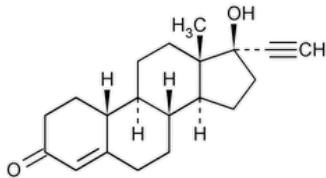


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Norethindrone



$C_{20}H_{26}O_2$ 298.42

19-Norpregn-4-en-20-yn-3-one, 17-hydroxy-, (17α)-.

17-Hydroxy-19-nor-17α-pregn-4-en-20-yn-3-one CAS RN®: 68-22-4; UNII: T18F433X4S.

» Norethindrone contains not less than 97.0 percent and not more than 102.0 percent of $C_{20}H_{26}O_2$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed containers.

USP REFERENCE STANDARDS (11)—

[USP Norethindrone RS](#)

Completeness of solution—The solution called for in the test for *Specific rotation* is clear and free from undissolved solid.

Change to read:

Identification, ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy](#): 197K▲ (CN 1-May-2020)

MELTING RANGE (741): between 202° and 208°.

SPECIFIC ROTATION (781S): between -30° and -38°.

Test solution: 20 mg per mL, in dioxane.

LOSS ON DRYING (731)—Dry it in vacuum at 105° for 3 hours: it loses not more than 0.5% of its weight.

Limit of ethynyl group—Dissolve 200 mg in about 40 mL of tetrahydrofuran. Add 10 mL of silver nitrate solution (1 in 10), and titrate with 0.1 N sodium hydroxide VS, either a glass-calomel or a silver–silver chloride electrode system with potassium nitrate filling solution. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N sodium hydroxide is equivalent to 2.503 mg of ethynyl group ($-C\equiv CH$). Not less than 8.18% and not more than 8.43% of ethynyl group is found.

Chromatographic purity

Test solution—Prepare a solution of Norethindrone in chloroform to contain 10 mg per mL.

Standard solutions—Prepare a solution of [USP Norethindrone RS](#) in chloroform to contain 10 mg per mL (*Standard stock solution*). Dilute accurately measured volumes of *Standard stock solution* with chloroform to obtain *Standard solutions A, B, C, and D* having known concentrations of 150, 50, 30, and 10 µg per mL, respectively.

Procedure—Separately apply 10 µL of the *Test solution* and 10 µL of each *Standard solution* to a thin-layer chromatographic plate (see [Chromatography \(621\)](#)) coated with a 0.25-mm layer of chromatographic silica gel mixture. Develop the chromatogram in a solvent system consisting of a mixture of chloroform and methanol (95:5) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chamber, mark the solvent front, and allow the solvent to evaporate. Spray the plate with a mixture of methanol and sulfuric acid (7:3), then heat the plate at 100° for 5 minutes: the R_F value of the principal spot from the *Test solution* corresponds to that of the principal spot from *Standard solution A*. Compare the intensities of any secondary spots observed in the chromatogram of the *Test solution* with those of the principal spots in the chromatograms of the *Standard solution*: no secondary spot from the chromatogram of the *Test solution* is larger or more intense than the principal spot obtained from *Standard solution B* (0.5%), and the sum of the intensities of the secondary spots obtained from the *Test solution* is not more intense than the principal spot obtained from *Standard solution A* (1.5%).

Assay—Dissolve about 100 mg of Norethindrone, 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 Norethindrone RS](#) in alcohol, and dilute quantitatively and stepwise with 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 240 nm, using alcohol as the blank. Calculate

the quantity, in mg, of $C_{20}H_{26}O_2$ in the portion of Norethindrone taken by the formula:

$$10C(A_u/A_s)$$

in which C is the concentration, in μg per mL, of [USP Norethindrone RS](#) in the Standard solution, and A_u and A_s are the absorbances of the solution of Norethindrone and the Standard solution, respectively.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
NORETHINDRONE	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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