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Ethynodiol Diacetate and Ethinyl Estradiol Tablets

DEFINITION

Ethynodiol Diacetate and Ethinyl Estradiol Tablets contain NLT 93.0% and NMT 107.0% of the labeled amount of ethynodiol diacetate ($C_{24}H_{32}O_4$), and NLT 90.0% and NMT 110.0% of the labeled amount of ethinyl estradiol ($C_{20}H_{24}O_2$).

IDENTIFICATION

The retention times of the ethynodiol diacetate and ethinyl estradiol peaks from the *Sample solution* correspond to those from the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Methanol, acetonitrile, and water (3:7:10)

Standard solution: Dissolve, with the aid of sonication if necessary, quantities of USP Ethynodiol Diacetate RS and USP Ethinyl Estradiol RS in *Mobile phase*. Dilute quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution having known concentrations, in mg/mL, of the Reference Standards, corresponding to about 1/25 of the labeled amounts of ethynodiol diacetate and ethinyl estradiol in the Tablets.

Sample solution: Place 10 Tablets in a 250-mL volumetric flask. Add a portion of *Mobile phase*, and sonicate until the Tablets are completely disintegrated. Cool to room temperature, dilute with *Mobile phase* to volume, and filter.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm; packing L10

Flow rate: 2 mL/min

Injection size: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 3000 theoretical plates for ethynodiol diacetate

Tailing factor: NMT 1.5 for ethynodiol diacetate

Relative standard deviation: NMT 2.0% for each peak due to ethynodiol diacetate and ethinyl estradiol

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $C_{24}H_{32}O_4$ in each Tablet taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of ethynodiol diacetate from the *Sample solution*

r_S = peak response of ethynodiol diacetate from the *Standard solution*

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

C_U = nominal concentration of ethynodiol diacetate in the *Sample solution*

Calculate the percentage of $C_{20}H_{24}O_2$ in each Tablet taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of ethinyl estradiol from the *Sample solution*

r_S = peak response of ethinyl estradiol from the *Standard solution*

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

C_U = nominal concentration of ethinyl estradiol in the *Sample solution*

Acceptance criteria: 93.0%–107.0% of the labeled amount of $C_{24}H_{32}O_4$ and 90.0%–110.0% of the labeled amount of $C_{20}H_{24}O_2$

PERFORMANCE TESTS

- **Disintegration ⟨701⟩:** 15 min, the use of disks being omitted
- **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements for *Content Uniformity* with respect to ethynodiol diacetate and to ethinyl estradiol

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.
- **USP Reference Standards ⟨11⟩**
  USP Ethinyl Estradiol RS
  USP Ethynodiol Diacetate RS

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

Topic/Question	Contact	Expert Committee
ETHYNODIOL DIACETATE AND ETHINYL ESTRADIOL TABLETS	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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