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

Betamethasone Sodium Phosphate Tablets

General Notices

Action and use

Glucocorticoid.

DEFINITION

Betamethasone Sodium Phosphate Tablets contain Betamethasone Sodium Phosphate.

The tablets comply with the requirements stated under Tablets 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. Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.
(1) Dissolve a quantity of the powdered tablets containing the equivalent of 2 mg of betamethasone in 25 mL of *water*, add 2.5 g of *sodium chloride* and 1 mL of *hydrochloric acid*, extract with 25 mL of *chloroform* and discard the chloroform layer. Extract with 25 mL of *tributyl orthophosphate* and discard the aqueous layer.
(2) Prepare in the same manner as solution (1) but using 2.5 mg of *betamethasone sodium phosphate BPCRS* in place of the powdered tablets.
(3) Mix equal volumes of solutions (1) and (2).
(4) Mix equal volumes of solution (1) and a solution prepared in the same manner as solution (1) but using 2.5 mg of *prednisolone sodium phosphate BPCRS* in place of the powdered tablets.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel G*.
(b) Use the mobile phase as described below prepared immediately before use.
(c) Apply 5 µL of each solution.
(d) Develop the plate to 15 cm.
(e) After removal of the plate, dry in air, heat at 110° for 10 minutes, spray the hot plate with *ethanolic sulfuric acid (20%)* and again heat at 110° for 10 minutes.

MOBILE PHASE

20 volumes of *acetic anhydride*, 20 volumes of *water* and 60 volumes of *butan-1-ol* prepared immediately before use.

SYSTEM SUITABILITY

The test is not valid unless the chromatogram obtained with solution (4) shows two principal spots with almost identical Rf values.

CONFIRMATION

The chromatograms obtained with solutions (1), (2) and (3) show single spots with identical Rf values.

B. Mix a quantity of the powdered tablets containing the equivalent of 0.4 mg of betamethasone with 1 mL of *sulfuric acid* and allow to stand for 5 minutes. A pale yellow colour is produced (distinction from prednisolone sodium phosphate tablets).

TESTS

Disintegration

Maximum time, 5 minutes, Appendix XII A1.

Uniformity of content

Tablets containing less than the equivalent of 2 mg and/or less than 2% w/w of betamethasone comply with the requirements stated under Tablets using the following method of analysis. Carry out the procedure protected from light. Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Dissolve one tablet as completely as possible in 5 mL of *water*, add 5 mL of *methanol* and filter.Add sufficient *methanol (50%)* to produce a solution expected to contain 0.00325% w/v of betamethasone sodium phosphate.
(2) 0.0065% w/v of *betamethasone sodium phosphate BPCRS* in *water*. Dilute 1 volume of this solution to 2 volumes with *methanol*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (20 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (10 µm) (Spherisorb ODS 1 is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 2 mL per minute.
(d) Use a column temperature of 60°.
(e) Use a detection wavelength of 241 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

45 volumes of *methanol* and 55 volumes of *citro-phosphate buffer pH 5.0*.

DETERMINATION OF CONTENT

Calculate the content of $C_{22}H_{29}FO_5$ in each tablet, determining the exact strength of the solution of *betamethasone sodium phosphate BPCRS* as described in the Assay.

ASSAY

Weigh and powder 20 tablets. Carry out the procedure protected from light. Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Shake a quantity of the powdered tablets containing 2.5 mg of betamethasone for 20 minutes with 25 mL of *water*, dilute to 50 mL with *methanol*, mix and filter through a glass fibre filter (Whatman GF/C is suitable).
(2) Dilute 5 mL of a 0.014% w/v solution of *betamethasone sodium phosphate BPCRS* in *water* (solution A) to 10 mL with *methanol*.

CHROMATOGRAPHIC CONDITIONS

The chromatographic procedure described under Uniformity of content may be used.

DETERMINATION OF CONTENT

Calculate the content of $C_{22}H_{29}FO_5$ in the tablets, determining the exact strength of $C_{22}H_{29}FO_5$ in solution (2) as follows. Dilute 5 mL of solution A to 25 mL with *water* and measure the *absorbance*, Appendix II B, of the resulting solution at the

maximum at 241 nm, taking 391 as the value of A(1%, 1 cm) for betamethasone.

STORAGE

Betamethasone Sodium Phosphate Tablets should be protected from light.

LABELLING

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