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

Aluminium Hydroxide Chewable Tablets

General Notices

Aluminium Hydroxide Tablets
Chewable Aluminium Hydroxide Tablets

DEFINITION

Aluminium Hydroxide Chewable Tablets contain, in each, 500 mg of Dried Aluminium Hydroxide in a suitable basis with a peppermint flavour.

The tablets comply with the requirements stated under Tablets and with the following requirements.

Content of aluminium oxide, Al_2O_3

Not less than the equivalent of 0.225 g.

IDENTIFICATION

The powdered tablets yield the reaction characteristic of *aluminium salts*, Appendix VI.

TESTS

Disintegration

The requirement for Disintegration does not apply to Aluminium Hydroxide Chewable Tablets.

Neutralising capacity

Pass a sufficient quantity of the powder prepared for use in the Assay through a sieve with a nominal mesh aperture of 150 µm. Mix a quantity of the powder containing 0.5 g of Dried Aluminium Hydroxide with a small quantity of *water* to give a smooth paste and slowly add further quantities of *water* to a total volume of 100 mL. Warm 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 1.6, 1.8 and 2.2 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. Subtract the volume of *0.1M sodium hydroxide VS* from 150 to obtain the number of mL of *0.1M hydrochloric acid VS* required for the neutralisation. Calculate the number of mL of *0.1M hydrochloric acid VS* required for the total weight of the tablets taken for the Assay and divide by the number of tablets. The result is not less than 115.

ASSAY

Weigh and powder 20 tablets, avoiding frictional heating. Dissolve a quantity of the powder containing 0.4 g of Dried Aluminium Hydroxide as completely as possible in a mixture of 3 mL of *hydrochloric acid* and 3 mL of *water* 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 VS*. 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.