



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

Hydrocortisone Ointment

[General Notices](#)

Action and use

Corticosteroid.

DEFINITION

Hydrocortisone Ointment contains Hydrocortisone in a suitable basis.

The ointment complies with the requirements stated under Topical Semi-solid 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

- A. Complies with test A for Identification described under [Hydrocortisone Cream](#) but preparing solution (1) in the following manner. For ointments containing more than 0.5% w/w of Hydrocortisone, disperse a quantity containing 25 mg of Hydrocortisone in 5 mL of hot [hexane](#), cool, extract with 10 mL of [methanol](#) (90%) and filter. For ointments containing 0.5% w/w or less of Hydrocortisone, disperse a quantity containing 5 mg of Hydrocortisone in 50 mL of hot [hexane](#), cool, extract with 10 mL of [methanol](#) (90%) and filter.
- B. In the Assay, the chromatogram obtained with solution (2) shows a peak with the same retention time as the peak due to hydrocortisone in the chromatogram obtained with solution (1).

ASSAY

Carry out the Assay described under [Hydrocortisone Cream](#) but prepare solution (2) in the following manner. For ointments containing more than 0.5% w/w of Hydrocortisone, disperse a quantity containing 25 mg of Hydrocortisone in 100 mL of hot [hexane](#), cool and extract with 20 mL of a solution prepared by mixing 3 volumes of [methanol](#) with 1 volume of a 15% w/v solution of [sodium chloride](#). Repeat the extraction using a further two 10 mL quantities of the methanolic sodium chloride solution. To the combined extracts add 5 mL of [methanol](#) and sufficient [water](#) to produce 100 mL, mix and filter through a glass microfibre filter (Whatman GF/C is suitable). For ointments containing 0.5% w/w or less of Hydrocortisone, prepare solution (2) in the same manner as solution (2) above but use a quantity containing 5 mg of Hydrocortisone.

STORAGE

Hydrocortisone Ointment should be protected from light.

