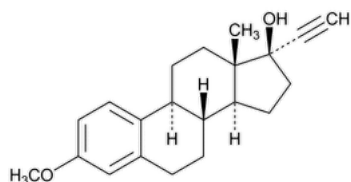


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Mestranol



$C_{21}H_{26}O_2$ 310.43

19-Norpregna-1,3,5(10)-trien-20-yn-17-ol, 3-methoxy-, (17 α)-;

3-Methoxy-19-nor-17 α -pregna-1,3,5(10)-trien-20-yn-17-ol CAS RN[®]: 72-33-3; UNII: B2V233XGE7.

DEFINITION

Mestranol contains NLT 97.0% and NMT 102.0% of mestranol ($C_{21}H_{26}O_2$), calculated on the dried basis.

IDENTIFICATION

Change to read:

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

Change to read:

- B. ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Ultraviolet-Visible Spectroscopy: 197U](#) ▲ (CN 1-MAY-2020)

Sample solution: 100 μ g/mL of Mestranol in methanol

Acceptance criteria: Meets the requirements

- C.

Standard solution: 1 mg/mL of [USP Mestranol RS](#) in chloroform

Sample solution: 1 mg/mL of Mestranol in chloroform

Chromatographic system

(See [Chromatography \(621\)](#), [Thin-Layer Chromatography](#).)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 10 μ L

Developing solvent system: Chloroform and dehydrated alcohol (29:1)

Spray reagent: Prepare as directed in *Solution A* in the Assay.

Analysis

Samples: *Standard solution* and *Sample solution*

Apply both solutions to a line parallel to and 2.5 cm from the bottom edge of a thin-layer chromatographic plate. Place the plate in the *Developing solvent system*. Develop the chromatogram until the solvent front has moved about 15 cm from the origin. Remove the plate from the chamber, allow the solvent to evaporate, and spray with *Spray reagent*. Heat the plate in an oven at 105° for 5 min, and observe under long-wavelength UV light.

Acceptance criteria: The R_F value of the principal spot of the *Sample solution* corresponds to that of the *Standard solution*.

ASSAY

PROCEDURE

Solution A: Pipet 30 mL of methanol into a 100-mL volumetric flask contained in an ice bath. Add slowly and cautiously and with continuous stirring about 65 mL of sulfuric acid, taking care that the temperature remains below 15°. Allow the solution to warm to room temperature, and dilute with sulfuric acid to volume.

Standard solution: 5 μ g/mL of [USP Mestranol RS](#) in chloroform

Sample solution: 5 μ g/mL of Mestranol in chloroform

Analysis: Pipet 4 mL each of the *Standard solution* and the *Sample solution* into separate glass-stoppered, 25-mL conical flasks. Evaporate the solutions under a slow current of air, without the aid of heat, to dryness. Dissolve the residue in 0.3 mL of methanol. Place the flasks in a water bath maintained at a temperature of 25°, and pipet into each, with constant swirling, 10 mL of *Solution A*. Insert the stoppers in the flasks. At 6 min, accurately timed after the addition of *Solution A*, concomitantly determine the absorbances of the solutions.

Instrumental conditions

Mode: Vis

Analytical wavelength: Maximum at about 545 nm

Cell: 1 cm

Blank: *Solution A*

Analysis

Samples: *Standard solution, Sample solution, and Blank*

Calculate the percentage of mestranol ($C_{21}H_{26}O_2$) in the portion of Mestranol taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of [USP Mestranol RS](#) in the *Standard solution* (µg/mL)

C_U = concentration of Mestranol in the *Sample solution* (µg/mL)

Acceptance criteria: 97.0%–102.0% on the dried basis

SPECIFIC TESTS

- [Loss on Drying \(731\)](#)

Analysis: Dry at 105° for 3 h.

Acceptance criteria: NMT 1.0%

- [Melting Range or Temperature \(741\)](#): 146°–154°, but the range between beginning and end of melting does not exceed 4°.

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

Sample solution: 20 mg, previously dried, per mL, in dioxane

Acceptance criteria: +2° to +8°

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed, light-resistant containers.

- [USP Reference Standards \(11\)](#)

[USP Mestranol RS](#)

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

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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