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Quality standards

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

Kaolin Mixture

General Notices

Kaolin Oral Suspension

DEFINITION

Kaolin Mixture is an *oral suspension* containing 20% w/v of Light Kaolin or Light Kaolin (Natural) and 5% w/v each of Light Magnesium Carbonate and Sodium Bicarbonate in a suitable vehicle with a peppermint flavour.

It should be recently prepared unless the kaolin has been sterilised.

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

Content of magnesium, Mg

1.04 to 1.25% w/w.

Content of sodium bicarbonate, NaHCO₃

4.05 to 4.65% w/w.

TESTS

Acid-insoluble matter

13.8 to 18.4% w/w when determined by the following method. Dry and ignite the residue reserved in the Assay for magnesium to constant weight at red heat.

ASSAY

For magnesium

To 3 g add 15 mL of <u>water</u>, make acidic to <u>litmus paper</u> by the cautious addition of <u>2M hydrochloric acid</u>, boil for 5 minutes, replacing the water lost by evaporation, cool and filter the supernatant liquid. Boil the residue with 20 mL of <u>water</u> and 10 mL of <u>2M hydrochloric acid</u>, cool, filter through the same filter and wash the residue with <u>water</u> until the washings are free from chloride. Reserve the residue for the test for Acid-insoluble matter. Dilute the combined filtrate and washings to 100 mL with <u>water</u>. To 20 mL add 0.1 g of <u>L-ascorbic acid</u>, make slightly alkaline to <u>litmus paper</u> with 5M <u>ammonia</u> and add 10 mL of <u>triethanolamine</u>, 10 mL of <u>ammonia buffer pH 10.9</u> and 1 mL of a 10% w/v solution of <u>potassium cyanide</u>. Titrate with 0.05M <u>disodium edetate VS</u>, using <u>mordant black 11 solution</u> as indicator, to a full blue colour. Each mL of 0.05M <u>disodium edetate VS</u> is equivalent to 1.215 mg of Mg.

For sodium bicarbonate

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Boil 10 g with 100 mL of <u>water</u> for 5 minutes, filter, boil the residue with 100 mL of <u>water</u> for 5 minutes and filter. Combine the filtrates, cool and titrate with <u>0.5m hydrochloric acid VS</u> using <u>methyl orange-xylene cyanol FF solution</u> as indicator. Add 10 mL of <u>ammonia buffer pH 10.9</u> and titrate with 0.05m <u>disodium edetate VS</u> using <u>mordant black 11 solution</u> as indicator. After subtracting one-fifth of the volume of 0.05m <u>disodium edetate VS</u>, each mL of <u>0.5m hydrochloric acid VS</u> is equivalent to 42.00 mg of NaHCO₃.