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

Dexamethasone Tablets

General Notices

Action and use

Glucocorticoid.

DEFINITION

Dexamethasone Tablets contain Dexamethasone.

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

Content of dexamethasone, $C_{22}H_{29}FO_5$

95.0 to 105.0% of the stated amount.

Carry out all of the following procedures protected from light.

IDENTIFICATION

Mix a quantity of the powdered tablets containing 20 mg of Dexamethasone with 5 mL of 0.1M *sodium hydroxide*, add 50 mL of *dichloromethane* and mix with the aid of ultrasound for 20 minutes, filter 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

Related substances

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

(1) To a quantity of the powdered tablets containing 2.5 mg of Dexamethasone add 10 mL of *acetonitrile*, mix with the aid of ultrasound and filter through a 0.45-µm filter. Dilute 4 mL of the filtrate to 10 mL with *water*.
(2) Dilute 1 volume of solution (1) to 100 volume with mobile phase A.
(3) 0.002% w/v each of *dexamethasone BPCRS* and *methylprednisolone BPCRS* in mobile phase A.
(4) Dilute 1 volume of solution (2) to 20 volumes with mobile phase A.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm) (Hypersil ODS is suitable).
(b) Use gradient elution and the mobile phases described below.
(c) Use a flow rate of 2.5 mL per minute.
(d) Use a column temperature of 45°.
(e) Use a detection wavelength of 254 nm.
(f) Inject 20 µL of each solution.

(g) The retention times are: methylprednisolone about 13 min and dexamethasone about 16 min.

MOBILE PHASE

Mobile phase A 15% v/v *acetonitrile*.

Mobile phase B *acetonitrile*.

Time (min)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comments
0	100	0	isocratic
15	100 → 0	0 → 100	begin linear gradient
40	0	100	end chromatogram, return to 100 A
41	100	0	begin equilibration with A
46 = 0	100	0	end equilibration, begin next chromatogram

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution factor* between methylprednisolone and dexamethasone is at least 2.8.

LIMITS

In the chromatogram obtained with solution (1):

the area of any *secondary peak* is not greater than 0.5 times the area of the principal peak in the chromatogram obtained with solution (2) (0.5%);

the sum of the areas of all the *secondary peaks* is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (1.0%).

Disregard any peak due to mobile phase A and any peak with an area less than the area of the principal peak in the chromatogram obtained with reference solution (4) (0.05%).

Uniformity of content

Tablets containing less than 2 mg and or less than 2% w/w of Dexamethasone 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) To one tablet, add sufficient *methanol (50%)* to produce a solution containing 0.0025% w/v of Dexamethasone, shake for 10 minutes and filter through glass-fibre filter (Whatman GF/C is suitable).
(2) 0.0025% w/v of *dexamethasone BPCRS* in *methanol (50%)*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (20 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (5 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 declared content of $C_{22}H_{29}FO_5$ in *dexamethasone BPCRS*.

ASSAY

For tablets containing less than 2 mg and/or less than 2% w/w of Dexamethasone

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 of Dexamethasone

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 powdered tablets containing 2.5 mg of Dexamethasone add 20 mL of *methanol (50%)*, shake for 20 minutes and filter through glass-fibre filter (Whatman GF/C is suitable).
(2) 0.0125% w/v of *dexamethasone BPCRS* in *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 declared content of $C_{22}H_{29}FO_5$ in *dexamethasone BPCRS*.

STORAGE

Dexamethasone Tablets should be protected from light.