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Norgestrel Tablets

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

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—

USP Norgestrel RS

Identification—Finely powder 20 Tablets, triturate the powder with 5 mL of chloroform, and allow the solids to settle. Apply 60 µL of the extract and 60 µL of a chloroform solution containing about 300 µg of USP Norgestrel RS per mL at points about 3 cm from one edge of a thin-layer chromatographic plate (see *Chromatography ⟨621⟩*) coated with a 0.25-mm layer of chromatographic silica gel mixture. Place the plate in a developing chamber containing a mixture of chloroform and alcohol (96:4) to a depth of 2 cm, the chamber having been previously equilibrated with the solvent mixture. Remove the plate when the solvent has moved about 15 cm from the line of application, dry at room temperature, spray with a mixture of 80 volumes of sulfuric acid and 20 volumes of alcohol, and heat at 105° for several minutes: the spot from the solution under test exhibits an R_F value identical to that of the spot from the Standard solution, and, when viewed under long-wavelength UV light, exhibits a red fluorescence similar to that from the Standard solution.

Disintegration ⟨701⟩: 15 minutes, the use of disks being omitted.

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

Assay—

Isoniazid reagent—Dissolve 0.25 g of isoniazid and 0.3 mL of hydrochloric acid in 500 mL of dehydrated alcohol.

Procedure—Weigh and finely powder not less than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 75 µg of norgestrel, to a 30-mL separator containing 5 mL of water. Extract with three 5-mL portions of chloroform, shaking for about 1 minute each time, and collecting the chloroform extracts through glass wool, previously moistened with chloroform, into a glass-stoppered test tube. Add 1 mL of dilute hydrochloric acid (1 in 12) to the remaining aqueous phase and extract with a fourth 5-mL portion of chloroform, collecting this chloroform extract as before and combining it with the previous three. To another glass-stoppered test tube transfer 20.0 mL of a solution of USP Norgestrel RS, in chloroform, having a known concentration of about 3.75 µg per mL. Evaporate the contents of both tubes in a water bath with the aid of a current of air to dryness. Add 5.0 mL of *Isoniazid reagent* to each tube, insert the stopper in each tube, and swirl occasionally for 1 hour. Concomitantly determine the absorbances of both solutions in 1-cm cells, at the wavelength of maximum absorbance at about 380 nm, using a suitable spectrophotometer, and using *Isoniazid reagent* as the blank. Calculate the quantity, in µg, of $C_{21}H_{28}O_2$ in the portion of Tablets taken by the formula:

$$20C(A_U/A_S)$$

in which C is the concentration, in µg per mL, of USP Norgestrel RS in the Standard solution, and A_U and A_S are the absorbances of the solutions from the Tablets and the Standard solution, respectively.

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

Topic/Question	Contact	Expert Committee
NORGESTREL TABLETS	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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