



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

Betamethasone Tablets

[General Notices](#)

Action and use

Glucocorticoid.

DEFINITION

Betamethasone Tablets contain Betamethasone.

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. Shake a quantity of the powdered tablets containing 25 mg of Betamethasone with 150 mL of [dichloromethane](#) for 30 minutes, filter, wash the filtrate with 20 mL of [water](#), dry over [anhydrous sodium sulfate](#), evaporate the solution to dryness and dry the residue at 105° for 2 hours. The [infrared absorption spectrum](#) of the residue, [Appendix II A](#), is concordant with the *reference spectrum* of betamethasone ([RS 029](#)).
- B. The residue obtained in test A complies with the test for the [identification of steroids](#), [Appendix III A](#), using [impregnating solvent I](#) and *mobile phase A*. At a fourth point apply to the plate 2 µL of a mixture of equal volumes of solution (1) and a 0.25% w/v solution of [dexamethasone BPCRS](#) in a mixture of 9 volumes of [chloroform](#) and 1 volume of [methanol](#). The chromatogram obtained with this solution shows two principal spots with almost identical R_f values.
- C. In the Assay, the chromatogram obtained with solution (1) shows a peak with the same retention time as the peak due to betamethasone in the chromatogram obtained with solution (2).

TESTS

[Uniformity of content](#)

Tablets containing less than 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 method for [liquid chromatography](#), [Appendix III D](#), using the following solutions.

- (1) Finely crush one tablet, add 20 mL of a 0.002% w/v solution of [hydrocortisone](#) in [methanol](#) (50%), shake for 10 minutes and filter through a glass-fibre filter paper (Whatman GF/C is suitable).
- (2) 0.0025% w/v of [betamethasone BPCRS](#) and 0.002% w/v of [hydrocortisone](#) (internal standard) in [methanol](#) (50%).

CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (25 cm × 5 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 1.4 mL per minute.
- (d) Use an ambient column temperature.
- (e) Use a detection wavelength of 238 nm.
- (f) Inject 20 µL of each solution.

MOBILE PHASE

47 volumes of [methanol](#) and 53 volumes of [water](#).

DETERMINATION OF CONTENT

Calculate the content of $C_{22}H_{29}FO_5$ in each tablet using the ratios of the peak areas and the declared content of $C_{22}H_{29}FO_5$ in [betamethasone BPCRS](#).

ASSAY

For tablets containing less than 2 mg and/or less than 2% w/w of [Betamethasone](#)

Use the average of the individual results determined in the test for Uniformity of content.

For Tablets containing 2 mg or more and 2% w/w or more of [Betamethasone](#)

Weigh and powder 20 tablets. Carry out the method for [liquid chromatography](#), [Appendix III D](#), using the following solutions.

- (1) To a quantity of the powder containing 2.5 mg of Betamethasone add 20 mL of [methanol](#) (50%), shake for 10 minutes and filter through a glass-fibre filter paper (Whatman GF/C is suitable).
- (2) 0.0125% w/v of [betamethasone BPCRS](#) and 0.010% w/v of [hydrocortisone](#) (internal standard) in [methanol](#) (50%).
- (3) Prepare the solution in the same manner as solution (1) but use 20 mL of a 0.01% w/v solution of [hydrocortisone](#) in [methanol](#) (50%) in place of the 20 mL of [methanol](#) (50%).

CHROMATOGRAPHIC CONDITIONS

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

DETERMINATION OF CONTENT

Calculate the content of $C_{22}H_{29}FO_5$ in the tablets using the ratios of the peak areas and the declared content of $C_{22}H_{29}FO_5$ in [betamethasone BPCRS](#).

STORAGE

Betamethasone Tablets should be protected from light.