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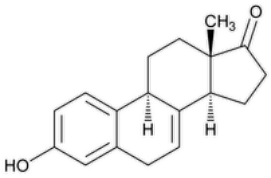
Equilin



$C_{18}H_{20}O_2$ 268.35

Estra-1,3,5(10),7-tetraen-17-one, 3-hydroxy-;

3-Hydroxyestra-1,3,5(10),7-tetraen-17-one CAS RN®: 474-86-2; UNII: 08O86EX0J4.

DEFINITION

Equilin contains NLT 97.0% and NMT 103.0% of equilin ($C_{18}H_{20}O_2$), 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

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and water (35:65)

Internal standard solution: 35 µg/mL of phenol in acetonitrile

Standard solution: 0.2 mg/mL of USP Equilin RS in *Internal standard solution*

Sample solution: 0.2 mg/mL of Equilin in *Internal standard solution*

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 2 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The retention times for phenol and equilin are 3 and 14 min, respectively.]

Suitability requirements

Resolution: NLT 5 between equilin and phenol. Adjust the operating parameters such that the peak of the *Standard solution* is about 0.7 full-scale.

Relative standard deviation: NMT 2.0% for five replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of equilin ($C_{18}H_{20}O_2$) in the portion of Equilin taken:

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

R_U = peak response ratio of equilin to the internal standard from the *Sample solution*

R_S = peak response ratio of equilin to the internal standard from the *Standard solution*

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

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

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

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.5%

SPECIFIC TESTS

• **Optical Rotation, *Specific Rotation* ⟨781S⟩**

Sample solution: 20 mg/mL, in dioxane

Acceptance criteria: +300° to +316°

• **Loss on Drying ⟨731⟩**

Analysis: Dry under vacuum at 105° for 1 h.

Acceptance criteria: NMT 0.5%

• **Clarity of Solution**

Sample solution: 1 mg/mL of Equilin prepared as follows. Add 100 mg to 100 mL of 1 N sodium hydroxide in a 125 mL conical flask.

Analysis: Heat the *Sample solution* on a steam bath until solution is complete, then cool, and transfer to a 100-mL color-comparison tube.

Acceptance criteria: The solution is clear.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **USP Reference Standards ⟨11⟩**

USP Equilin RS

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

Topic/Question	Contact	Expert Committee
EQUILIN	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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