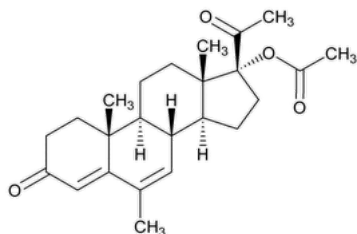


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Megestrol Acetate



$C_{24}H_{32}O_4$ 384.51

Pregna-4,6-diene-3,20-dione, 17-(acetyloxy)-6-methyl-

17-Hydroxy-6-methylpregna-4,6-diene-3,20-dione acetate CAS RN®: 595-33-5; UNII: TJ2M0FR8ES.

DEFINITION

Megestrol Acetate contains NLT 97.0% and NMT 103.0% of megestrol acetate ($C_{24}H_{32}O_4$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K▲](#) (CN 1-MAY-2020)

ASSAY

• PROCEDURE

Mobile phase: Acetonitrile and water (55:45)

Diluent: Acetonitrile and water (40:60)

Internal standard solution: 0.8 mg/mL of propylparaben in acetonitrile

Standard stock solution: 1 mg/mL of [USP Megestrol Acetate RS](#) in acetonitrile

Standard solution: 80 µg/mL each of [USP Megestrol Acetate RS](#) and propylparaben in *Diluent* from the *Standard stock solution* and *Internal standard solution*, respectively

Sample stock solution: 1 mg/mL of Megestrol Acetate in acetonitrile

Sample solution: 80 µg/mL each of Megestrol Acetate and propylparaben in *Diluent* from the *Sample stock solution* and *Internal standard solution*, respectively

Chromatographic system

(See [Chromatography \(621\), System Suitability.](#))

Mode: LC

Detector: UV 280 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1 mL/min

Injection volume: 25 µL

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for propylparaben and megestrol acetate are about 0.4 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 8.0 between propylparaben and megestrol acetate

Relative standard deviation: NMT 2.0% for the peak response ratio of megestrol acetate to propylparaben

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of megestrol acetate ($C_{24}H_{32}O_4$) in the portion of Megestrol Acetate taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of megestrol acetate to propylparaben from the *Sample solution*

R_s = peak response ratio of megestrol acetate to propylparaben from the *Standard solution*

C_s = concentration of [USP Megestrol Acetate RS](#) in the *Standard solution* (mg/mL)

C_u = concentration of Megestrol Acetate in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–103.0% on the anhydrous basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.2%, with a platinum dish being used and ignition at 600 ± 25°

SPECIFIC TESTS

- [COMPLETENESS OF SOLUTION \(641\)](#)

Sample: 500 mg in 10 mL of acetone

Acceptance criteria: Meets the requirements

- [MELTING RANGE OR TEMPERATURE \(741\)](#): 213°–220°, but the range between the beginning and the end of melting does not exceed 3°.

- [OPTICAL ROTATION, Specific Rotation \(781S\)](#)

Sample solution: 20 mg/mL in chloroform

Acceptance criteria: +8.8° to +12.0° (*t* = 20°)

- [WATER DETERMINATION, Method I \(921\)](#): NMT 0.5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers, protected from light.

- [USP REFERENCE STANDARDS \(11\)](#)

[USP Megestrol Acetate RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
MEGESTROL ACETATE	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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