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Fluoxymesterone Tablets

» Fluoxymesterone Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of fluoxymesterone ($C_{20}H_{29}FO_3$).

Packaging and storage—Preserve in well-closed containers, protected from light.

USP Reference standards ⟨11⟩—

USP Fluoxymesterone RS
USP Norethindrone RS

Identification—Triturate a quantity of powdered Tablets, equivalent to about 20 mg of fluoxymesterone, with 20 mL of hot chloroform, and decant the supernatant through a filter. Repeat the extraction with two 20-mL portions of hot chloroform. Evaporate the combined chloroform solutions on a water bath to dryness, digest the residue with 5 mL of acetone, decant the supernatant, add to it 20 mL of water, and filter off the precipitate. Dissolve the precipitate in 5 mL of acetone, add 20 mL of water, and filter: the precipitate, after being dried at 105° for 3 hours, meets the requirements for *Identification* test *A* under *Fluoxymesterone*.

Dissolution ⟨711⟩—

Medium: 0.01 N hydrochloric acid; 900 mL.

Apparatus 2: 75 rpm.

Time: 60 minutes.

Determine the amount of $C_{20}H_{29}FO_3$ dissolved by employing the following method.

Mobile phase—Prepare a degassed and filtered solution of water and acetonitrile (58:42). Make adjustments if necessary (see *Chromatography ⟨621⟩*).

Internal standard solution—Dissolve a quantity of USP Norethindrone RS in alcohol to obtain a solution having a final concentration of about 46 µg per mL.

Standard solution—Transfer about 28 mg of USP Fluoxymesterone RS, accurately weighed, to a 25-mL volumetric flask, dissolve in and dilute with alcohol to volume, and mix. Pipet 5 mL of the resulting solution into a 250-mL volumetric flask, dilute with *Dissolution Medium* to volume, and mix. Pipet 5 mL of this solution and 2 mL of *Internal standard solution* into a 25-mL volumetric flask, dilute with *Dissolution Medium* to volume, and mix.

Test solution—Pipet a filtered 20-mL aliquot of the solution under test and 2 mL of *Internal standard solution* into a 25-mL volumetric flask, dilute with *Dissolution Medium* to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 254-nm detector and a 4-mm × 30-cm column that contains packing L1. The flow rate is about 3 mL per minute. Chromatograph replicate injections of the *Standard solution,* and measure the peak responses as directed for *Procedure:* the relative retention times are 0.5 for fluoxymesterone and 1.0 for norethindrone; the resolution, *R,* between fluoxymesterone and norethindrone is not less than 2; and the relative standard deviation is not more than 2.0%.

Procedure—Inject a volume (about 20 µL) of the *Test solution* into the chromatograph, record the chromatogram, and measure the responses for the major peaks. Calculate the amount of $C_{20}H_{29}FO_3$ dissolved by comparison with the *Standard solution,* similarly chromatographed.

Tolerances—Not less than 70% *(Q)* of the labeled amount of $C_{20}H_{29}FO_3$ is dissolved in 60 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

PROCEDURE FOR CONTENT UNIFORMITY—

Internal standard solution, Mobile phase, and *Standard preparation*— Prepare as directed in the *Assay* under *Fluoxymesterone*.

Test preparation—Transfer 1 Tablet to a suitable container, add 2 mL of water, and sonicate for 30 minutes or until the Tablet completely disintegrates. Add an accurately measured volume of *Internal standard solution* (5.0 mL for each mg of fluoxymesterone in the Tablet), and shake the mixture for 15 minutes. Filter a portion of the chloroform layer, and use the clear filtrate.

Procedure—Proceed as directed in the *Assay* under *Fluoxymesterone,* using the *Test preparation* in place of the *Assay preparation.* Calculate the quantity, in mg, of fluoxymesterone ($C_{20}H_{29}FO_3$) in the Tablet taken by the formula:

$$(TC/D)(R_U/R_S)$$

in which T is the labeled quantity, in mg, of fluoxymesterone in the Tablet; D is the concentration, in mg per mL, of fluoxymesterone in the *Test preparation*, based on the labeled quantity per Tablet and the extent of dilution; and the other terms are as defined therein.

Assay—

Internal standard solution, Mobile phase, and *Standard preparation*—Prepare as directed in the *Assay* under *Fluoxymesterone*.

Assay preparation—Accurately weigh 20 Tablets, and grind to a fine powder in a mortar and pestle. Accurately weigh a portion of the powder, equivalent to about 5 mg of fluoxymesterone, and transfer to a suitable container. Add 20.0 mL of *Internal standard solution,* sonicate for 10 minutes, and shake for 15 minutes. Filter a portion of the liquid, and analyze the clear filtrate as directed for *Procedure*.

Procedure—Proceed as directed in the *Assay* under *Fluoxymesterone*. Calculate the quantity, in mg, of fluoxymesterone ($C_{20}H_{29}FO_3$) in the portion of Tablets taken by the formula:

$$20C(R_U/R_S)$$

in which the terms are as defined therein.

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

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

Chromatographic Database Information: Chromatographic Database

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