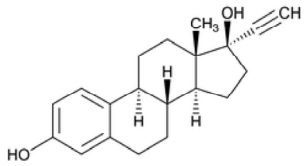
Ethinyl Estradiol



$C_{20}H_{24}O_2$ 296.40

19-Norpregna-1,3,5(10)-trien-20-yne-3, 17-diol, (17α)-;

19-Nor-17α-pregna-1,3,5(10)-trien-20-yne-3,17-diol [57-63-6]; UNII: 423D2T571U.

DEFINITION

Ethinyl Estradiol contains NLT 97.0% and NMT 102.0% of $C_{20}H_{24}O_2$, 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: 50 µg/mL in alcohol

Wavelength: 281 nm

Acceptance criteria: Absorptivities, calculated on the dried basis, do not differ by more than 3.0%.

ASSAY

• **PROCEDURE**

Mobile phase: Acetonitrile and water (1:1)

Internal standard solution: 0.5 mg/mL of ethylparaben in *Mobile phase*

Standard solution: 0.2 mg/mL of USP Ethinyl Estradiol RS in *Mobile phase*, prepared as follows. Transfer 10 mg of USP Ethinyl Estradiol RS to a 50-mL volumetric flask, and add 10 mL of *Mobile phase* and 5.0 mL of *Internal standard solution*. Dilute with *Mobile phase* to volume.

Sample stock solution: 1.0 mg/mL of Ethinyl Estradiol in *Mobile phase*

Sample solution: 0.2 mg/mL of Ethinyl Estradiol, prepared as follows. Combine 10.0 mL of the *Sample stock solution* and 5.0 mL of *Internal standard solution* in a 50-mL volumetric flask. Dilute with *Mobile phase* to volume.

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 280 nm

Column: 4.6-mm × 15-cm; packing L1

Flow rate: 1 mL/min

Injection size: 25 µL

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for ethylparaben and ethinyl estradiol are about 0.6 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 4.5 between the ethylparaben and ethinyl estradiol peaks

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ethinyl estradiol ($C_{20}H_{24}O_2$) taken:

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

R_U = peak response ratio from the *Sample solution*

R_S = peak response ratio from the *Standard solution*

C_S = concentration of USP Ethinyl Estradiol RS in the *Standard solution* (mg/mL)

C_U = concentration of Ethinyl Estradiol in the *Sample solution* (mg/mL)

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

IMPURITIES

• **COMPLETENESS OF SOLUTION:** Dissolve 100 mg in 5 mL of alcohol; the solution is clear and free from undissolved solid.

SPECIFIC TESTS

• **MELTING RANGE OR TEMPERATURE** ⟨741⟩**:** 180°–186°. It may exist also in a polymorphic modification, melting at 142°–146°.

• **OPTICAL ROTATION,** *SPECIFIC ROTATION*⟨781S⟩

Sample solution: 50 mg/mL, using sonication if necessary, in colorless pyridine from a freshly opened container

Acceptance criteria: −28.0° to −29.5°

• **LOSS ON DRYING** ⟨731⟩**:** Dry a sample at 105° for 3 h: it loses NMT 1.0% of its weight.

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight, nonmetallic, light-resistant containers.

• **USP REFERENCE STANDARDS** ⟨11⟩

USP Ethinyl Estradiol RS

Auxiliary Information- Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
ETHINYL ESTRADIOL	Gerald Hsu Senior Scientific Liaison	CHM52015 Chemical Medicines Monographs 5

Chromatographic Database Information: Chromatographic Database

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