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

Dexamethasone Sodium Phosphate Oral Solution

General Notices

Action and use

Glucocorticoid

DEFINITION

Dexamethasone Sodium Phosphate Oral Solution contains Dexamethasone Sodium Phosphate in a suitable vehicle.

The oral solution complies with the requirements stated under Oral Liquids 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.

Carry out all of the following procedures protected from light.

IDENTIFICATION

A. Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.
(1) To a quantity of the oral solution containing 25 mg of Dexamethasone Sodium Phosphate add sufficient *methanol* to produce 100 mL, centrifuge and use the supernatant liquid.
(2) 0.025% w/v of *dexamethasone sodium phosphate BPCRS* in *methanol*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel F_{254}*.
(b) Use the mobile phase as described below.
(c) Apply 5 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

20 volumes of *glacial acetic acid*, 20 volumes of *water* and 60 volumes of *butanol*.

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).

B. In the Assay, the principal peak in the chromatogram obtained with solution (1) has the same retention time as the peak in the chromatogram obtained with solution (2).

TESTS

Related substances

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions in *methanol (40%)*.

(1) To a quantity of the oral solution containing 10 mg of Dexamethasone Sodium Phosphate add sufficient *methanol (40%)* to produce 100 mL and filter.
(2) 0.0001% w/v of *dexamethasone sodium phosphate BPCRS*.
(3) 0.0001% w/v of *betamethasone sodium phosphate BPCRS*.
(4) 0.0025% w/v of each of *dexamethasone BPCRS* and *betamethasone BPCRS*.
(5) Dilute 5 volumes of solution (2) to 100 volumes.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (10 cm × 2.0 mm) packed with *octylsilyl silica gel for chromatography* (3 µm) (Luna C8 is suitable).
(b) Use gradient elution and the mobile phase described below.
(c) Use a flow rate of 0.25 mL per minute.
(d) Use a column temperature of 30°.
(e) Use a detection wavelength of 240 nm.
(f) Inject 25 µL of each solution.

MOBILE PHASE

Mobile phase A 39 volumes of *methanol* and 61 volumes of a 0.68% w/v solution of *potassium dihydrogen orthophosphate*; adjust the pH to 3.5 with *dilute orthophosphoric acid* or *dilute sodium hydroxide*.

Mobile phase B 41 volumes of *methanol* and 59 volumes of a 0.68% w/v solution of *potassium dihydrogen orthophosphate*; adjust the pH to 3.5 with *dilute orthophosphoric acid* or *dilute sodium hydroxide*.

Time (min)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
0	100	0	isocratic
30→40	100→0	0→100	linear gradient
40→75	0	100	isocratic
75→80	0→100	100→0	linear gradient
80→90	100	0	re-equilibration

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (4), the *resolution factor* between the peaks due to dexamethasone and betamethasone is at least 1.5.

LIMITS

In the chromatogram obtained with solution (1):

the area of any peak due to betamethasone sodium phosphate is not greater than half the area of the principal peak in the chromatogram obtained with solution (3) (0.5%);

the area of any *secondary peak* is not greater than 0.2 times the area of the principal peak in the chromatogram obtained with solution (2) (0.2%);

the sum of the impurities is not greater than 1.0%.

Disregard any peak due to dexamethasone and any peak with an area less than the area of the principal peak in the chromatogram obtained with solution (5) (0.05%).

Free dexamethasone

In the Assay, the area of any peak due to dexamethasone in the chromatogram obtained with solution (1) is not greater than the area of the corresponding peak in the chromatogram obtained with solution (2) (34%).

ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions in *methanol (45%)*.

(1) To a quantity of the oral solution containing the equivalent of 8 mg of Dexamethasone Sodium Phosphate add sufficient *methanol (45%)* to produce 100 mL and filter through a 0.45-µm nylon filter.
(2) 0.008% w/v of *dexamethasone sodium phosphate BPCRS* and 0.0027% w/v of *dexamethasone BPCRS*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (15 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm) (Nucleosil C18 is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1.0 mL per minute.
(d) Use a column temperature of 30°.
(e) Use a detection wavelength of 240 nm.
(f) Inject 10 µL of each solution.

MOBILE PHASE

44 volumes of *methanol* and 56 volumes of a 0.68% w/v solution of *potassium dihydrogen orthophosphate*, adjust the pH to 3.5 with *dilute orthophosphoric acid* or *dilute sodium hydroxide*.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (2), the *resolution factor* between the peaks due to dexamethasone sodium phosphate and dexamethasone is at least 10.0.

DETERMINATION OF CONTENT

Calculate the content of $C_{22}H_{28}FNa_2O_8P$ using the declared content of $C_{22}H_{28}FNa_2O_8P$ in *dexamethasone sodium phosphate BPCRS* and 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 1.3158 mg of $C_{22}H_{28}FNa_2O_8P$.

Calculate the total content of $C_{22}H_{28}FNa_2O_8P$ in the oral solution from the equivalent amount of dexamethasone sodium phosphate due to Free dexamethasone and combining this with the content of dexamethasone sodium phosphate.