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Dydrogesterone Tablets

» Dydrogesterone Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{21}H_{28}O_2$.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—

USP Dydrogesterone RS

Identification—Extract a quantity of the powdered Tablets, containing about 60 mg of Dydrogesterone, with 20 mL of methanol, filter, and evaporate to dryness: the residue so obtained responds to *Identification* test *A* under *Dydrogesterone*.

Dissolution ⟨711⟩—

Medium: 0.3% sodium lauryl sulfate; 500 mL.

Apparatus 2: 100 rpm.

Time: 60 minutes.

Procedure—Determine the amount of $C_{21}H_{28}O_2$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 295 nm of filtered portions of the solution under test, suitably diluted with *Dissolution Medium*, if necessary, in comparison with a Standard solution having a known concentration of USP Dydrogesterone RS in the same medium.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{21}H_{28}O_2$ is dissolved in 60 minutes.

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

Assay—

Mobile phase, Standard preparation, System suitability preparation, and *Chromatographic system*—Proceed as directed in the *Assay* under *Dydrogesterone*.

Assay preparation—Weigh and finely powder not less than 20 Tablets. Transfer a portion of the powder, equivalent to about 20 mg of Dydrogesterone, to a 200-mL volumetric flask, add about 100 mL of *Mobile phase*, and sonicate for 10 minutes. Cool to room temperature, dilute with *Mobile phase* to volume, and mix.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and determine the peak responses by area measurement. Calculate the quantity, in mg, of $C_{21}H_{28}O_2$ in the portion of Tablets taken by the formula:

$$200C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Dydrogesterone RS in the *Standard preparation*, and r_U and r_S are the Dydrogesterone peak area responses 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
DYDROGESTERONE TABLETS	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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