Edition: BP 2025 (Ph. Eur. 11.6 update)

Aluminium Hydroxide Oral Suspension

General Notices

DEFINITION

Aluminium Hydroxide Oral Suspension is an aqueous suspension of Dried Aluminium Oxide together with varying quantities of basic aluminium carbonate. It contains the equivalent of 4% w/w of aluminium oxide and has a peppermint flavour.

The oral suspension complies with the requirements stated under Oral Liquids and with the following requirements.

Content of aluminium oxide, Al_2O_3

The equivalent of 3.5 to 4.4% w/w.

CHARACTERISTICS

A white suspension from which small amounts of clear liquid may separate on standing. It may exhibit thixotropic properties.

IDENTIFICATION

A solution in 2M *hydrochloric acid* yields the reaction characteristic of *aluminium salts*, Appendix VI.

TESTS

Alkalinity

pH, when diluted with an equal volume of *carbon dioxide-free water*, not more than 7.5, Appendix V L.

Neutralising capacity

Disperse 5 g in 100 mL of *water*, heat to 37°, add 100 mL of *0.1M hydrochloric acid VS* previously heated to 37° and stir continuously, maintaining the temperature at 37°. The pH of the solution, at 37°, after 10, 15 and 20 minutes, is not less than 1.8, 2.3 and 3.0 respectively and at no time during this period is it more than 4.0. Add 10 mL of *0.5M hydrochloric acid VS* previously heated to 37°, stir continuously for 1 hour maintaining the temperature at 37° and titrate the solution with *0.1M sodium hydroxide VS* to pH 3.5. Not more than 50 mL of *0.1M sodium hydroxide VS* is required.

Ammonium salts

To 25 g in an ammonia-distillation apparatus add 25 mL of 5M *sodium hydroxide* and 250 mL of *water*, distil about 100 mL, collecting the distillate in 25 mL of *0.1M hydrochloric acid VS*, and titrate the excess of acid with *0.1M sodium hydroxide VS*

using *methyl red solution* as indicator. Not less than 20.0 mL of *0.1M sodium hydroxide VS* is required.

Arsenic

Dissolve 2.0 g in 18 mL of *brominated hydrochloric acid* and 32 mL of *water*. 25 mL of the resulting solution complies with the *limit test for arsenic*, Appendix VII (1 ppm).

Chloride

Dissolve 0.30 g in 2 mL of 2M *nitric acid*, boil, cool, dilute to 250 mL with *water* and filter. 15 mL of the filtrate complies with the *limit test for chlorides*, Appendix VII (0.3%).

Sulfate

Dissolve 0.50 g in 5 mL of 2M *hydrochloric acid*, boil, cool, dilute to 200 mL with *water* and filter. 12.5 mL of the filtrate, diluted to 15 mL with 2M *hydrochloric acid*, complies with the *limit test for sulfates*, Appendix VII (0.5%).

Microbial contamination

Carry out a quantitative evaluation for Enterobacteria and certain other Gram-negative bacteria, Appendix XVI B1. 0.01 mL of the preparation gives a negative result, Table I (most probable number of bacteria per gram fewer than 10^2).

ASSAY

Dissolve 5 g in 3 mL of *hydrochloric acid* by warming on a water bath, cool to below 20° and dilute to 100 mL with *water*. To 20 mL of this solution add 40 mL of 0.05M *disodium edetate VS*, 80 mL of *water* and 0.15 mL of *methyl red solution* and neutralise by the drop wise addition of 1M *sodium hydroxide*. Heat on a water bath for 30 minutes, add 3 g of *hexamine* and titrate with 0.05M *lead nitrate VS* using 0.5 mL of *xylenol orange solution* as indicator. Each mL of 0.05M *disodium edetate VS* is equivalent to 2.549 mg of Al_2O_3.

STORAGE

Aluminium Hydroxide Oral Suspension should be kept at a temperature not exceeding 30°. It should not be allowed to freeze.