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Nandrolone Decanoate Injection

» Nandrolone Decanoate Injection is a sterile solution of Nandrolone Decanoate in Sesame Oil, with a suitable preservative. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of nandrolone decanoate ($C_{28}H_{44}O_3$).

Packaging and storage—Preserve in single-dose or in multiple-dose containers, preferably of Type I glass, protected from light.

USP Reference standards ⟨11⟩—

USP Nandrolone RS
USP Nandrolone Decanoate RS

Identification—Dilute a volume of Injection with acetone to provide a solution containing approximately 5 mg of nandrolone decanoate per mL. This solution responds to *Identification* test *C* under *Nandrolone Decanoate*, 5-µL portions of the test solution and the Standard solution being used.

Limit of nandrolone—

Standard preparation—Dissolve 25.0 mg of USP Nandrolone RS in 50.0 mL of acetone. Dilute 5.0 mL of this solution with acetone to 50.0 mL, and mix.

Test preparation—Transfer an accurately measured volume of Injection, equivalent to about 50 mg of nandrolone decanoate, to a 10-mL volumetric flask, dilute with acetone to volume, and mix.

Procedure—Apply 10 µL each of the *Standard preparation* and of the *Test preparation* to a suitable thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel mixture. Allow the spots to dry, and develop the chromatogram in a solvent system consisting of a mixture of *n*-heptane and acetone (3:1) 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. Return the dry plate to the developing chamber containing the same solvent system, and again develop the chromatogram until the solvent front has moved the same distance from the origin. Remove the plate from the developing chamber, and allow the solvent to evaporate. Locate the spots on the plate by lightly spraying with a 4 in 10 solution of sulfuric acid in methanol and heating at about 100° for 10 minutes. Cool, and examine under long-wavelength UV light: any yellow fluorescent spot from the *Test preparation* at an R_f value of about 0.2 is not greater in size or intensity than that produced by the *Standard preparation* at the same R_f value, corresponding to not more than 1.0% of nandrolone.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products* ⟨1⟩.

Assay—

0.02 M Ammonium acetate solution—Transfer about 1.6 g of ammonium acetate to a 1-liter volumetric flask. Dissolve in and dilute with water to volume.

Mobile phase—Prepare a filtered and degassed mixture of alcohol and *0.02 M Ammonium acetate solution* (66:34). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed quantity of USP Nandrolone Decanoate RS with tetrahydrofuran, and dilute quantitatively and stepwise if necessary, with tetrahydrofuran to obtain a solution having a known concentration of about 0.2 mg per mL.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 400 mg of nandrolone decanoate to a 200-mL volumetric flask, dilute with tetrahydrofuran to volume, and mix. Transfer 10.0 mL of this solution to a 100-mL volumetric flask, dilute with tetrahydrofuran to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 4.6-mm × 15-cm column containing 5-µm packing L1. The flow rate is about 1.5 mL per minute. The column temperature is maintained at 40°. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the capacity factor, *k'*, for nandrolone decanoate is not less than 5.3; the tailing factor for the Nandrolone Decanoate peak is not more than 1.4; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{28}H_{44}O_3$ in each mL of the

Injection taken by the formula:

$$2000(C/V)\ (r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Nandrolone Decanoate RS in the *Standard preparation; V* is the volume, in mL, of the injection taken to prepare the *Assay preparation*, and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
NANDROLONE DECANOATE INJECTION	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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