Water (*2.5.12*): 42.0 per cent to 48.0 per cent, determined on 50.0 mg.

ASSAY

Dissolve 0.500 g in 25.0 ml of *water R*. Carry out the complexometric titration of aluminium (*2.5.11*). Titrate with *0.1 M zinc sulphate* until the colour of the indicator changes from greyish-green to pink. Carry out a blank titration.

1 ml of *0.1 M sodium edetate* is equivalent to 24.14 mg of $AlCl_3,6H_2O$.

STORAGE

In an airtight container.

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ALUMINIUM HYDROXIDE, HYDRATED, FOR ADSORPTION

Aluminii hydroxidum hydricum ad adsorptionem

$[AlO(OH)],nH_2O$

DEFINITION

Content: 90.0 per cent to 110.0 per cent of the content of aluminium stated on the label.

NOTE: *shake the gel vigorously for at least 30 s immediately before examining.*

CHARACTERS

Appearance: white or almost white, translucent, viscous, colloidal gel. A supernatant may be formed upon standing.

Solubility: a clear or almost clear solution is obtained with alkali hydroxide solutions and mineral acids.

IDENTIFICATION

Solution S (see Tests) gives the reaction of aluminium.

To 10 ml of solution S add about 0.5 ml of *dilute hydrochloric acid R* and about 0.5 ml of *thioacetamide reagent R*. No precipitate is formed. Add dropwise 5 ml of *dilute sodium hydroxide solution R*. Allow to stand for 1 h. A gelatinous white precipitate is formed which dissolves upon addition of 5 ml of *dilute sodium hydroxide solution R*. Gradually add 5 ml of *ammonium chloride solution R* and allow to stand for 30 min. The gelatinous white precipitate is re-formed.

TESTS

Solution S. Add 1 g to 4 ml of *hydrochloric acid R*. Heat at 60 °C for 1 h, cool, dilute to 50 ml with *distilled water R* and filter if necessary.

pH (*2.2.3*): 5.5 to 8.5.

Adsorption power. Dilute the substance to be examined with *distilled water R* to obtain an aluminium concentration of 5 mg/ml. Prepare *bovine albumin R* solutions with the following concentrations of bovine albumin: 0.5 mg/ml, 1 mg/ml, 2 mg/ml, 3 mg/ml, 5 mg/ml and 10 mg/ml. If necessary, adjust the gel and the *bovine albumin R* solutions to pH 6.0 with *dilute hydrochloric acid R* or *dilute sodium hydroxide solution R*.

For adsorption, mix 1 part of the diluted gel with 4 parts of each of the solutions of *bovine albumin R* and allow to stand at room temperature for 1 h. During this time shake the mixture vigorously at least 5 times. Centrifuge or filter through a non-protein-retaining filter. Immediately determine the protein content (*2.5.33, Method 2*) of either the supernatant or the filtrate.

It complies with the test if no bovine albumin is detectable in the supernatant or filtrate of the 2 mg/ml *bovine albumin R* solution (maximum level of adsorption) and in the supernatant or filtrate of *bovine albumin R* solutions of lower concentrations. Those containing 3 mg/ml, 5 mg/ml and 10 mg/ml *bovine albumin R* solutions may show bovine albumin in the supernatant or filtrate, proportional to the amount of bovine albumin in the solutions.

Sedimentation. If necessary, adjust the substance to be examined to pH 6.0 using *dilute hydrochloric acid R* or dilute *sodium hydroxide solution R*. Dilute with *distilled water R* to obtain an aluminium concentration of approximately 5 mg/ml. If the aluminium content of the substance to be examined is lower than 5 mg/ml, adjust to pH 6.0 and dilute with a 9 g/l solution of *sodium chloride R* to obtain an aluminium concentration of about 1 mg/ml. After shaking for at least 30 s, place 25 ml of the preparation in a 25 ml graduated cylinder and allow to stand for 24 h.

It complies with the test if the volume of the clear supernatant is less than 5 ml for the gel with an aluminium content of about 5 mg/ml.

It complies with the test if the volume of the clear supernatant is less than 20 ml for the gel with an aluminium content of about 1 mg/ml.

