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Danazol Capsules

» Danazol Capsules contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{22}H_{27}NO_2$.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—

USP Danazol RS

Identification—Shake the contents of a sufficient number of Capsules, equivalent to about 50 mg of Danazol, with 50 mL of chloroform, and filter. Evaporate the filtrate on a steam bath with the aid of a stream of nitrogen to dryness: the IR absorption spectrum of a potassium bromide dispersion of the residue, previously dried, exhibits maxima at the same wavelengths as that of a similar preparation of USP Danazol RS.

Dissolution ⟨711⟩—

Medium: 0.75% sodium lauryl sulfate solution; 900 mL.

Apparatus 2: 75 rpm.

Time: 30 minutes.

Procedure—Determine the amount of $C_{22}H_{27}NO_2$ dissolved as follows. Remove an aliquot from the solution under test at a point midway between the stirring shaft and the wall of the vessel and approximately midway in depth. Measure the amount in solution in filtered portions of the *Dissolution Medium*, suitably diluted with the *Dissolution Medium*, at the wavelength of maximum absorbance at about 286 nm, with a suitable spectrophotometer, in comparison with a solution of known concentration of USP Danazol RS prepared as follows. Transfer 10 mg of USP Danazol RS, accurately weighed, to a 10-mL volumetric flask, and dissolve in isopropyl alcohol. Transfer 2.0 mL to a 100-mL volumetric flask, dilute with *Dissolution Medium* to volume, and mix.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{22}H_{27}NO_2$ is dissolved in 30 minutes.

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

Assay—

Mobile phase—Prepare a filtered and degassed mixture of acetonitrile, methanol, and water (4:3:3). Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard preparation—Dissolve an accurately weighed quantity of USP Danazol RS in *Mobile phase* to obtain a solution having a known concentration of about 0.2 mg per mL.

Assay preparation—Accurately weigh the contents of not less than 20 Capsules. Mix the contents, and transfer an accurately weighed portion of the powder, equivalent to about 100 mg of danazol, to a 100-mL volumetric flask. Add about 50 mL of *Mobile phase*, and shake by mechanical means for about 10 minutes. Dilute with *Mobile phase* to volume, mix, and filter, discarding the first 5 mL of the filtrate. Pipet 5 mL of the filtrate into a 25-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. Filter a portion of this solution through a 0.45-µm porosity filter, discarding the first 5 mL of the filtrate.

Chromatographic system (see *System Suitability* under *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 270-nm detector and a 3.9-mm × 15-cm column that contains 4-µm packing L1. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed under *Procedure:* the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 20 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 danazol in the portion of Capsules taken by the formula:

$$500C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Danazol 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
DANAZOL CAPSULES	Documentary Standards Support	SM52020 Small Molecules 5

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REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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