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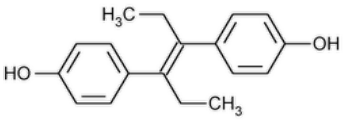
Diethylstilbestrol



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

Phenol 4,4'-(1,2-diethyl-1,2-ethenediyl)bis-, (*E*)-.

α,α'-Diethyl-(*E*)-4,4'-stilbenediol CAS RN®: 56-53-1; UNII: 731DCA35BT.

» Diethylstilbestrol contains not less than 97.0 percent and not more than 100.5 percent of $C_{18}H_{20}O_2$, calculated on the dried basis.

Packaging and storage—Preserve in tight, light-resistant containers. Store at room temperature.

USP Reference standards ⟨11⟩—

USP Diethylstilbestrol RS

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Ultraviolet-Visible Spectroscopy: 197U*▲ *(CN 1-May-2020)* —

Solution: 10 µg per mL.

Medium: alcohol.

Absorptivities at 230 to 350 nm do not differ by more than 3.0%.

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay.*

Melting range ⟨741⟩**:** between 169° and 175°, but the range between beginning and end of melting does not exceed 4°.

Acidity or alkalinity—A solution of 100 mg in 5 mL of neutralized 70% alcohol is neutral to litmus.

Loss on drying ⟨731⟩—Dry it at 105° for 2 hours: it loses not more than 0.5% of its weight.

Residue on ignition ⟨281⟩**:** not more than 0.05%.

Assay—

Diluent—Prepare a mixture of alcohol and water (1:1).

Mobile phase—Prepare a filtered and degassed mixture of methanol and water (3:1). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed quantity of USP Diethylstilbestrol RS in *Diluent,* and dilute quantitatively, and stepwise if necessary, with *Diluent* to obtain a solution having a known concentration of about 20 µg per mL.

System suitability solution—Dissolve 10 mg of USP Diethylstilbestrol RS in 50 mL of chloroform, and allow the solution to stand in the dark for not less than 5 hours. Pipet 5.0 mL of this solution into a 50-mL volumetric flask, and evaporate to dryness under a current of air. Dissolve the residue (the *cis-* and *trans*-isomers of diethylstilbestrol) in *Diluent,* sonicating if necessary. Dilute with *Diluent* to volume, and mix.

Assay preparation—Dissolve an accurately weighed quantity of Diethylstilbestrol in *Diluent,* and dilute quantitatively, and stepwise if necessary, with *Diluent* to obtain a solution having a concentration of about 20 µg per mL.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 4.6-mm × 25-cm column that contains packing L1. The flow rate is about 1 mL per minute. Chromatograph the *System suitability solution,* and record the peak responses as directed for *Procedure:* the relative retention times are about 1.00 for *trans*-diethylstilbestrol and 1.33 for *cis*-diethylstilbestrol; and the resolution, *R,* between *trans*-diethylstilbestrol and *cis*-diethylstilbestrol is not less than 4.0. Chromatograph the *Standard preparation,* and record the peak responses for the *trans*-isomer as directed for *Procedure:* the column efficiency is not less than 3000 theoretical plates; the tailing factor 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 areas of the peak responses for the *cis-* and *trans*-isomers of diethylstilbestrol. Calculate the quantity, in µg, of $C_{18}H_{20}O_2$ in the portion of Diethylstilbestrol taken by the formula:

$$C(r_{t,U} + 1.26r_{c,U})/(r_{t,S} + 1.26r_{c,S})$$

in which *C* is the concentration, in µg per mL, of USP Diethylstilbestrol RS in the *Standard preparation;* and $r_{t,U}$ and $r_{t,S}$ are the peak responses

for the *trans*-isomer obtained from the *Assay preparation* and the *Standard preparation,* respectively; and $r_{c,U}$ and $r_{c,S}$ are the peak responses for the *cis*-isomer 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
DIETHYLSTILBESTROL	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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