Quality standards

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Barium Sulfate for Suspension

General Notices

Barium Sulphate for Suspension

Action and use

Radio-opaque preparation used in the investigation of the gastro-intestinal tract.

Preparation

Barium Sulfate Oral Suspension

DEFINITION

Barium Sulfate for Suspension is a dry mixture of Barium Sulfate with a suitable dispersing agent and may contain suitable flavours and suitable antimicrobial preservatives.

Content of barium sulfate, BaSO₄

90.0 to 110.0% of the stated amount.

CHARACTERISTICS

A fine, white or creamy white powder.

IDENTIFICATION

- A. Ignite 1 g to constant weight. To 0.2 g of the residue add 5 mL of a 50% w/v solution of <u>sodium carbonate</u> and boil for 5 minutes. Add 10 mL of <u>water</u> and filter. Reserve the residue for test B. Acidify a portion of the filtrate with <u>2m hydrochloric acid</u>. The solution yields the reactions characteristic of <u>sulfates</u>, <u>Appendix VI</u>.
- B. Wash the residue reserved in test A with <u>water</u>, add 5 mL of 2m <u>hydrochloric acid</u>, mix well and filter. Add 0.3 mL of 1m <u>sulfuric acid</u> to the filtrate. A white precipitate is produced which is insoluble in 2m <u>hydrochloric acid</u>.

TESTS

Acidity or alkalinity

pH of an aqueous suspension containing the equivalent of 60% w/w of Barium Sulfate or, for lower strengths, the aqueous suspension at the strength of intended use, 3.5 to 8.5, <u>Appendix V L</u>.

Loss on drying

When dried at 105° for 4 hours, loses not more than 1.0% of its weight. Use 1 g.

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ASSAY

To a quantity containing 0.6 g of Barium Sulfate in a platinum dish add 5 g of <u>sodium carbonate</u> and 5 g of <u>potassium carbonate</u> and mix. Heat to 1000° and maintain at this temperature for 15 minutes. Allow to cool and suspend the residue in 150 mL of <u>water</u>. Wash the dish with 2 mL of 6M <u>acetic acid</u> and add the washings to the suspension. Cool in ice and decant the supernatant liquid, transferring as little of the solid matter as possible to the filter. Wash the residue with successive quantities of a 2% w/v solution of <u>sodium carbonate</u> until the washings are free from sulfate and discard the washings. Add 5 mL of 2M <u>hydrochloric acid</u> to the filter, wash through into the vessel containing the bulk of the solid matter with <u>water</u>, add 5 mL of <u>hydrochloric acid</u> and dilute to 100 mL with <u>water</u>. Add 10 mL of a 40% w/v solution of <u>ammonium acetate</u>, 25 mL of a 10% w/v solution of <u>potassium dichromate</u> and 10 g of <u>urea</u>. Cover and digest in a hot-air oven at 80° to 85° for 16 hours. Filter whilst still hot through a sintered-glass filter (<u>ISO</u> 4793, porosity grade 4, is suitable), washing the precipitate initially with a 0.5% w/v solution of <u>potassium dichromate</u> and finally with 2 mL of <u>water</u>. Dry to constant weight at 105°. Each g of the residue is equivalent to 0.9213 g of barium sulfate, BaSO₄.