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

Desogestrel Tablets

General Notices

Action and use

Progestogen.

DEFINITION

Desogestrel Tablets contain Desogestrel.

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

Content of desogestrel, $C_{22}H_{30}O$

90.0 to 105.0% of the stated amount.

IDENTIFICATION

A. In the Assay, the principal peak in the chromatogram obtained with solution (1) has the same retention time as the principal peak in the chromatogram obtained with solution (2).
B. Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions in *dichloromethane*.
(1) Disperse a quantity of powdered tablets containing 0.75 mg of Desogestrel in 8 mL of *dichloromethane*, mix with the aid of ultrasound and dilute to 10 mL with *dichloromethane* and filter.
(2) 0.0075% w/v of *desogestrel BPCRS*.
(3) 0.0075% w/v each of *desogestrel BPCRS* and *lynestrenol BPCRS*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a silica gel 60 precoated plate for high performance thin-layer chromatography (Merck silica gel 60 HPTLC plates are suitable).
(b) Use the mobile phase described below.
(c) Apply 2 µL of each solution.
(d) After removal of the plate, dry in air, spray it with *ethanolic sulfuric acid (2%)*, heat at 110° for 10 minutes and examine under *ultraviolet light (365 nm)*.

MOBILE PHASE

A mixture of 20 volumes of *ethyl acetate* and 80 volumes of *toluene*.

SYSTEM SUITABILITY

The test is not valid unless the chromatogram obtained with solution (3) shows two clearly separated spots.

CONFIRMATION

The principal spot in the chromatogram obtained with solution (1) is similar in colour, position and size to the principal spot in the chromatogram obtained with solution (2).

TESTS

Dissolution

Comply with the requirements for Monographs of the British Pharmacopoeia 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 500 mL of a 0.3% w/v solution of *sodium lauryl sulfate*, 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 45 minutes withdraw a sample of the medium and filter. Use the filtered medium, diluted with a 0.3% w/v solution of *sodium lauryl sulfate* if necessary, expected to contain 0.000015% w/v of Desogestrel.
(2) 0.000015% w/v of *desogestrel BPCRS* in a mixture of 1 volume of *propan-2-ol* and 99 volumes of a 0.3% w/v solution of *sodium lauryl sulfate*.

CHROMATOGRAPHIC CONDITIONS

(a) A stainless steel column (15 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography R* (5 µm) (Zorbax ODS is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1.5 mL per minute.
(d) Use a column temperature of 40°.
(e) Use a detection wavelength of 205 nm.
(f) Inject 200 µL of each solution.

MOBILE PHASE

5 volumes of *water* and 95 volumes of *acetonitrile*.

DETERMINATION OF CONTENT

Calculate the content of $C_{22}H_{30}O$ in the medium from the chromatograms obtained and using the declared content of $C_{22}H_{30}O$ in *desogestrel BPCRS*.

LIMITS

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

Related substances

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions in 20 volumes of *water* and 80 volumes of *acetonitrile* (Solution A).

(1) Disperse a quantity of powdered tablets containing 0.75 mg of Desogestrel in 15 mL of solution A, mix with the aid of ultrasound and dilute with sufficient solution A to produce 20 mL, mix and filter.
(2) Dilute 1 volume of solution (1) to 100 volumes with solution A and further dilute 2 mL of this solution to 10 mL with solution A.
(3) 0.00375% w/v of *desogestrel BPCRS*, 0.000075% w/v of *desogestrel impurity D BPCRS* and 0.0000375% w/v of *desogestrel impurity E BPCRS*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (15 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography R* (5 µm) (Zorbax ODS is suitable).

(b) Use a gradient elution and the mobile phase described below.
(c) Use a flow rate of 2 mL per minute.
(d) Use a column temperature of 40°.
(e) Use detection wavelengths of 230 nm and 210 nm.
(f) Inject 25 µL of each solution.

MOBILE PHASE

Mobile phase A *acetonitrile*.

Mobile phase B 50 volumes of *acetonitrile* and 50 volumes of *water*.

Time (Minutes)	Mobile phase A%	Mobile phase B%	Comment
0-4.5	0	100	isocratic
4.5-4.6	0→100	100→0	linear gradient
4.6-10.7	100	0	isocratic
10.7-10.8	100→0	0→100	linear gradient
10.8-14	0	100	re-equilibration

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), at 210 nm the *resolution* between the peaks due to desogestrel impurity E and desogestrel impurity D is at least 1.5 and the retention time of desogestrel impurity D is not greater than 6 minutes.

LIMITS

In the chromatogram obtained with solution (1) at 210 nm:

the area of any peak due to desogestrel impurity E is not greater than the area of the corresponding peak in the chromatogram obtained with solution (3) (1%);

the area of any other peak other than the principal peak is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (0.2%).

In the chromatogram obtained with solution (1) at 230 nm:

the area of any peak due to desogestrel impurity D is not greater than the area of the corresponding peak in the chromatogram obtained with solution (3) (2%).

Uniformity of content

Tablets containing less than 2 mg and/or less than 2% w/w of Desogestrel 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 in 20 volumes of *water* and 80 volumes of *acetonitrile* (Solution A).

(1) To one tablet add 5 mL of solution A, mix with the aid of ultrasound and add sufficient solution A to produce a solution expected to contain 0.00075% w/v of Desogestrel.
(2) 0.00075% w/v of *desogestrel BPCRS*.
(3) 0.00075% w/v of *desogestrel BPCRS*, 0.000015% w/v of *desogestrel impurity D BPCRS* and 0.0000075% w/v of *desogestrel impurity E BPCRS*.

CHROMATOGRAPHIC CONDITIONS

The chromatographic procedure described under Related substances may be used with the following amendments:

(a) Use a detection wavelength of 210 nm.
(b) Inject 125 µL of each solution.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the peaks due to desogestrel impurity D and desogestrel is at least 1.5 and the retention time of desogestrel impurity D is not greater than 6 minutes.

DETERMINATION OF CONTENT

Calculate the content of $C_{22}H_{30}O$ in the tablets using the declared content of $C_{22}H_{30}O$ in *desogestrel BPCRS*.

ASSAY

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

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 Desogestrel

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions in 20 volumes of *water* and 80 volumes of *acetonitrile* (Solution A).

(1) To a quantity of powdered tablets containing 0.75 mg of Desogestrel add 10 mL of solution A, mix with the aid of ultrasound and add sufficient solution A to produce 20 mL.
(2) 0.00375% w/v of *desogestrel BPCRS*.
(3) 0.00375% w/v of *desogestrel BPCRS*, 0.000075% w/v of *desogestrel impurity D BPCRS* and 0.0000375% w/v of *desogestrel impurity E BPCRS*.

CHROMATOGRAPHIC CONDITIONS

The chromatographic procedure described under Related substances may be used with a detection wavelength of 210 nm.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the peaks due to desogestrel impurity D and desogestrel is at least 1.5 and the retention time of desogestrel impurity D is not greater than 6 minutes.

DETERMINATION OF CONTENT

Calculate the content of $C_{22}H_{30}O$ in the tablets using the declared content of $C_{22}H_{30}O$ in *desogestrel BPCRS*.

IMPURITIES

The impurities limited by the requirements of this monograph include impurities D and E listed under Desogestrel.