



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

## Fluocinolone Ointment

### [General Notices](#)

### Action and use

Glucocorticoid.

### DEFINITION

Fluocinolone Ointment contains Fluocinolone Acetonide or Fluocinolone Acetonide Dihydrate in a suitable basis.

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

### Content of fluocinolone acetonide, $C_{24}H_{30}F_2O_6$

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 60 volumes of n-hexane, 40 volumes of [chloroform](#), 10 volumes of [methanol](#) and 1 volume of [triethylamine](#) as the mobile phase. Apply separately to the plate 5  $\mu$ L of each of the following solutions. For solution (1) disperse, by shaking, a quantity of the preparation being examined containing 0.25 mg of fluocinolone acetonide in 2 mL of [chloroform](#), add 10 mL of [methanol](#), shake vigorously, cool in ice for 15 minutes, centrifuge at 3000 revolutions per minute for 15 minutes, decant the clear, supernatant liquid, evaporate to dryness on a water bath in a current of nitrogen and dissolve the residue in 1 mL of [chloroform](#). Solution (2) contains 0.025% w/v solution of [fluocinolone acetonide BPCRS](#) in [chloroform](#). After removal of the plate, allow it to dry in air until the solvent has evaporated, heat at 105° for 5 minutes and spray whilst hot 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).

B. In the Assay the chromatogram obtained with solution (3) shows a peak with the same retention time as the peak due to fluocinolone acetonide in the chromatogram obtained with solution (1).

### ASSAY

Carry out the method for [liquid chromatography, Appendix III D](#), using the following solutions. Solution (1) contains 0.0050% w/v of [fluocinolone acetonide BPCRS](#) and 0.40% v/v of [toluene](#) (internal standard) in [methanol](#) (80%).

For ointments containing 0.01% w/w or less of fluocinolone acetonide prepare solution (2) in the following manner. To a quantity of the ointment containing 0.5 mg of fluocinolone acetonide add 50 mL of [2,2,4-trimethylpentane](#) and 8 mL of [methanol](#) (80%), warm gently on a water bath until the preparation is dispersed and shake vigorously for 2 minutes. Separate the lower, aqueous methanolic layer and wash the upper layer with 1 mL of [methanol](#) (80%), adding the washing to the previous extract. To the combined extracts add sufficient [methanol](#) (80%) to produce 10 mL. Prepare solution (3) in the same manner as solution (2) but adding 1 mL of a 4% v/v solution of the internal standard in [methanol](#) to the combined extracts before dilution to 10 mL.

For ointments containing 0.025% w/w of fluocinolone acetonide, prepare solution (2) in the following manner. To a quantity of the ointment containing 1.25 mg of fluocinolone acetonide add 50 mL of [2,2,4-trimethylpentane](#) and 20 mL of [methanol](#) (80%), warm gently on a water bath until the preparation is dispersed and shake vigorously for 2 minutes. Separate the lower, aqueous methanolic layer and wash the upper layer with 2 mL of [methanol](#) (80%), adding the washing to the previous extract. To the combined extracts add sufficient [methanol](#) (80%) to produce 25 mL. Prepare solution (3) in the same manner as solution (2) but adding 1 mL of a 10% v/v solution of the internal standard in [methanol](#) to the combined extracts before dilution to 25 mL.

The chromatographic procedure may be carried out using (a) a stainless steel column (20 cm × 5 mm) packed with [octadecylsilyl silica gel for chromatography](#) (5 µm) (Spherisorb ODS 1 is suitable), (b) a mixture of 55 volumes of [water](#), 45 volumes of [acetonitrile](#) and 0.1 volume of [glacial acetic acid](#) as the mobile phase with a flow rate of 1 mL per minute and (c) a detection wavelength of 238 nm.

Calculate the content of  $C_{24}H_{30}F_2O_6$  in the ointment using the declared content of  $C_{24}H_{30}F_2O_6$  in [fluocinolone acetonide](#) [BPCRS](#).

## **LABELLING**

When the active ingredient is Fluocinolone Acetonide Dihydrate, the quantity is stated in terms of the equivalent amount of fluocinolone acetonide.