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

Betamethasone Valerate Ointment

General Notices

Action and use

Glucocorticoid.

DEFINITION

Betamethasone Valerate Ointment contains Betamethasone Valerate in a suitable basis.

The ointment complies with the requirements stated under Topical Semi-solid Preparations 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. Complies with test A for Identification described under Betamethasone Valerate Lotion preparing solution (1) in the following manner. Disperse a quantity of the ointment containing the equivalent of 1 mg of betamethasone in 10 mL of *methanol* by heating on a water bath until the methanol 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 0.5 mL of *chloroform*. Solution (2) contains 0.24% w/v of *betamethasone valerate BPCRS* in *chloroform*.
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 (1).

ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions. For solution (1) mix 10 mL of a solution containing 0.024% w/v of *betamethasone valerate BPCRS* and 0.0012% w/v of *betamethasone 21-valerate BPCRS* in *ethanol (65%)* with 5 mL of a 0.072% w/v solution of *beclometasone dipropionate BPCRS* (internal standard) in *ethanol (65%)* and dilute to 50 mL with *ethanol (65%)*. For solution (2) disperse a quantity of the ointment containing the equivalent of 2 mg of betamethasone in 100 mL of hot *hexane*, cool, extract with 20 mL of *ethanol (65%)* and filter the lower, ethanolic layer through absorbent cotton previously washed with *ethanol (65%)*; repeat the extraction of the hexane mixture with two 10-mL quantities of *ethanol (65%)*, filtering each extract in turn through the absorbent cotton and dilute the combined filtrates to 50 mL with *ethanol (65%)*. Prepare solution (3) in the same manner as solution (2) but add 5 mL of the 0.072% w/v solution of the internal standard in *ethanol (65%)* before diluting to 50 mL.

The chromatographic procedure may be carried out using (a) a stainless steel column (10 cm × 5 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm) (Spherisorb ODS 1 is suitable) and maintained at 60°, (b) as the mobile phase with a flow rate of 2 mL per minute a mixture of *absolute ethanol* and *water* adjusted so that 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 more than 1.0 (a mixture of 42 volumes of *absolute ethanol* and 58 volumes of *water* is usually suitable) and (c) a detection wavelength of 238 nm.

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

STORAGE

Betamethasone Valerate Ointment should be protected from light.

LABELLING

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