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

Mometasone Ointment

General Notices

Action and use

Glucocorticoid.

DEFINITION

Mometasone Ointment contains Mometasone Furoate in a suitable basis.

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

Content of mometasone furoate, $C_{27}H_{30}Cl_2O_6$

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 ointment containing 0.5 mg of Mometasone Furoate in 4 mL of *methanol (80%)* by heating on a water bath until the temperature reaches 80°. Shake for 20 minutes and cool in ice for 30 minutes and filter.
(2) 0.0125% w/v of *mometasone furoate BPCRS* in *methanol (80%)*.
(3) A mixture of equal volumes of solutions (1) and (2).

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel F_{254}* (Merck silica gel 60 F_{254} plates are suitable).
(b) Use the mobile phase as described below, allow the tank to saturate for 60 minutes.
(c) Apply 20 µL of each solution.
(d) Develop the plate to 15 cm.
(e) After removal of the plate, dry in air and examine under *ultraviolet light (254 nm)*.

MOBILE PHASE

3 volumes of *acetonitrile*, 10 volumes of *methanol*, 26 volumes of *ethyl acetate* and 61 volumes of *toluene*.

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 (1) shows a peak with the same retention time as the peak due to mometasone furoate in the chromatogram obtained with solution (2).

TESTS

Related substances

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions. *Carry out the procedure protected from light and prepare solutions immediately before use.*

Solution A 0.1 volumes of *glacial acetic acid*, 50 volumes of *acetonitrile* and 50 volumes of *water*.
(1) Completely disperse a quantity of the ointment containing 10 mg of Mometasone Furoate in 25 mL of *acetonitrile* on a water bath at a temperature of 80° and allow to cool. Add 20 mL of *acetonitrile* and 30 mL of solution A and shake for 30 minutes. Add sufficient solution A to produce 100 mL and filter.
(2) Dilute 1 volume of solution (1) to 200 volumes with a solution containing 45 volumes of *acetonitrile* and 55 volumes of solution A.
(3) Dissolve 5 mg of *mometasone furoate for system suitability EPCRS* in 4.5 mL of *acetonitrile* and add sufficient solution A to produce 10 mL.
(4) Dilute 2 volumes of solution (2) to 10 volumes with a solution containing 45 volumes of *acetonitrile* and 55 volumes of solution A.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *end-capped octadecylsilyl silica gel for chromatography* (5 µm) (Symmetry C18 is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1 mL per minute.
(d) Use an ambient temperature.
(e) Use a detection wavelength of 254 nm.
(f) Inject 20 µL of each solution.
(g) Allow the chromatography to proceed for 2.5 times the retention time of mometasone furoate.

MOBILE PHASE

Equal volumes of *acetonitrile* and *water*.

When the chromatograms are recorded under the prescribed conditions, the relative retentions with reference to mometasone furoate (retention time about 25 minutes) are: impurity C, about 0.9 and impurity J, about 1.5.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between impurity C and mometasone furoate is at least 2.5.

LIMITS

In the chromatogram obtained with solution (1):

the area of any *secondary peak* is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (0.5%);

the sum of the areas of all *secondary peaks* is not greater than twice the area of the principal peak in the chromatogram obtained with solution (2) (1%).

Disregard any peak with an area less than the area of the principal peak in the chromatogram obtained with solution (4) (0.1%).

ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions. *Carry out the procedure protected from light and prepare solutions immediately before use.*

Solution A 0.1 volumes of glacial acetic acid, 50 volumes of *acetonitrile* and 50 volumes of *water*.
(1) Completely disperse a quantity of the ointment containing 10 mg of Mometasone Furoate in 25 mL of *acetonitrile* on a water bath at a temperature of 80° and allow to cool. Add 20 mL of *acetonitrile* and 30 mL of solution A and shake for 30 minutes. Add sufficient solution A to produce 100 mL and filter.
(2) Dissolve 10 mg of *mometasone furoate BPCRS* in 45 mL of *acetonitrile* and add sufficient solution A to produce 100 mL.

(3) Dissolve 5 mg of *mometasone furoate for system suitability EPCRS* in 4.5 mL of *acetonitrile* and add sufficient solution A to produce 10 mL.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between impurity C and mometasone furoate is at least 2.5.

DETERMINATION OF CONTENT

Calculate the content of $C_{27}H_{30}Cl_2O_6$ in the preparation being examined using the declared content of $C_{27}H_{30}Cl_2O_6$ in *mometasone furoate BPCRS*.

IMPURITIES

The impurities limited by the requirements of this monograph include impurity C and impurity J listed under Mometasone Furoate.