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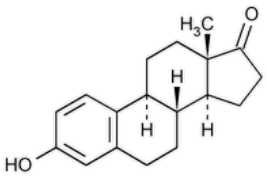
Estrone



$C_{18}H_{22}O_2$ 270.37

Estra-1,3,5(10)-trien-17-one, 3-hydroxy-.

3-Hydroxyestra-1,3,5(10)-trien-17-one CAS RN®: 53-16-7; UNII: 2DI9HA706A.

» Estrone contains not less than 97.0 percent and not more than 103.0 percent of $C_{18}H_{22}O_2$, calculated on the dried basis.

Packaging and storage—Preserve in tight, light-resistant containers. Store at 25°, excursions permitted between 15° and 30°.

USP Reference standards ⟨11⟩—

USP Estrone RS

Clarity of solution—Add 100 mg to 100 mL of 1 N sodium hydroxide in a 125-mL conical flask, heat on a steam bath until solution is complete, then cool, and transfer to a 100-mL color-comparison tube: the solution is clear.

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)* —

Solution: 50 µg per mL.

Medium: alcohol, heated on a steam bath and cooled to room temperature.

Specific rotation ⟨781S⟩**:** between +158° and +165°.

Test solution: 10 mg, previously dried, per mL, in dioxane.

Loss on drying ⟨731⟩—Dry it at 105° for 3 hours: it loses not more than 0.5% of its weight.

Residue on ignition ⟨281⟩**:** not more than 0.5%.

Limit of equilenin and equilin—Dissolve 10 mg in sufficient alcohol to make 50 mL. Transfer 5 mL of the solution to a small beaker. Add 5 mL of a buffer solution prepared by dissolving 2 mL of glacial acetic acid and 13.3 g of anhydrous sodium acetate in water to make 100 mL, warm to about 50°, and add 1 mL of a freshly prepared 1 in 200 solution of 2,6-dibromoquinone-chlorimide in alcohol. Mix, and allow to stand for 30 minutes. Transfer the solution to a small separator, add 10 mL of chloroform and 20 mL of 1 N sodium hydroxide, and shake vigorously for 2 minutes. Separate the chloroform layer, and filter rapidly through a dry filter paper into a dry test tube, discarding the first 2 mL of the filtrate. Viewed transversely against a white background, the chloroform filtrate shows no more red color than that produced by similarly treating 5 mL of an alcohol solution containing 20 µg of equilenin.

Ordinary impurities ⟨466⟩—

Test solution: acetone.

Standard solution: acetone.

Eluant: a mixture of chloroform and acetone (9:1), in a nonequilibrated chamber.

Visualization: 5.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of acetonitrile and 0.05 M monobasic potassium phosphate (1:1). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Transfer about 20 mg of USP Estrone RS, accurately weighed, to a 100-mL volumetric flask, add methanol to volume, and mix. If necessary, sonicate to aid solution. Transfer 5 mL of this solution to a 25-mL volumetric flask, dilute with *Mobile phase* to volume, and mix to obtain a *Standard preparation* having a known concentration of about 40 µg of USP Estrone RS per mL.

Assay preparation—Transfer about 20 mg of Estrone, accurately weighed, to a 100-mL volumetric flask, add methanol to volume, and mix. If necessary, sonicate to aid solution. Transfer 5.0 mL of this solution to a 25-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 280-nm detector and a 4-mm × 15-cm column that contains 5-µm packing L1. The flow rate is about 1 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the column efficiency determined from the analyte peak is not less than 1500 theoretical plates, the tailing factor for the analyte peak is not more than 2.0, and the relative standard deviation for replicate injections is not more than 2.0%. *Procedure*—Separately inject equal volumes (about 50 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{18}H_{22}O_2$ in the portion of Estrone taken by the formula:

$$0.5C(r_U/r_S)$$

in which C is the concentration, in µg per mL, of USP Estrone RS in the *Standard preparation;* and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

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

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

Chromatographic Database Information: Chromatographic Database

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