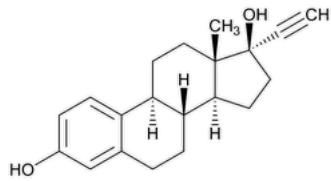


Status: Currently Official on 14-Feb-2025  
Official Date: Official as of 01-May-2020  
Document Type: USP Monographs  
DocId: GUID-7AF30D4F-668B-42DE-92A2-9942C482C3B7\_2\_en-US  
DOI: [https://doi.org/10.31003/USPNF\\_M31440\\_02\\_01](https://doi.org/10.31003/USPNF_M31440_02_01)  
DOI Ref: pkw5f

© 2025 USPC  
Do not distribute

# Ethinyl Estradiol



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

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

19-Nor-17 $\alpha$ -pregna-1,3,5(10)-trien-20-yne-3,17-diol CAS RN<sup>®</sup>: 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  $\mu$ g/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  $\times$  15-cm; packing L1

**Flow rate:** 1 mL/min

**Injection size:** 25  $\mu$ L

#### 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 | <a href="#">Documentary Standards Support</a> | SM52020 Small Molecules 5 |

**Chromatographic Database Information:** [Chromatographic Database](#)

**Most Recently Appeared In:**

Pharmacopeial Forum: Volume No. PF 37(3)

**Current DocID:** GUID-7AF30D4F-668B-42DE-92A2-9942C482C3B7\_2\_en-US

**DOI:** [https://doi.org/10.31003/USPNF\\_M31440\\_02\\_01](https://doi.org/10.31003/USPNF_M31440_02_01)

**DOI ref:** [pkw5f](#)