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

Prednisolone Soluble Tablets

General Notices

Soluble Prednisolone Tablets

Action and use

Glucocorticoid.

DEFINITION

Prednisolone Soluble Tablets contain Prednisolone Sodium Phosphate.

The tablets comply with the requirements stated under Tablets and with the following requirements.

Content of prednisolone, $C_{21}H_{28}O_5$

90.0 to 105.0% of the stated amount.

IDENTIFICATION

A. Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.
(1) Add a quantity of powdered tablets containing the equivalent of 7.5 mg of prednisolone to 10 mL of *water*, leave to stand for 30 minutes, swirl and filter.
(2) 0.1% w/v of *prednisolone sodium phosphate BPCRS*.
(3) Equal volumes of solutions (1) and (2).
(4) Equal volumes of solution (2) and a 0.1% w/v solution of *betamethasone sodium phosphate BPCRS*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel F_{254}*.
(b) Use the mobile phase as described below.
(c) Apply 10 µL of each solution.
(d) Develop the plate to 15 cm.
(e) After removal of the plate, allow it to dry in air, heat at 105° for 10 minutes and examine under *ultraviolet light (254 nm)*.

MOBILE PHASE

33 volumes of *water*, 47 volumes of *glacial acetic acid* and 120 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 principal spots with similar Rf values.

B. In the Assay, the chromatogram obtained with solution (1) shows a peak with the same retention time as the peak due to prednisolone sodium phosphate in the chromatogram obtained with solution (2).

TESTS

Dissolution

Comply with the requirements in the dissolution test for tablets and capsules, Appendix XII B1.

TEST CONDITIONS

(a) Use Apparatus 2, rotating the paddle at 50 revolutions per minute.
(b) Use 900 mL of *water*, at a temperature of 37°, as the medium.

PROCEDURE

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

(1) After 15 minutes withdraw a sample of the medium and filter. Use the filtered medium, diluted with *water* if necessary, to produce a solution expected to contain the equivalent of 0.00055% w/v of prednisolone.
(2) 0.00074% w/v of *prednisolone sodium phosphate BPCRS* in *water*.
(3) 0.0006% w/v each of *prednisolone sodium phosphate BPCRS* and *prednisolone BPCRS* in the mobile phase.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (15 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm) (Luna 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 247 nm.
(f) Inject 100 µL of each solution.

MOBILE PHASE

26 volumes of *acetonitrile* and 74 volumes of *water* containing 0.544% w/v of *potassium dihydrogen orthophosphate* and 0.240% w/v of *hexylamine*. When the chromatograms are recorded under the prescribed conditions, the relative retention with reference to prednisolone sodium phosphate (retention time about 6.5 minutes) of prednisolone is about 1.3.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the peaks due to prednisolone sodium phosphate and prednisolone is at least 4.5.

DETERMINATION OF CONTENT

Calculate the content of $C_{21}H_{28}O_5$ (prednisolone) in the medium using the calculated content of $C_{21}H_{27}Na_2O_8P$ in *prednisolone sodium phosphate BPCRS*. Each mg of $C_{21}H_{27}Na_2O_8P$ is equivalent to 0.7440 mg of $C_{21}H_{28}O_5$.

LIMITS

The amount of prednisolone released is not less than 75% (Q) of the stated amount.

Free prednisolone

In the test for Related substances, the area of any peak due to prednisolone in the chromatogram obtained with solution (1) is not greater than the area of the principal peak in the chromatogram obtained with solution (5) (4%).

Related substances

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

(1) Add a quantity of powdered tablets containing the equivalent of 20 mg of prednisolone to 8 mL of the mobile phase, leave to stand for 30 minutes and swirl. Add sufficient mobile phase to produce 10 mL and filter.
(2) Dilute 1 volume of solution (1) to 50 volumes with the mobile phase.
(3) 0.004% w/v each of *prednisolone sodium phosphate BPCRS* and *prednisolone BPCRS* in the mobile phase.
(4) Dilute 1 volume of solution (2) to 20 volumes with the mobile phase.
(5) Dilute 1 volume of solution (1) to 25 volumes with the mobile phase.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Dissolution may be used with an injection volume of 20 µL. Allow the chromatography to proceed for 3 times the retention time of prednisolone sodium phosphate.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the peaks due to prednisolone sodium phosphate and prednisolone is at least 4.5.

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) (2%);

the area of not more than one *secondary peak* is greater than half the area of the principal peak in the chromatogram obtained with solution (2) (1%);

the sum of the areas of all the *secondary peaks* is not greater than 1.5 times the area of the principal peak in the chromatogram obtained with solution (2) (3%).

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

ASSAY

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

(1) Add a quantity of powdered tablets containing the equivalent of 5 mg of prednisolone to 5 mL of *water*, leave to stand for 30 minutes and swirl. Add sufficient *water* to produce 20 mL and filter.
(2) 0.034% w/v of *prednisolone sodium phosphate BPCRS*.
(3) 0.025% w/v each of *prednisolone sodium phosphate BPCRS* *and* *prednisolone BPCRS*.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Dissolution may be used with an injection volume of 20 µL.

SYSTEM SUITABILITY

The assay is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the peaks due to prednisolone sodium phosphate and prednisolone is at least 4.5.

DETERMINATION OF CONTENT

Calculate the content of $C_{21}H_{28}O_5$ (prednisolone) in the tablets using the calculated content of $C_{21}H_{27}Na_2O_8P$ in *prednisolone sodium phosphate BPCRS*. Each mg of $C_{21}H_{27}Na_2O_8P$ is equivalent to 0.7440 mg of $C_{21}H_{28}O_5$.

STORAGE

Prednisolone Soluble Tablets should be protected from light.

LABELLING

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