Chlorides (*2.4.4*): maximum 0.33 per cent.

Dissolve 0.5 g in 10 ml of *dilute nitric acid R* and dilute to 500 ml with *water R*.

Nitrates: maximum 100 ppm.

Place 5 g in a test-tube immersed in ice-water, add 0.4 ml of a 100 g/l solution of *potassium chloride R*, 0.1 ml of *diphenylamine solution R* and, dropwise with shaking, 5 ml of *sulphuric acid R*. Transfer the tube to a water-bath at 50 °C. After 15 min, any blue colour in the solution is not more intense than that in a standard prepared at the same time and in the same manner using 5 ml of *nitrate standard solution (100 ppm NO_3) R*.

Sulphates (*2.4.13*): maximum 0.5 per cent.

Dilute 2 ml of solution S to 20 ml with *water R*.

Ammonium (*2.4.1, Method B*): maximum 50 ppm, determined on 1.0 g.

Prepare the standard using 0.5 ml of *ammonium standard solution (100 ppm NH_4) R*.

Arsenic (*2.4.2, Method A*): maximum 1 ppm, determined on 1 g.

Iron (*2.4.9*): maximum 15 ppm, determined on 0.67 g.

Heavy metals (*2.4.8*): maximum 20 ppm.

Dissolve 2.0 g in 10 ml of *dilute nitric acid R* and dilute to 20 ml with *water R*. The solution complies with test A. Prepare the reference solution using *lead standard solution (2 ppm Pb) R*.

Bacterial endotoxins (*2.6.14*): less than 5 IU of endotoxin per milligram of aluminium, if intended for use in the manufacture of an adsorbed product without a further appropriate procedure for the removal of bacterial endotoxins.

ASSAY

Dissolve 10.00 g in 10 ml of *hydrochloric acid R1*, heating on a water-bath. Cool and dilute to 20 ml with *water R*. To 10 ml of the solution, add *dilute ammonia R1* until a precipitate is obtained. Add the smallest quantity of *dilute hydrochloric acid R* needed to dissolve the precipitate and dilute to 20 ml with *water R*. Carry out the complexometric titration of aluminium (*2.5.11*). Carry out a blank titration.

STORAGE

At a temperature not exceeding 30 °C. Do not allow to freeze. If the substance is sterile, store in a sterile, airtight, tamper-proof container.

LABELLING

The label states the declared content of aluminium.

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corrected 6.0

ALUMINIUM MAGNESIUM SILICATE

Aluminii magnesii silicas

DEFINITION

Mixture of particles with colloidal particle size of montmorillonite and saponite, free from grit and non-swellable ore.

Content:

– *aluminium* (Al; A_r 26.98): 95.0 per cent to 105.0 per cent of the value stated on the label;
– *magnesium* (Mg; A_r 24.30): 95.0 per cent to 105.0 per cent of the value stated on the label.

CHARACTERS

Appearance: almost white powder, granules or plates.

Solubility: practically insoluble in water and in organic solvents.

It swells in water to produce a colloidal dispersion.

IDENTIFICATION

A. Fuse 1 g with 2 g of *anhydrous sodium carbonate R*. Warm the residue with *water R* and filter. Acidify the filtrate with *hydrochloric acid R* and evaporate to dryness on a water-bath. 0.25 g of the residue gives the reaction of silicates (*2.3.1*).

B. Dissolve the remainder of the residue obtained in identification test A in a mixture of 5 ml of *dilute hydrochloric acid R* and 10 ml of *water R*. Filter and add *ammonium chloride buffer solution pH 10.0 R*. A white, gelatinous precipitate is formed. Centrifuge and keep the supernatant for identification C. Dissolve the remaining precipitate in *dilute hydrochloric acid R*. The solution gives the reaction of aluminium (*2.3.1*).

C. The supernatant liquid obtained after centrifugation in identification test B gives the reaction of magnesium (*2.3.1*).

TESTS

pH (*2.2.3*): 9.0 to 10.0.

Disperse 5.0 g in 100 ml of *carbon dioxide-free water R*.

Arsenic (*2.4.2, Method A*): maximum 3 ppm.

