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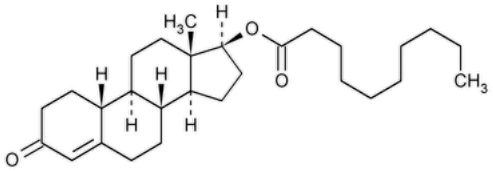
Nandrolone Decanoate



$C_{28}H_{44}O_3$ 428.65

Estr-4-en-3-one, 17-[(1-oxodecyl)oxy]-, (17β)-;

17β-Hydroxyestr-4-en-3-one decanoate CAS RN®: 360-70-3; UNII: H45187T098.

DEFINITION

Nandrolone Decanoate contains NLT 97.0% and NMT 103.0% of nandrolone decanoate ($C_{28}H_{44}O_3$), calculated on the dried basis.

IDENTIFICATION

- **A. Spectroscopic Identification Tests ⟨197⟩, Infrared Spectroscopy:** 197K
- **B. Spectroscopic Identification Tests ⟨197⟩, Ultraviolet-Visible Spectroscopy:** 197U

  Analytical wavelength: 239 nm

  Sample solution: 10 µg/mL in alcohol

  Acceptance criteria: Absorptivities, calculated on the dried basis, do not differ by more than 3.0%.
- **C. Thin-Layer Chromatography**

  Standard solution: 5 mg/mL of USP Nandrolone Decanoate RS in acetone

  Sample solution: 5 mg/mL of Nandrolone Decanoate in acetone

  Chromatographic system

  (See *Chromatography ⟨621⟩, Thin-Layer Chromatography*.)

  Mode: TLC

  Adsorbent: 0.25-mm layer of chromatographic silica gel

  Application volume: 10 µL

  Developing solvent system: Acetone and *n*-Heptane (1:3)

  Spray reagent: Sulfuric acid in alcohol (1 in 50)

  Analysis: Allow the spots to dry, and develop the chromatogram in a *Developing solvent system* until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the solvent to evaporate. Locate the spots on the plate by lightly spraying with *Spray reagent* and heating in an oven at 110° for 15 min.

  Acceptance criteria: The R_F value of the principal spot from the *Sample solution* corresponds to that from the *Standard solution*.

ASSAY

Change to read:

- **Procedure**

[Note—Use low-actinic glassware throughout this procedure.]

Mobile phase: Methanol and water (95:5)

Standard solution: 0.2 mg/mL of USP Nandrolone Decanoate RS in methanol

Sample solution: 0.2 mg/mL of Nandrolone Decanoate in methanol

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 240 nm

Column: 8-mm × 10-cm; packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Capacity factor, k': NLT 1.3

Column efficiency: NLT 8000 theoretical plates

Tailing factor: 0.9–2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ▲nandrolone decanoate▲ (ERR 1-Jun-2022) ($C_{28}H_{44}O_3$) in the portion of Nandrolone Decanoate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of nandrolone decanoate from the *Sample solution*

r_S = peak response pf nandrolone decanoate from the *Standard solution*

C_S = concentration of USP Nandrolone Decanoate RS in the *Standard solution* (mg/mL)

C_U = concentration of Nandrolone Decanoate in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–103.0% on the dried basis

IMPURITIES

• **Organic Impurities**

Mobile phase: *n*-Heptane and *n*-propyl alcohol (97:3)

System suitability solution: 0.25 mg/mL of USP Nandrolone Decanoate RS, 0.25 mg/mL of dimethyl phthalate, and 0.16 mg/mL USP Nandrolone RS in *Mobile phase*

Sample solution: 0.26 mg/mL of Nandrolone Decanoate in *Mobile phase*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 238 nm

Column: 4.6-mm × 25-cm; packing L10

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *System suitability solution*

[Note—The relative retention times for dimethyl phthalate and nandrolone decanoate are 0.67 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 9.0 between dimethyl phthalate and nandrolone decanoate

[Note—The nandrolone peak elutes before 4.5 times the elution time of nandrolone decanoate.]

Tailing factor: NMT 1.3, nandrolone decanoate and dimethyl phthalate

Relative standard deviation: NMT 2.0%

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Nandrolone Decanoate ($C_{28}H_{44}O_3$) taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response for each impurity

r_T = sum of the responses of all the peaks

Acceptance criteria

Total impurities: NMT 3.0%

SPECIFIC TESTS

• **Melting Range or Temperature ⟨741⟩:** 33°–38°

• **Optical Rotation, *Specific Rotation*⟨781S⟩**

Sample solution: 10 mg/mL of Nandrolone Decanoate (previously dried) in dioxane

Acceptance criteria: +32° to +36°

• **Loss on Drying ⟨731⟩**

Analysis: Dry a sample in a vacuum over silica gel for 4 h.

Acceptance criteria: NMT 0.5%

• **Completeness and Clarity of Solution:** A solution of Nandrolone Decanoate in dioxane (1 in 50) is clear.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers, and store in a refrigerator.

• **USP Reference Standards** ⟨11⟩

USP Nandrolone RS

17β-Hydroxyestr-4-en-3-one.

$C_{18}H_{26}O_2$ 274.40

USP Nandrolone Decanoate RS

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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