



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

Fluocinonide Cream

[General Notices](#)

Action and use

Glucocorticoid.

DEFINITION

Fluocinonide Cream contains Fluocinonide in a suitable basis.

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

Content of fluocinonide, $C_{26}H_{32}F_2O_7$

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.

- (1) Disperse a quantity of the cream containing 2.5 mg of Fluocinonide in 25 mL of [methanol](#) (80%), add 50 mL of [ether](#) and shake vigorously to produce a clear, homogeneous solution. Add 15 mL of [water](#), shake and transfer the lower layer to a second separating funnel. Add 100 mL of [water](#), extract with 10 mL of [chloroform](#), filter the chloroform layer through filter paper and evaporate to a volume of about 1 mL in a current of air on a water bath.
- (2) 0.1% w/v of [fluocinonide BPCRS](#) in a mixture of 1 volume of [methanol](#) and 9 volumes of [dichloromethane](#).

CHROMATOGRAPHIC CONDITIONS

- (a) Use as the coating [silica gel F₂₅₄](#).
- (b) Use the mobile phase as described below.
- (c) Apply 10 µL of each solution.
- (d) Develop the plate to 15 cm.
- (e) After removal of the plate, dry in air and examine under [ultraviolet light \(254 nm\)](#).

MOBILE PHASE

12 volumes of [water](#), 80 volumes of [methanol](#), 150 volumes of [ether](#) and 770 volumes of [dichloromethane](#). Mix the water and the methanol before adding to the remaining solvents of the mobile phase.

CONFIRMATION

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 retention time of the principal peak in the chromatogram obtained with solution (1) is similar to that of the principal peak in the chromatogram obtained with solution (2).

ASSAY

Carry out the method for [liquid chromatography, Appendix III D](#), using the following solutions.

- (1) Disperse a quantity of the cream containing 1.5 mg of Fluocinonide in 20 mL of [methanol \(80%\)](#), warming gently over a water bath if necessary. Add 50 mL of [2,2,4-trimethylpentane](#), shake for 2 minutes and transfer the lower aqueous methanol layer to a 50-mL flask. Repeat the extraction with a further 20 mL of [methanol \(80%\)](#). Dilute the combined extracts to volume with the same solvent.
- (2) 0.003% w/v of [fluocinonide BPCRS](#) in [methanol \(80%\)](#).

CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (20 cm × 4.6 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 238 nm.
- (f) Inject 20 µL of each solution.

MOBILE PHASE

0.1 volume of [glacial acetic acid](#), 45 volumes of [acetonitrile](#) and 55 volumes of [water](#).

DETERMINATION OF CONTENT

Calculate the content of $C_{26}H_{32}F_2O_7$ in the cream using the declared content of $C_{26}H_{32}F_2O_7$ in [fluocinonide BPCRS](#).