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

Mometasone Aqueous Nasal Spray

General Notices

Action and use

Glucocorticoid.

DEFINITION

Mometasone Aqueous Nasal Spray is an aqueous suspension of Mometasone Furoate in a suitable pressurised container fitted with an appropriate nasal delivery system.

The nasal spray complies with the requirements stated under Nasal Preparations and with the following requirements.

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

80.0 to 120.0% of the amount stated to be delivered by actuation of the valve.

IDENTIFICATION

A. Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.
(1) Discharge the container a sufficient number of times to obtain 0.5 mg of Mometasone Furoate and disperse in 4 mL of *methanol (80%)*. Shake vigorously, filter and use the filtrate.
(2) 0.0125% w/v of *mometasone furoate BPCRS* in methanol (80%).
(3) Equal volumes of solution (1) and solution (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*.

SYSTEM SUITABILITY

The test is not valid unless the chromatogram obtained with solution (3) exhibits a single compact spot the same size and shape as that obtained with solution (2).

CONFIRMATION

The principal spot in the chromatogram obtained with solution (1) is similar in position and size to that in the chromatogram obtained with solution (2).

B. In the Assay, the principal peak in the chromatogram obtained with solution (1) corresponds to 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 A, 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) Discharge the container a sufficient number of times to obtain 1 mg of Mometasone Furoate, add 3 mL of *acetonitrile* and 2 mL of solution A. Mix with the aid of ultrasound, add sufficient solution A to produce 10 mL and centrifuge.
(2) Dilute 1 volume of solution (1) to 200 volumes with 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 1 volume of solution (2) to 5 volumes with solution A.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column 25 cm × 4.6 mm packed with *end-capped octydecylsilyl 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 column 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 24 minutes) are: impurity C, about 0.9; 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 any *secondary peaks* is not greater than four times the area of the principal peak in the chromatogram obtained with solution (2) (2%).

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*.
Solution B 6 volumes of *acetonitrile* and 94 volumes of solution A.

(1) Discharge the container a sufficient number of times to obtain 1 mg of Mometasone Furoate and disperse in 0.6 mL of *acetonitrile*. Mix with the aid of ultrasound, add sufficient solution A to produce 10 mL and centrifuge.
(2) Dissolve 25 mg of *mometasone furoate BPCRS* in 1.5 mL of *acetonitrile* and dilute to 25 mL with solution A. Dilute 1 volume of this solution to 10 volumes with solution B.
(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 Nasal spray 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 those listed under Mometasone Furoate.