter paper with a small amount of a mixture of neutralized ethanol and diethyl ether (1:1), combine the filtrate and the washings, and add 2.1 mL of 0.1 mol/L potassium hydroxide VS: a red color develops.

(2) Water-soluble salts—Heat 2.0 g of Aluminum Monostearate with 80 mL of water in a loosely stoppered conical flask on a water bath for 30 minutes with occasional shaking. After cooling, filter through dry filter paper, wash the residue with a small amount of water, combine the washings with the filtrate, add water to make 100 mL, evaporate 50 mL of this solution on a water bath, and heat strongly at 600°C: the mass of the residue is not more than 10.0 mg.

(3) Heavy metals—Heat 1.0 g of Aluminum Monostearate over a small flame with caution at the beginning, and continue the heating, gradually raising the temperature, to ash. After cooling, add 10 mL of diluted hydrochloric acid (1 in 2), evaporate on a water bath, and boil the residue with 20 mL of water for 1 minute. Cool, filter, wash the residue with water, combine the filtrate and the washings, and add 2 mL of dilute acetic acid and water to make 50 mL. Perform the test using this solution as the test solution. Evaporate 10 mL of diluted hydrochloric acid (1 in 2) on a water bath to dryness, add 2 mL of dilute acetic acid and 5.0 mL of Standard Lead Solution, dilute with water to make 50 mL, and use this solution as the control solution (not more than 50 ppm).

(4) Arsenic—Mix 1.0 g of Aluminum Monostearate with 2 g of magnesium nitrate hexahydrate, ignite over a small flame, moisten the residue after cooling with 0.5 mL of nitric acid, and heat. Heat again the residue with 10 mL of dilute sulfuric acid until white fumes evolve, add water to make 5 mL, and perform the test with this solution as the test solution using Apparatus B (not more than 2 ppm).

Loss on drying Not more than 3.0% (1 g, 105°C, 3 hours).

Assay Weigh accurately about 1 g of Aluminum Monostearate, previously dried, ignite gently to ash, and cool. Add dropwise 0.5 mL of nitric acid, evaporate on a water bath by heating, and then heat strongly between 900°C and 1100°C to a constant mass. After cooling, weigh rapidly the ignited residue, and designate the mass as aluminum oxide (Al₂O₃: 101.96).

Amount (mg) of aluminum (Al)
= amount (mg) of aluminum oxide (Al₂O₃) × 0.5293

Containers and storage Containers—Well-closed containers.

Aluminum Potassium Sulfate

Alum

硫酸アルミニウムカリウム

AlK(SO₄)₂·12H₂O: 474.39

Aluminum Potassium Sulfate contains not less than 99.5% of AlK(SO₄)₂·12H₂O.

Description Aluminum Potassium Sulfate occurs as colorless or white crystals or powder. It is odorless. It has a slightly sweet, strongly astringent taste.

It is freely soluble in water, and practically insoluble in ethanol (95) and in diethyl ether. A solution of Aluminum Potassium Sulfate (1 in 20) is acid.

Identification A solution of Aluminum Potassium Sulfate (1 in 10) responds to the Qualitative Tests for aluminum salt, to the Qualitative Tests (1), (3) and (4) for potassium salt, and to the Qualitative Tests (1) and (3) for sulfate.

Purity (1) Heavy metals—Proceed with 1.0 g of Aluminum Potassium Sulfate according to Method 1, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(2) Iron—Prepare the test solution with 1.0 g of Aluminum Potassium Sulfate according to Method 1, and perform the test according to Method A. Prepare the control solution with 2.0 mL of Standard Iron Solution (not more than 20 ppm).

(3) Arsenic—Prepare the test solution with 0.6 g of Aluminum Potassium Sulfate, according to Method 1, and perform the test using apparatus B (not more than 3.3 ppm).

Assay Weigh accurately about 4.5 g of Aluminum Potassium Sulfate, and dissolve in water to make exactly 200 mL. Take exactly 20 mL of this solution, and add exactly 30 mL of 0.05 mol/L disodium dihydrogen ethylenediamine tetraacetate VS and 20 mL of acetic acid-ammonium acetate buffer solution, pH 4.8, boil for 5 minutes, and cool. Add 55 mL of ethanol (95), and titrate with 0.05 mol/L zinc acetate VS (indicator: 2 mL of dithizone TS), until the color of the solution changes from light dark green to light red. Perform a blank determination.

Each mL of 0.05 mol/L disodium dihydrogen ethylenediamine tetraacetate VS
= 23.720 mg of AlK(SO₄)₂·12H₂O

Containers and storage Containers—Tight containers.