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

Hydrocortisone Acetate Cream

General Notices

Action and use

Corticosteroid.

DEFINITION

Hydrocortisone Acetate Cream contains Hydrocortisone Acetate in a suitable basis.

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

Content of hydrocortisone acetate, $C_{23}H_{32}O_6$

90.0 to 110.0% of the stated amount.

IDENTIFICATION

A. Carry out the method for *thin-layer chromatography*, Appendix III A, using *silica gel G* as the coating substance and a mixture of 77 volumes of *dichloromethane*, 15 volumes of *ether*, 8 volumes of *methanol* and 1.2 volumes of *water* as the mobile phase. Apply separately to the plate 5 µL of each of the following solutions.

For creams containing more than 0.5% w/w of Hydrocortisone Acetate, prepare two solutions in the following manner. For solution (1) mix a quantity of the cream containing 25 mg of Hydrocortisone Acetate with 10 mL of *methanol (90%)*, add 50 mL of hot *hexane* and shake. Discard the upper layer, add 5 g of *anhydrous sodium sulfate* to the lower layer, mix and filter through a glass microfibre filter (Whatman GF/C is suitable). Solution (2) is a mixture of equal volumes of solution (1) and a 0.25% w/v solution of *hydrocortisone acetate BPCRS* in *methanol*.

For creams containing 0.5% w/w or less of Hydrocortisone Acetate, prepare solution (1) in the same manner as solution (1) described above but using a quantity of the cream containing 5 mg of Hydrocortisone Acetate. Solution (2) is a mixture of equal volumes of solution (1) and a 0.05% w/v solution of *hydrocortisone acetate BPCRS* in *methanol*.

After removal of the plate, allow it to dry in air and spray with *alkaline tetrazolium blue solution*. The principal spot in the chromatogram obtained with solution (1) corresponds to that in the chromatogram obtained with solution (2), which appears as a single, compact spot.

B. In the Assay, the chromatogram obtained with solution (2) shows a peak with the same retention time as the peak due to hydrocortisone acetate in the chromatogram obtained with solution (1).

ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

For creams containing more than 0.5% w/w of Hydrocortisone Acetate, prepare solutions (1) and (2) in the following manner. For solution (1) dissolve 25 mg of *hydrocortisone acetate BPCRS* in 45 mL of *methanol*, add 5 mL of a 0.5% w/v solution of *betamethasone* (internal standard) in *methanol* and add sufficient *water* to produce 100 mL. For solution (2) disperse, by shaking, a quantity containing 25 mg of Hydrocortisone Acetate in 40 mL of a solution prepared by mixing

75 mL of *methanol* with 25 mL of a 15% w/v solution of *sodium chloride*. Add 50 mL of hot *hexane*, shake and separate the lower layer. Repeat the extraction using two 10 mL quantities of the methanolic sodium chloride solution. Add 5 mL of *methanol* to the combined extracts and sufficient *water* to produce 100 mL, mix and filter through a glass microfibre filter paper (Whatman GF/C is suitable).

For creams containing 0.5% w/w or less of Hydrocortisone Acetate, prepare solutions (1) and (2) in the following manner. For solution (1) dissolve 5 mg of *hydrocortisone acetate BPCRS* in 45 mL of *methanol* and add 5 mL of a 0.110% w/v solution of *betamethasone* (internal standard) in *methanol* and sufficient *water* to produce 100 mL. Prepare solution (2) in the same manner as solution (2) above but use a quantity containing 5 mg of Hydrocortisone Acetate.

For all creams prepare solution (3) in the same manner as solution (2) but adding 5 mL of the appropriate internal standard solution in place of the 5 mL of methanol before diluting to volume.

The chromatographic procedure may be carried out using (a) a stainless steel column (10 cm × 5 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm) (Spherisorb ODS 1 is suitable), (b) *methanol (50%)* as the mobile phase with a flow rate of 2 mL per minute and (c) a detection wavelength of 240 nm.

Calculate the content of $C_{23}H_{32}O_6$ in the preparation being examined using the declared content of $C_{23}H_{32}O_6$ in *hydrocortisone acetate BPCRS*.