



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

Beclometasone Cream

[General Notices](#)

Action and use

Glucocorticoid.

DEFINITION

Beclometasone Cream contains Beclometasone Dipropionate in a suitable basis.

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

Content of beclometasone dipropionate, $C_{28}H_{37}ClO_7$

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 preparation being examined containing 0.5 mg of Beclometasone Dipropionate in 20 mL of [methanol \(80%\)](#) by heating on a water bath until the methanol begins to boil. Shake vigorously, cool in ice for 30 minutes and centrifuge. Mix 10 mL of the supernatant liquid with 3 mL of [water](#) and 5 mL of [chloroform](#), shake vigorously, allow the layers to separate, evaporate the chloroform layer to dryness in a current of nitrogen with gentle heating and dissolve the residue in 1 mL of [chloroform](#).
- (2) 0.025% w/v of [beclometasone dipropionate BPCRS](#) in [chloroform](#).
- (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 10 μ L of each solution.
- (d) Develop the plate to 15 cm.
- (e) After removal of the plate, allow it to dry in air until the solvent has evaporated, heat at 105° for 5 minutes and, while hot, spray with [alkaline tetrazolium blue solution](#).

MOBILE PHASE

100 volumes of [chloroform](#), 10 volumes of [acetone](#) and 5 volumes of [absolute ethanol](#).

CONFIRMATION

The principal spot in the chromatogram obtained with solution (1) corresponds to that in the chromatogram obtained with solution (2). 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 beclometasone dipropionate in the chromatogram obtained with solution (1).

ASSAY

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

For creams containing 0.025% w/w of Beclometasone Dipropionate.

- (1) Mix 10 mL of [methanol \(80%\)](#) containing 0.01% w/v of [beclometasone dipropionate BPCRS](#) and 0.0005% w/v of [beclometasone 17-propionate BPCRS](#) with 2 mL of a 0.05% w/v solution of [testosterone propionate](#) (internal standard) in [methanol \(80%\)](#) and dilute to 50 mL with the same solvent.
- (2) Disperse a quantity of the preparation being examined containing 1 mg of Beclometasone Dipropionate in 20 mL of hot [methanol \(90%\)](#), add 25 mL of [2,2,4-trimethylpentane](#), cool, shake the mixture and filter the lower layer through a small plug of absorbent cotton previously washed with [methanol \(80%\)](#). Repeat the extraction of the trimethylpentane solution with two further 10 mL quantities of [methanol \(80%\)](#), filtering the extracts through the absorbent cotton. Combine the extracts and add sufficient [methanol \(80%\)](#) to produce 50 mL. If the resulting solution is more than slightly cloudy, filter.
- (3) Prepare in the same manner as solution (2) but add 2 mL of a 0.05% w/v solution of the internal standard in [methanol \(80%\)](#) before diluting to 50 mL.

For creams containing 0.5% w/w of Beclometasone Dipropionate.

- (1) Mix 25 mL of [methanol \(80%\)](#) containing 0.04% w/v of [beclometasone dipropionate BPCRS](#) and 0.002% w/v of [beclometasone 17-propionate BPCRS](#) with 20 mL of a 0.05% w/v solution of [testosterone propionate](#) (internal standard) in [methanol \(80%\)](#) and dilute to 200 mL with the same solvent.
- (2) Add 100 mL of [methanol \(80%\)](#) to a quantity of the preparation being examined containing 10 mg of Beclometasone Dipropionate and heat on a water bath, with swirling, until the preparation has dispersed. Cool, dilute to 200 mL with [methanol \(80%\)](#) and filter.
- (3) Prepare in the same manner as solution (2) but add 20 mL of a 0.05% w/v solution of the internal standard in [methanol \(80%\)](#) before diluting to 200 mL.

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 a column temperature of 60°.
- (e) Use a detection wavelength of 238 nm.
- (f) Inject 20 µL of each solution.

MOBILE PHASE

A mixture of [methanol](#) and [water](#) such that the [resolution factor](#) between the peaks due to beclometasone 17-propionate (retention time about 1.5 minutes) and beclometasone dipropionate (retention time about 2 minutes) is greater than 2.0 (a mixture of 70 volumes of [methanol](#) and 30 volumes of [water](#) is usually suitable).

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (1), the [resolution factor](#) between the peaks due to beclometasone 17-propionate (retention time about 1.5 minutes) and beclometasone dipropionate (retention time about 2 minutes) is greater than 2.0.

DETERMINATION OF CONTENT

Calculate the content of $C_{28}H_{37}ClO_7$ in the preparation being examined using the declared content of $C_{28}H_{37}ClO_7$ in [beclometasone dipropionate BPCRS](#).

STORAGE

Beclometasone Cream should be protected from light.