Transfer 16.6 g to a 250 ml beaker containing 100 ml of *dilute hydrochloric acid R*. Mix, cover with a watch glass and boil gently, with occasional stirring, for 15 min. Allow the insoluble matter to settle and decant the supernatant liquid through a rapid-flow filter paper into a 250 ml volumetric flask, retaining as much sediment as possible in the beaker. To the residue in the beaker add 25 ml of hot *dilute hydrochloric acid R*, stir, heat to boiling, allow the insoluble matter to settle and decant the supernatant liquid through the filter into the volumetric flask. Repeat the extraction with 4 additional quantities, each of 25 ml, of hot *dilute hydrochloric acid R*, decanting each supernatant liquid through the filter into the volumetric flask. At the last extraction, transfer as much of the insoluble matter as possible onto the filter. Allow the combined filtrates to cool to room temperature and dilute to 250.0 ml with *dilute hydrochloric acid R*. Dilute 5.0 ml of this solution to 25.0 ml with *dilute hydrochloric acid R*.

Lead: maximum 15.0 ppm.

Atomic absorption spectrometry (*2.2.23, Method I*).

Test solution. Transfer 10.0 g to a 250 ml beaker containing 100 ml of *dilute hydrochloric acid R*. Mix, cover with a watch glass and boil for 15 min. Allow to cool to room temperature and allow the insoluble matter to settle. Decant the supernatant liquid through a rapid-flow filter paper into a 400 ml beaker. To the insoluble matter in the 250 ml beaker add 25 ml of hot *water R*. Stir, allow the insoluble matter to settle and decant the supernatant liquid through the filter into the 400 ml beaker. Repeat the extraction with 2 additional quantities, each of 25 ml, of *water R*, decanting each time the supernatant liquid through the filter into the 400 ml beaker. Wash the filter with 25 ml of hot *water R*, collecting this filtrate in the 400 ml beaker. Concentrate the combined filtrates to about 20 ml by gently boiling. If a precipitate appears, add about 0.1 ml of *nitric acid R*, heat to boiling and allow to cool to room temperature. Filter the concentrated extracts through a rapid-flow filter paper into a 50 ml volumetric flask. Transfer the remaining contents of the 400 ml beaker through the filter paper and into the flask with *water R*. Dilute this solution to 50.0 ml with *water R*.

Reference solutions. Prepare the reference solutions using *lead standard solution (10 ppm Pb) R*, diluted as necessary with *water R*.

Source: lead hollow-cathode lamp.

Wavelength: 217 nm.

Atomisation device: oxidising air-acetylene flame.

Loss on drying (*2.2.32*): maximum 8.0 per cent, determined on 1.000 g by drying in an oven at 105 °C.

Microbial contamination. Total viable aerobic count (*2.6.12*) not more than 10^3 micro-organisms per gram, determined by plate count. It complies with the test for *Escherichia coli* (*2.6.13*).

ASSAY

Aluminium. Atomic absorption spectrometry (*2.2.23, Method I*).

Test solution. In a platinum crucible mix 0.200 g with 1.0 g of *lithium metaborate R*. Heat slowly at first and ignite at 1000-1200 °C for 15 min. Allow to cool, then place the crucible in a 100 ml beaker containing 25 ml of *dilute nitric acid R* and add an additional 50 ml of *dilute nitric acid R*, filling and submerging the crucible. Place a polytetrafluoroethylene-coated magnetic stirring bar in the crucible and stir gently with a magnetic stirrer until dissolution is complete. Pour the contents into a 250 ml beaker and remove the crucible. Warm the solution and transfer through a rapid-flow filter paper into a 250 ml volumetric flask, wash the filter and beaker with *water R* and dilute to 250.0 ml with *water R* (solution A). To 20.0 ml of solution A add 20 ml of a 10 g/l solution of *sodium chloride R* and dilute to 100.0 ml with *water R*.

Reference solutions. Dissolve, with gentle heating, 1.000 g of *aluminium R* in a mixture of 10 ml of *hydrochloric acid R* and 10 ml of *water R*. Allow to cool, then dilute to 1000.0 ml with *water R* (1 mg of aluminium per millilitre). Into 3