



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

Beclometasone Ointment

[General Notices](#)

Action and use

Glucocorticoid.

DEFINITION

Beclometasone Ointment contains Beclometasone Dipropionate in a suitable basis.

The ointment 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) Dissolve a quantity of the ointment containing 0.5 mg of Beclometasone Dipropionate in 2 mL of [chloroform](#) by heating on a water bath, add 10 mL of [methanol](#) and heat on the water bath until the mixture begins to boil. Shake vigorously, cool in ice for 30 minutes and filter. Evaporate the filtrate to dryness in a current of nitrogen with gentle heating and dissolve the residue in 1 mL of [chloroform](#).
- (2) 0.05% 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

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

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

- (1) Disperse a quantity of the ointment containing 1 mg of Beclometasone Dipropionate in 25 mL of hot [2,2,4-trimethylpentane](#), cool and extract the mixture with successive quantities of 20, 10 and 10 mL of [methanol](#) (80%), filtering each extract in turn through a small plug of absorbent cotton previously washed with [methanol](#) (80%). Combine the filtrates and dilute to 50 mL with [methanol](#) (80%).
- (2) 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.
- (3) Prepare solution (3) in the same manner as solution (1) but add 2 mL of a 0.05% w/v solution of the internal standard in [methanol](#) (80%) before diluting to 50 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 30 volumes of [water](#) and 70 volumes of [methanol](#) is usually suitable).

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (2), 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 Ointment should be protected from light.