



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

## Hydrocortisone Cream

### [General Notices](#)

### Action and use

Corticosteroid.

### DEFINITION

Hydrocortisone Cream contains Hydrocortisone in a suitable basis.

*The cream 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. Carry out the method for [thin-layer chromatography, Appendix III A](#), using the following solutions.

*For creams containing more than 0.5% w/w of [Hydrocortisone](#):*

- (1) Mix a quantity containing 25 mg of Hydrocortisone with 10 mL of [methanol](#) (90%), add 50 mL of hot [hexane](#) and shake. Separate the lower layer, add 5 g of [anhydrous sodium sulfate](#), mix and filter through a glass microfibre filter (Whatman GF/C is suitable).
- (2) 0.25% w/v of [hydrocortisone BPCRS](#) in [methanol](#).
- (3) A mixture of equal volumes of solutions (1) and (2).

*For creams containing 0.5% w/w or less of [Hydrocortisone](#):*

- (1) Prepare in the same manner as solution (1) above but use a quantity containing 5 mg of Hydrocortisone.
- (2) 0.05% w/v of [hydrocortisone BPCRS](#) in [methanol](#).
- (3) A mixture of equal volumes of solutions (1) and (2).

### CHROMATOGRAPHIC CONDITIONS

- (a) Use as the coating [silica gel G](#).
- (b) Use the mobile phase as described below.
- (c) Apply 5  $\mu$ L of each solution.
- (d) Develop the plate to 15 cm.
- (e) After removal of the plate, dry in air, spray with [alkaline tetrazolium blue solution](#) and examine in white light.

### 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); if it does not, the principal spot in the chromatogram obtained with solution (3) 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 in the chromatogram obtained with solution (3).

## 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](#):*

Prepare a 0.5% w/v solution of [betamethasone](#) (internal standard) in [methanol](#) (solution A).

(1) Disperse, by shaking, a quantity of the cream containing 25 mg of Hydrocortisone in 40 mL of a mixture of 3 volumes of [methanol](#) and 1 volume 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 a further two 10-mL quantities of the methanolic sodium chloride solution. To the combined extracts add 5 mL of solution A and sufficient [water](#) to produce 100 mL, mix and filter through a glass microfibre paper (Whatman GF/C is suitable).

(2) Prepare in the same manner as solution (1), but add 5 mL of [methanol](#) in place of the 5 mL of solution A.

(3) Dissolve 25 mg of [hydrocortisone BPCRS](#) in 45 mL of [methanol](#), add 5 mL of solution A and add sufficient [water](#) to produce 100 mL.

*For creams containing 0.5% w/w or less of [Hydrocortisone](#):*

Prepare a 0.110% w/v solution of [betamethasone](#) (internal standard) in [methanol](#) (solution B).

(1) Disperse, by shaking, a quantity of the cream containing 5 mg of Hydrocortisone in 40 mL of a mixture of 3 volumes of [methanol](#) and 1 volume 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 a further two 10-mL quantities of the methanolic sodium chloride solution. To the combined extracts add 5 mL of solution B and sufficient [water](#) to produce 100 mL, mix and filter through a glass microfibre paper (Whatman GF/C is suitable).

(2) Prepare in the same manner as solution (1), but add 5 mL of [methanol](#) in place of the 5 mL of solution B.

(3) Dissolve 5 mg of [hydrocortisone BPCRS](#) in 45 mL of [methanol](#) and add 5 mL of solution B and sufficient [water](#) to produce 100 mL.

### CHROMATOGRAPHIC CONDITIONS

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

### MOBILE PHASE

[methanol](#) (50%).

### DETERMINATION OF CONTENT

Calculate the content of  $C_{21}H_{30}O_5$  in the cream using the ratios of the peaks and the declared content of  $C_{21}H_{30}O_5$  in [hydrocortisone BPCRS](#).