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

Dexamethasone Sodium Phosphate Eye Drops, Solution

General Notices

Action and use

Glucocorticoid.

DEFINITION

Dexamethasone Sodium Phosphate Eye Drops, Solution are a sterile Solution of Dexamethasone Sodium Phosphate in a suitable vehicle.

The eye drops comply with the requirements stated under Eye Preparations and with the following requirements.

Content of dexamethasone sodium phosphate, $C_{22}H_{28}FNa_2O_8P$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

Mix a quantity of the eye drops containing 20 mg of Dexamethasone Sodium Phosphate with 5 mL of 0.1M *sodium hydroxide*, add 50 mL of *dichloromethane* and mix with the aid of ultrasound for 20 minutes, filter the dichloromethane layer and evaporate to dryness using a rotary evaporator. Dry the residue at 105° for 2 hours. The *infrared absorption* spectrum of the dried residue, Appendix II A, is concordant with the *reference spectrum* of dexamethasone *(RS 089)*.

TESTS

Alkalinity

pH, 7.0 to 7.5, Appendix V L.

Related substances

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

(1) Disperse a quantity of the eye drops containing 20 mg of Dexamethasone Sodium Phosphate in 70 mL, mix with the aid of ultrasound for 10 minutes, dilute to 100 mL and filter.
(2) Dilute 3 volumes of solution (1) to 100 volumes.
(3) 0.02% w/v of *dexamethasone impurity standard BPCRS*.
(4) Dilute 1 volume of solution (1) to 100 volumes and dilute 1 volume of this solution to 10 volumes

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (15 cm × 3.9 mm) packed with *octadecylsilyl silica gel for chromatography R* (5 µm) (Waters Symmetry C18 is suitable).
(b) Use isocratic elution and the mobile phase described below.

(c) Use a flow rate of 1.5 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 254 nm.
(f) Inject 50 µL of each solution.
(g) For solution (1), allow the chromatography to proceed for six times the retention time of dexamethasone sodium phosphate.

MOBILE PHASE

27 volumes of *acetonitrile* and 73 volumes of a 0.3% w/v solution of *orthophosphoric acid* that has been previously adjusted to pH 3.0 with 2M *sodium hydroxide*.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3):

the *resolution factor* between the peaks due to impurity 3 and dexamethasone is at least 1.5;

the chromatogram closely resembles the chromatogram supplied with *dexamethasone impurity standard BPCRS*.

LIMITS

In the chromatogram obtained with solution (1):

the sum of the areas of any *secondary peaks* is not greater than the area of the peak in the chromatogram obtained with solution (2) (3%).

Disregard any peak with an area less than the area of the 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 in the mobile phase.

(1) Disperse a quantity of the eye drops containing 20 mg of Dexamethasone Sodium Phosphate in 70 mL, mix with the aid of ultrasound for 10 minutes, dilute to 100 mL and filter.
(2) 0.015% w/v of *dexamethasone BPCRS*.
(3) 0.02% w/v of *dexamethasone impurity standard BPCRS*.

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 factor* between the peaks due to impurity 3 and dexamethasone is at least 1.5;

the chromatogram closely resembles the chromatogram supplied with *dexamethasone impurity standard BPCRS*.

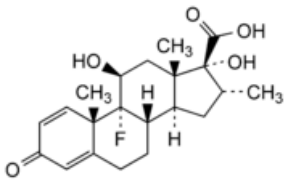
DETERMINATION OF CONTENT

Calculate the content of $C_{22}H_{28}FNa_2O_8P$ in the eye drops using the declared content of $C_{22}H_{29}FO_5$ in *dexamethasone BPCRS*. Each mg of $C_{22}H_{29}FO_5$ is equivalent to 1.3157 mg of $C_{22}H_{28}FNa_2O_8P$.

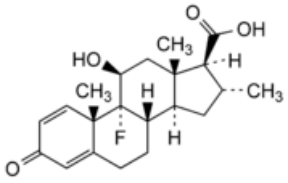
STORAGE

Dexamethasone Sodium Phosphate Eye Drops should be stored in accordance with the manufacturer’s instructions.

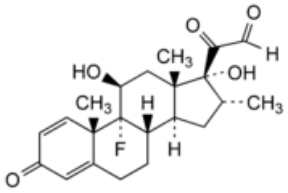
IMPURITIES



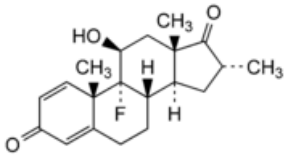
1. dexamethasone-17β-carboxylic acid,



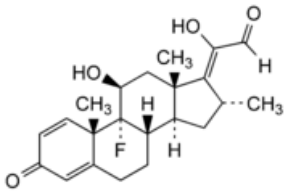
2. dexamethasone-17α-dehydroxy-17β-carboxylic acid,



3. dexamethasone-21-aldehyde,



4. dexamethasone-17-ketone,



5. dexamethasone-17(20)-enol-21-aldehyde.