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

Hydrocortisone Acetate Ointment

General Notices

Action and use

Corticosteroid.

DEFINITION

Hydrocortisone Acetate Ointment contains Hydrocortisone Acetate in a suitable basis.

The ointment 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 the following solutions.

For ointments containing more than 0.5% w/w of Hydrocortisone Acetate

(1) Disperse a quantity containing 25 mg of Hydrocortisone Acetate in 5 mL of hot *hexane*, cool, extract with 10 mL of *methanol (90%)* and filter.
(2) Equal volumes of solution (1) and a 0.25% w/v solution of *hydrocortisone acetate BPCRS* in *methanol*.

For ointments containing 0.5% w/w or less of Hydrocortisone Acetate

(1) Disperse a quantity containing 5 mg of Hydrocortisone Acetate in 5 mL of hot *hexane*, cool, extract with 10 mL of *methanol (90%)* and filter.
(2) Equal volumes of solution (1) and a 0.05% w/v solution of *hydrocortisone acetate BPCRS* in *methanol*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel G*.
(b) Use the mobile phase as described below.
(c) Apply 5 µL of each solution.
(d) After removal of the plate, dry in air and spray with *alkaline tetrazolium blue solution*.

MOBILE PHASE

1.2 volumes of *water*, 8 volumes of *methanol*, 15 volumes of *ether* and 77 volumes of *dichloromethane*.

CONFIRMATION

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 ointments containing more than 0.5% w/w of Hydrocortisone Acetate

(1) Disperse a quantity of the ointment containing 25 mg of Hydrocortisone Acetate in 100 mL of hot *hexane*, cool and extract with 20 mL of a solution prepared by mixing 3 volumes of *methanol* and 1 volume of a 15% w/v solution of *sodium chloride*. 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 (Whatman GF/C is suitable).
(2) 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 sufficient *water* to produce 100 mL.
(3) Prepare in the same manner as solution (1) but add 5 mL of the internal standard solution in place of the 5 mL of methanol before diluting to volume.

For ointments containing 0.5% w/w or less of Hydrocortisone Acetate

(1) Disperse a quantity of the ointment containing 5 mg of Hydrocortisone Acetate in 100 mL of hot *hexane*, cool and extract with 20 mL of a solution prepared by mixing 3 volumes of *methanol* and 1 volume of a 15% w/v solution of *sodium chloride*. 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 (Whatman GF/C is suitable).
(2) Dissolve 5 mg of *hydrocortisone acetate BPCRS* in 45 mL of *methanol*, add 5 mL of a 0.110% w/v solution of *betamethasone* (internal standard) in *methanol* and add sufficient *water* to produce 100 mL.
(3) Prepare in the same manner as solution (1) but add 5 mL of the internal standard solution in place of the 5 mL of methanol before diluting to volume.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column 10 cm × 5 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm) (Spherisorb ODS 1 is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 2 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 240 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

50 volumes of *methanol* and 50 volumes of *water*.

DETERMINATION OF CONTENT

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

STORAGE

Hydrocortisone Acetate Ointment should be protected from light.