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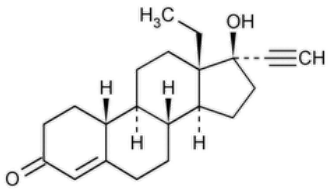
Norgestrel



$C_{21}H_{28}O_2$ 312.45

18,19-Dinorpregn-4-en-20-yn-3-one, 13-ethyl-17-hydroxy-, (17α)-(±)-.

(±)-13-Ethyl-17-hydroxy-18,19-dinor-17α-pregn-4-en-20-yn-3-one CAS RN®: 6533-00-2; UNII: 3J8Q1747Z2.

» Norgestrel contains not less than 98.0 percent and not more than 102.0 percent of $C_{21}H_{28}O_2$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—
USP Norgestrel RS

Change to read:

Identification, ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020) —If differences appear, dissolve portions of both the test specimen and the Reference Standard in ethyl acetate, evaporate the solutions on a steam bath to dryness, and repeat the test.

Melting range, *Class I* ⟨741⟩: between 205° and 212°, but the range between beginning and end of melting does not exceed 4°.

Optical rotation ⟨781A⟩: between −0.1° and +0.1°.

Test solution: 50 mg, previously dried, per mL, in chloroform.

Loss on drying ⟨731⟩—Dry it at 105° for 3 hours: it loses not more than 0.5% of its weight.

Residue on ignition ⟨281⟩: not more than 0.3%.

Chromatographic purity—

Phosphomolybdic acid reagent—Add 10 g of phosphomolybdic acid to 100 mL of alcohol, and stir the mixture for not less than 30 minutes. Filter before use.

Test preparation—Prepare a solution of Norgestrel in chloroform to contain 10.0 mg per mL.

Standard solution and *Standard dilutions*—Prepare a solution of USP Norgestrel RS in chloroform to contain 10 mg per mL (*Standard solution*). Prepare a series of dilutions of *Standard solution* in chloroform to contain 0.20, 0.10, 0.05, 0.02, and 0.01 mg per mL (*Standard dilutions*).

Procedure—Apply 10-µL volumes of *Standard solution*, the *Test preparation*, and each of the five *Standard dilutions* at equidistant points along a line 2.5 cm from one edge of a 20- × 20-cm thin-layer chromatographic plate (see *Chromatography ⟨621⟩*) coated with a 0.25-mm layer of chromatographic silica gel mixture and previously activated by heating at 100° for 15 minutes. Place the plate in a suitable developing chamber that contains and has been equilibrated with a mixture of 96 volumes of chloroform and 4 volumes of alcohol, seal the chamber, and allow the chromatogram to develop until the solvent front has moved 15 cm above the line of application. Remove the plate, allow the solvent to evaporate, then spray uniformly with *Phosphomolybdic acid reagent*, and heat it at 105° for 10 to 15 minutes. The lane of the *Test preparation* exhibits its principal spot at the same R_F as the principal spot of *Standard solution*. If spots other than the principal spot are observed in the lane of the *Test preparation*, estimate the concentration of each by comparison with the *Standard dilutions*. The spots from the 0.20-, 0.10-, 0.05-, 0.02-, and 0.01-mg per mL dilutions are equivalent to 2.0, 1.0, 0.5, 0.2, and 0.1% of impurities, respectively. The requirements of the test are met if the sum of the impurities in the *Test preparation* does not exceed 2.0%.

Limit of ethynyl group—Proceed as directed in the test for *Limit of ethynyl group* under *Norethindrone*. Not less than 7.81% and not more than 8.18% of ethynyl group is found.

Assay—Dissolve about 100 mg of Norgestrel, accurately weighed, in alcohol, and dilute quantitatively and stepwise with alcohol to obtain a solution containing about 10 µg per mL. Dissolve an accurately weighed quantity of USP Norgestrel RS in alcohol to obtain a Standard solution having a known concentration of about 10 µg per mL. Concomitantly determine the absorbances of both solutions in 1-cm cells at the

wavelength of maximum absorbance at about 241 nm, with a suitable spectrophotometer, using alcohol as the blank. Calculate the quantity, in mg, of $C_{21}H_{28}O_2$ in the portion of Norgestrel taken by the formula:

$$10C(A_U/A_S)$$

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 solution of Norgestrel and the Standard solution, respectively.

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

Topic/Question	Contact	Expert Committee
NORGESTREL	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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