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Compound Benzoic Acid Ointment

General Notices

Whitfield's Ointment

DEFINITION

Compound Benzoic Acid Ointment contains 6.0% w/w of Benzoic Acid and 3.0% w/w of Salicylic Acid in a suitable emulsifying basis.

Extemporaneous preparation

The following formula and directions apply.

Benzoic Acid in *fine powder*	60 g
Salicylic Acid in *fine powder*	30 g
Emulsifying Ointment	910 g

Triturate the Benzoic Acid and the Salicylic Acid with a portion of the Emulsifying Ointment until smooth and gradually incorporate the remainder of the Emulsifying Ointment.

The ointment complies with the requirements stated under Topical Semi-solid Preparations and with the following requirements.

Content of benzoic acid, $C_7H_6O_2$

5.7 to 6.3% w/w.

Content of salicylic acid, $C_7H_6O_3$

2.7 to 3.3% w/w.

IDENTIFICATION

Carry out the method for *thin-layer chromatography*, Appendix III A, using a silica gel F_{254} precoated plate (Merck silica gel 60 F_{254} plates are suitable) and a mixture of 80 volumes of *toluene* and 20 volumes of *glacial acetic acid* as the mobile phase. Apply separately to the plate 2 µL of each of the following solutions. For solution (1) warm 1 g of the ointment with 10 mL of *chloroform*, cool and filter. Solution (2) contains 0.6% w/v of *benzoic acid* and 0.3% w/v of *salicylic acid* in *chloroform*. After removal of the plate, allow the solvent to evaporate in a current of air and examine under *ultraviolet light (254 nm)*. The chromatogram obtained with solution (1) shows spots corresponding in colour and position to those in the chromatogram obtained with solution (2). Examine under *ultraviolet light (365 nm)*. The chromatogram obtained with solution (1) shows a blue fluorescent spot corresponding in colour and position to that in the chromatogram obtained with solution (2). Spray the plate with *iron(III) chloride solution R1*. The chromatogram obtained with solution (1) shows a purple spot corresponding in position to the blue fluorescent spot observed under ultraviolet light (365 nm) and corresponding in colour and position to the spot in the chromatogram obtained with solution (2).

ASSAY

For benzoic acid

To 2 g add 150 mL of *water*, warm until melted and titrate with *0.1M sodium hydroxide VS* using *phenolphthalein solution R1* as indicator. Reserve the solution for the Assay for salicylic acid. After the subtraction of 1 mL for each 13.81 mg of $C_7H_6O_3$ found in the Assay for salicylic acid, each mL of *0.1M sodium hydroxide VS* is equivalent to 12.21 mg of $C_7H_6O_2$.

For salicylic acid

Cool the titrated solution obtained in the Assay for benzoic acid, dilute to 250 mL with *water* and filter. To 5 mL of the filtrate add sufficient *iron(III) nitrate solution* to produce 50 mL. Filter, if necessary, to remove haze and measure the *absorbance* of the resulting solution at the maximum at 530 nm, Appendix II B, using *iron(III) nitrate solution* in the reference cell. Calculate the content of $C_7H_6O_3$ from the absorbance obtained by repeating the operation using 5 mL of a 0.024% w/v solution of *salicylic acid* and beginning at the words ‘add sufficient *iron(III) nitrate solution* ...’.