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Hydrocortisone Oromucosal Tablets

General Notices

Action and use

Corticosteroid.

DEFINITION

Hydrocortisone Oromucosal Tablets are mucoadhesive buccal tablets containing hydrocortisone sodium succinate prepared by buffering Hydrocortisone Hydrogen Succinate.

The tablets comply with the requirements stated under Oromucosal Preparations and with the following requirements.

Content of hydrocortisone, $C_{21}H_{30}O_5$

90.0 to 110.0% of the stated amount.

IDENTIFICATION

Carry out the method for *thin-layer chromatography*, Appendix III A, using a *TLC silica gel plate* (Merck silica gel 60 F_{254} plates are suitable) and a mixture of 20 volumes of *acetic anhydride*, 20 volumes of *water* and 60 volumes of *butan-1-ol* as the mobile phase. Apply separately to the plate 5 µL of each of the following solutions. For solution (1) shake a quantity of the tablets containing the equivalent of 25 mg of hydrocortisone with 10 mL of *methanol*, filter and use the filtrate. For solution (2) dissolve 50 mg of *hydrocortisone acetate BPCRS* in sufficient *methanol* to produce 20 mL. Solution (3) contains equal volumes of solutions (1) and (2). After removal of the plate, allow it to dry in air, spray with *ethanolic sulfuric acid (20%)*, heat at 120° for 10 minutes, allow to cool and examine under *ultraviolet light (365 nm)*. The principal spot in the chromatogram obtained with solution (1) corresponds to that in the chromatogram obtained with solution (2). The test is not valid unless the chromatogram obtained with solution (3) shows a single compact spot.

TESTS

Disintegration

The tablets disintegrate in not less than 10 minutes when examined by the *disintegration test for tablets and capsules*, Appendix XII A1, but using *water* at 24° to 26°.

Free hydrocortisone

Not more than 15% of the stated amount when determined by the following method. Weigh and powder 20 tablets. For solution (1) disperse a quantity of the powdered tablets containing the equivalent of 7.5 mg of hydrocortisone in 15 mL of a phosphate buffer prepared by dissolving 5.8 g of *anhydrous disodium hydrogen orthophosphate* and 1.6 g of *sodium dihydrogen orthophosphate* in 1000 mL of *water* and adjusting the pH to 7.4, if necessary, by adding 10 mg quantities of either *anhydrous disodium hydrogen orthophosphate* or *sodium dihydrogen orthophosphate*. Shake and extract with three 25-mL quantities of *chloroform*, combine the extracts in a second separating funnel, wash the combined extracts with 2 mL

of *water*, filter the chloroform layer through a plug of absorbent cotton, previously moistened with *chloroform*, into a 250-mL round-bottomed flask, wash the funnel and absorbent cotton plug with two 10-mL quantities of *chloroform* and add the washings to the flask; evaporate to dryness using a rotary evaporator, allow to cool and dissolve the residue in 50 mL of *aldehyde-free ethanol (96%)*. Solution (2) contains 0.00225% w/v of *hydrocortisone BPCRS* in *aldehyde-free ethanol (96%)*.

Protect all the solutions from light. Transfer 10 mL of solution (1) into a stoppered test-tube and repeat for solution (2). Place in a water bath at 35° for 10 minutes, add 1 mL of *triphenyltetrazolium chloride solution* and 1 mL of *dilute tetramethylammonium hydroxide solution* to each tube, stopper and mix well; allow the tubes to stand in the water bath at 35° for a further 25 minutes, remove from the water bath and allow to stand in water for 5 minutes at room temperature. Measure the *absorbance* of the resulting solutions in a stoppered cell at the maximum at 485 nm, Appendix II B, using in the reference cell a solution prepared at the same time and in the same manner using 10 mL of *aldehyde-free ethanol (96%)*.

Calculate the content of free hydrocortisone.

ASSAY

Weigh and powder 20 tablets. Shake a quantity of the powdered tablets containing the equivalent of 25 mg of hydrocortisone with 50 mL of *water* for 10 minutes, dilute to 100 mL with *water*, filter and discard the first 20 mL of the filtrate; dilute 4 mL of the remaining filtrate to 100 mL with *water* and measure the *absorbance*, Appendix II B, at the maximum at 248 nm using *water* in the reference cell. Calculate the content of hydrocortisone, $C_{21}H_{30}O_5$, in the tablets using 449 as the value of A(1%, 1 cm) at the maximum at 248 nm.

LABELLING

The quantity of active ingredient is stated in terms of the equivalent amount of hydrocortisone.