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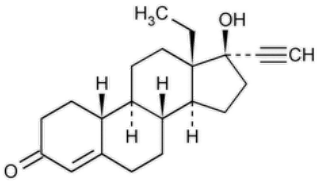
Levonorgestrel



$C_{21}H_{28}O_2$ 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®: 797-63-7; UNII: 5W7SIA7YZW.

» Levonorgestrel 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, light-resistant containers.

USP Reference standards ⟨11⟩—

USP Levonorgestrel RS

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests* ⟨197⟩, *Infrared Spectroscopy: 197K*▲ (CN 1-May-2020)

B: Meeting the requirements of the tests for *Specific rotation* and *Melting range* provides identification distinguishing it from norgestrel.

Melting range ⟨741⟩: between 232° and 239°, but the range between beginning and end of melting does not exceed 4°.

Specific rotation ⟨781S⟩: between −30° and −35°.

Test solution: 20 mg per mL, in chloroform.

Loss on drying ⟨731⟩—Dry it at 105° for 5 hours: it loses not more than 0.5% of its weight.

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

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, using 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≡CH). Not less than 7.81% and not more than 8.18% of ethynyl group is found.

Chromatographic purity—Proceed as directed in the test for *Chromatographic purity* under *Norgestrel,* using USP Levonorgestrel RS in place of USP Norgestrel RS. The requirements of the test are met if the sum of the impurities in the *Test preparation* does not exceed 2.0% and no single impurity is greater than 0.5%.

Assay—Using USP Levonorgestrel RS, proceed as directed in the *Assay* under *Norgestrel*, except to read “Levonorgestrel” in place of “Norgestrel.”

OFFICIAL

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

Topic/Question	Contact	Expert Committee
LEVONORGESTREL	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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