

Aluminium hydroxide (Aluminii hydroxidum)**Molecular formula.** $\text{Al}(\text{OH})_3$ **Relative molecular mass.** 78.00**Chemical name.** Aluminium hydroxide; CAS Reg. No. 21645-51-2.**Description.** A white, fine, amorphous powder; odourless.**Solubility.** Practically insoluble in water and ethanol (~750 g/l) TS; soluble in hydrochloric acid (~70 g/l) TS and sodium hydroxide (~80 g/l) TS.**Category.** Antacid.**Storage.** Aluminium hydroxide should be kept in a tightly closed container.**Requirements****Definition.** Aluminium hydroxide contains not less than 71.9% and not more than 94.9% of $\text{Al}(\text{OH})_3$.**Identity test**

Dissolve 0.10 g by heating in 5 mL of sodium hydroxide (~80 g/l) TS. To the clear solution add 0.5 g of ammonium chloride R; a white, gelatinous precipitate is produced.

Heavy metals. For the preparation of the test solution dissolve 0.5 g, while heating, in 5 mL of acetic acid (~300 g/l) TS, dilute to 10 mL with water and filter. Adjust the pH of the filtrate to 3-4, dilute to 40 mL with water and mix. Determine the heavy metals content as described under [2.2.3 Limit test for heavy metals](#), according to Method A; not more than 60 µg/g.

Arsenic. Use a solution of 3.3 g in 20 mL of sulfuric acid (~100 g/l) TS and 35 mL of water and proceed as described under [2.2.5 Limit test for arsenic](#); the arsenic content is not more than 5 µg/g.

Ammonium salts. Transfer 5.0 g to an ammonia distillation apparatus, add 25 mL of sodium hydroxide (~200 g/l) TS and 200 mL of water, distil about 100 mL, collecting the distillate in 25.0 mL of hydrochloric acid (0.1 mol/l) VS.

Titrate the excess acid with sodium hydroxide (0.1 mol/l) VS using methyl red/ethanol TS as indicator; not less than 22.5 mL of sodium hydroxide (0.1 mol/l) VS is required.

Chlorides. Dissolve 0.10 g in 2 mL of nitric acid (~130 g/l) TS, boil, cool, dilute to 10 mL with water and filter. Proceed with 5 mL of the filtrate as described under [2.2.1 Limit test for chlorides](#); the chloride content is not more than 10 mg/g.

Sulfates. Dissolve 0.10 g in 5 mL of hydrochloric acid (~70 g/l) TS, boil, cool, dilute to 10 mL with water and filter. Proceed with the filtrate as described under [2.2.2 Limit test for sulfates](#); the sulfate content is not more than 5 mg/g.

Neutralizing capacity. Pass a sufficient quantity of the test substance, triturated if necessary, through a sieve of nominal mesh aperture 150 µm, add 0.50 g to 200 mL of hydrochloric acid (0.05 mol/l) VS previously heated to 37 °C, and stir continuously, maintaining the temperature at 37 °C; the pH of the solution at 37 °C, after 10, 15, and 20 minutes, is not less than 1.8, 2.3, and 3.0, respectively, and at no time more than 4.0. Add 10 mL of hydrochloric acid (0.5 mol/l) VS previously heated to 37 °C, stir continuously for 1 hour, maintaining the temperature at 37 °C. Titrate the solution with sodium hydroxide (0.1 mol/l) VS to pH 3.5. The neutralizing capacity is not less than 83.3% of the theoretical amount when calculated by the formula $(1000)(150-y)/A \times W \times 38.46$, in which y is the number of mL of sodium hydroxide (0.1 mol/l) VS required, A is the percent of $\text{Al}(\text{OH})_3$ obtained in the assay, W is the quantity, in g, of test substance taken, and 38.46 is the theoretical value of each g of $\text{Al}(\text{OH})_3$.

Alkaline impurities. The pH of a 0.04 g/mL suspension in carbon-dioxide-free water R is not more than 10.0.

Assay. Proceed with about 0.15 g, accurately weighed, as described under [2.5 Complexometric titrations](#) for aluminium. Each mL of disodium edetate (0.05 mol/l) VS is equivalent to 3.900 mg of $\text{Al}(\text{OH})_3$.