Quality standards

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Hexachlorophene Dusting Powder

General Notices

Hexachlorophene Cutaneous Powder Zinc and Hexachlorophene Dusting Powder

Action and use

Antiseptic.

DEFINITION

Hexachlorophene Dusting Powder is a *cutaneous powder*. It is a mixture of Hexachlorophene and Zinc Oxide with a suitable inert diluent.

The dusting powder complies with the requirements stated under Topical Powders and with the following requirements.

Content of hexachlorophene, C₁₃H₆Cl₆O₂

90.0 to 110.0% of the stated amount.

Content of zinc oxide, ZnO

90.0 to 110.0% of the stated amount.

IDENTIFICATION

- A. Shake a quantity of the powder containing 30 mg of Hexachlorophene with 25 mL of <u>ether</u> for 15 minutes, filter, wash the filtrate with 10 mL of <u>water</u>, dry the ether layer over <u>anhydrous sodium sulfate</u>, filter and evaporate to dryness. The <u>infrared absorption spectrum</u> of the residue, <u>Appendix II A</u>, is concordant with the <u>reference spectrum</u> of hexachlorophene (RS 174).
- B. Shake a quantity of the powder containing 30 mg of Zinc Oxide with 10 mL of 2M hydrochloric acid for 15 minutes and filter. 5 mL of the filtrate yields the reaction characteristic zinc salts, Appendix VI.

ASSAY

For hexachlorophene

Shake a quantity of the powder containing 15 mg of Hexachlorophene with 50 mL of <u>methanolic tris(hydroxymethyl)methylamine solution</u> for 10 minutes, filter through a sintered-glass crucible (<u>ISO</u> 4793, porosity grade 3, is suitable), wash the filter with two 10 mL quantities of the tris(hydroxymethyl)methylamine solution and dilute the combined filtrate and washings to 100 mL with the same solution. Dilute 10 mL of the resulting solution to 50 mL with <u>methanolic tris(hydroxymethyl)methylamine solution</u> and measure the <u>absorbance</u> at the maximum at 312 nm, <u>Appendix II</u> B, using in the reference cell a solution prepared by diluting a further 10 mL of the solution to 50 mL with <u>acidified methanol</u>. An absorbance of 0.432 is equivalent to 15 mg of C₁₃H₆Cl₆O₂ in the weight of powder taken.

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For zinc oxide

To a quantity of the powder containing 90 mg of Zinc Oxide add 10 mL of 2m nitric acid and 20 mL of water, boil for 2 minutes, cool, filter and wash the filter with two 25 mL quantities of water. To the combined filtrate and washings add 3 g of hexamine and titrate with 0.05m disodium edetate VS using 2 mL of xylenol orange solution as indicator. Each mL of 0.05m disodium edetate VS is equivalent to 4.068 mg of ZnO.

LABELLING

The label states that the preparation should not be applied to infants or to large areas of skin except in accordance with medical advice.