



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

Megestrol Tablets

[General Notices](#)

Action and use

Progestogen.

DEFINITION

Megestrol Tablets contain Megestrol Acetate.

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

Content of megestrol acetate, $C_{24}H_{32}O_4$

92.5 to 107.5% of the stated amount.

IDENTIFICATION

Shake a quantity of the powdered tablets containing 40 mg of Megestrol Acetate with 250 mL of [chloroform](#) for 30 minutes, filter into a separating funnel, wash the filtrate with 20 mL of [water](#) and evaporate the chloroform. The residue, after drying at 60° at a pressure not exceeding 0.7 kPa for 2 hours, complies with the following tests.

- A. The [infrared absorption spectrum](#), [Appendix II A](#), is concordant with the *reference spectrum* of megestrol acetate ([RS 211](#)).
- B. Complies with the test for [identification of steroids](#), [Appendix III A](#), using [impregnating solvent II](#) and *mobile phase D*.

TESTS

[Disintegration](#)

Maximum time, 30 minutes, [Appendix XII A1](#).

Related foreign steroids

Carry out the method for [thin-layer chromatography](#), [Appendix III A](#), using the following solutions.

- (1) Shake a quantity of the powdered tablets containing 100 mg of Megestrol Acetate with 10 mL of a mixture of 1 volume of [methanol](#) and 9 volumes of [chloroform](#) for 10 minutes, centrifuge and use the clear supernatant liquid.
- (2) 0.005% w/v of [megestrol BPCRS](#) in a mixture of 1 volume of [methanol](#) and 9 volumes of [chloroform](#).

CHROMATOGRAPHIC CONDITIONS

- (a) Use a silica gel precoated plate (Merck silica gel 60 plates are suitable).
- (b) Use the mobile phase as described below.
- (c) Apply 5 µL of each solution.

(d) Develop the plate to 15 cm.

(e) After removal of the plate, dry in air, spray with spray with [ethanolic sulfuric acid](#) (20%), heat at 110° for 10 minutes and examine under [ultraviolet light \(365 nm\)](#).

MOBILE PHASE

0.5 volume of [water](#), 8 volumes of [methanol](#) and 92 volumes of [1,2-dichloroethane](#).

LIMITS

Any [secondary spot](#) in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (2) (0.5%).

ASSAY

Prepare a 0.016% w/v solution of [propyl 4-hydroxybenzoate](#) (internal standard) in [acetonitrile](#) (solution A).

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

(1) Shake a quantity of the powdered tablets containing 80 mg of Megestrol Acetate with 10 mL of [water](#) for 10 minutes, add 75 mL of [acetonitrile](#), shake for 30 minutes, dilute to 100 mL with [acetonitrile](#), centrifuge and dilute 10 mL of the clear supernatant liquid to 50 mL with a 40% v/v solution of [acetonitrile](#); to 5 mL of this solution add 10 mL of [acetonitrile](#) and dilute to 50 mL with a 40% v/v solution of [acetonitrile](#).

(2) Mix 4 mL of a 0.02% w/v solution of [megestrol acetate BPCRS](#) in [acetonitrile](#) with 10 mL of solution A and dilute to 50 mL with a 40% v/v solution of [acetonitrile](#).

(3) Prepare solution (3) in the same manner as solution (1) but adding 10 mL of solution A in place of the 10 mL of [acetonitrile](#).

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 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 mL per minute.

(d) Use an ambient column temperature.

(e) Use a detection wavelength of 280 nm.

(f) Inject 20 µL of each solution.

MOBILE PHASE

32 volumes of [water](#) and 68 volumes of [acetonitrile](#).

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (2), the [resolution factor](#) between the peaks due to propyl 4-hydroxybenzoate and megestrol acetate is at least 8.0.

DETERMINATION OF CONTENT

Calculate the content of $C_{24}H_{32}O_4$ in the tablets using the declared content of $C_{24}H_{32}O_4$ in [megestrol acetate BPCRS](#).