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

Betamethasone Valerate Lotion

General Notices

Betamethasone Valerate Cutaneous Solution

Action and use

Glucocorticoid.

DEFINITION

Betamethasone Valerate Lotion is a *cutaneous solution*. It contains Betamethasone Valerate in a suitable vehicle.

The lotion complies with the requirements stated under Liquids for Cutaneous Application and with the following requirements.

Content of betamethasone, $C_{22}H_{29}FO_5$

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.
(1) Disperse a quantity of the preparation being examined containing the equivalent of 1 mg of betamethasone with 5 mL of *methanol (80%)* by heating on a water bath until the methanol begins to boil. Shake vigorously, cool in ice and filter. Transfer the filtrate to a separating funnel and add 0.5 mL of *water* and 1 mL of *chloroform*. Shake vigorously, allow the layers to separate and use the chloroform layer.
(2) 0.05% w/v of *betamethasone valerate 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 µL of each solution.
(d) Develop the plate to 15 cm.
(e) After removal of the plate, dry in air until the solvent has evaporated, heat at 105° for 5 minutes and spray while hot 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 in position and colour to that in the chromatogram obtained with solution (2). The 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 betamethasone valerate in the chromatogram obtained with solution (3).

ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Disperse a quantity of the lotion containing the equivalent of 3 mg of betamethasone in a mixture of 10 mL of *ethanol (65%)* and 50 mL of *hexane*, shake for 2 minutes and filter the lower, ethanolic layer through absorbent cotton previously washed with *ethanol (65%)*. Repeat the extraction of the hexane mixture with two 5-mL quantities of *ethanol (65%)*, filtering the ethanol extracts through the absorbent cotton, add 5 mL of a 0.11% w/v solution of *beclometasone dipropionate BPCRS* (internal standard)to the combined filtrates and mix.
(2) Disperse a quantity of the lotion containing the equivalent of 3 mg of betamethasone in a mixture of 10 mL of *ethanol (65%)* and 50 mL of *hexane*, shake for 2 minutes and filter the lower, ethanolic layer through absorbent cotton previously washed with *ethanol (65%)*. Repeat the extraction of the hexane mixture with two 5-mL quantities of *ethanol (65%)*, filtering the ethanol extracts through the absorbent cotton, add 5 mL of *ethanol (65%)* to the combined filtrates and mix.
(3) Mix 20 mL of a solution containing 0.018% w/v of *betamethasone valerate BPCRS* and 0.0010% w/v of *betamethasone 21-valerate BPCRS* in *ethanol (65%)* with 5 mL of a 0.11% w/v solution of *beclometasone dipropionate BPCRS* (internal standard) in *ethanol (65%)*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (10 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 a column temperature of 60°.
(e) Use a detection wavelength of 238 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

42 volumes of *absolute ethanol* and 58 volumes of *water*.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution factor* between the peaks due to betamethasone valerate (retention time about 5 minutes) and betamethasone 21-valerate (retention time about 7 minutes) is greater than 1.0. If necessary, adjust the mobile phase.

DETERMINATION OF CONTENT

Calculate the content of $C_{22}H_{29}FO_5$ in the lotion using the declared content of $C_{22}H_{29}FO_5$, in *betamethasone valerate BPCRS*.

STORAGE

Betamethasone Valerate Lotion should be protected from light.

LABELLING

The quantity of active ingredient is stated in terms of the equivalent amount of betamethasone.