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

Norethisterone Tablets

General Notices

Action and use

Progestogen.

DEFINITION

Norethisterone Tablets contain Norethisterone.

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

Content of norethisterone, $C_{20}H_{26}O_2$

90.0 to 110.0% of the stated amount.

IDENTIFICATION

Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.

(1) Crush one tablet in sufficient *ethanol* (*96%*) to produce a final solution containing approximately 0.035% w/v of Norethisterone, warm to 50° for 10 minutes, mix with the aid of ultrasound, allow to cool and centrifuge to obtain a clear supernatant liquid.
(2) 0.035% w/v of *norethisterone BPCRS* in *ethanol* (*96%*).

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel* (Merck silica gel 60 plates are suitable).
(b) Use the mobile phase as described below.
(c) Apply 20 µL of each solution.
(d) Develop the plate to 10 cm.
(e) After removal of the plate, dry in air, spray with a mixture of 30 volumes of *methanol* and 70 volumes of *sulfuric acid* and examine under *ultraviolet light* (*365 nm*).

MOBILE PHASE

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

CONFIRMATION

The principal spot in the chromatogram obtained with solution (1) corresponds in position and colour to that 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 Norethisterone 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) Disperse one tablet in 2 mL of *water* with the aid of ultrasound for 15 minutes, add sufficient *methanol* to produce 5 mL, centrifuge for 10 minutes and use the clear supernatant liquid.
(2) 0.007% w/v of *norethisterone BPCRS* in *methanol* (*60%*).

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 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 1 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 254 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

28 volumes of *water* and 72 volumes of *methanol*.

DETERMINATION OF CONTENT

Calculate the content of $C_{20}H_{26}O_2$ in each tablet using the declared content of $C_{20}H_{26}O_2$ in *norethisterone BPCRS*.

ASSAY

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

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 Norethisterone

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

(1) Mix a quantity of the powdered tablets containing 5 mg of Norethisterone in 10 mL of *water* with the aid of ultrasound for 15 minutes, add sufficient *methanol* to produce 25 mL, centrifuge for 10 minutes and use the supernatant liquid.
(2) 0.02% w/v of *norethisterone BPCRS* in *methanol* (60%).

CHROMATOGRAPHIC CONDITIONS

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

DETERMINATION OF CONTENT

Calculate the content of $C_{20}H_{26}O_2$ in the tablets using the declared content of $C_{20}H_{26}O_2$ in *norethisterone BPCRS*.

STORAGE

Norethisterone Tablets should be protected from light.