

Status: Currently Official on 16-Feb-2025
 Official Date: Official Prior to 2013
 Document Type: USP Monographs
 DocId: GUID-DD7A0640-C875-4FC2-B4D7-1768A71466B0_2_en-US
 DOI: https://doi.org/10.31003/USPNF_M59140_02_01
 DOI Ref: p4xvi

© 2025 USPC
 Do not distribute

Oxandrolone Tablets

» Oxandrolone Tablets contain not less than 92.0 percent and not more than 108.0 percent of the labeled amount of oxandrolone ($C_{19}H_{30}O_3$).

Packaging and storage—Preserve in tight, light-resistant containers.

Labeling—When more than one *Dissolution Test* is given, the labeling states the *Dissolution Test* used only if *Test 1* is not used.

USP REFERENCE STANDARDS (11)—

[USP Oxandrolone RS](#)

Identification—

A: [Thin-Layer Chromatographic Identification Test \(201\)](#)—

Standard solution: 5 mg per mL in chloroform.

Test solution—Transfer a portion of finely powdered Tablets, equivalent to about 20 mg of oxandrolone, to a 50-mL stoppered centrifuge tube, add 4 mL of chloroform, shake by mechanical means for 10 minutes, centrifuge for about 15 minutes, and filter a portion of the chloroform layer.

Application volume: 10 μ L.

Developing solvent system: a mixture of chloroform and methanol (19:1).

Procedure—Locate the spots on the plate by lightly spraying with dilute sulfuric acid (1 in 2) and heating on a hot plate or under a lamp until spots appear: the R_f value of the principal spot obtained from the *Test solution* corresponds to that obtained from the *Standard solution*.

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation*, as obtained in the *Assay*.

DISSOLUTION (711)—

TEST 1—

Medium: a solution of water and isopropanol (7:3); 500 mL.

Apparatus 2: 100 rpm.

Time: 60 minutes.

Determine the amount of $C_{19}H_{30}O_3$ dissolved by employing the following method.

Internal standard solution—Dissolve accurately weighed quantities of 17 α -methyltestosterone, and dilute quantitatively, and stepwise if necessary, with acetonitrile to obtain a solution having a concentration of about 0.2 mg per mL (for Tablets with a 2.5-mg label claim) and about 0.8 mg per mL (for Tablets with a 10-mg label claim).

Standard solution—Dissolve an accurately weighed quantity of [USP Oxandrolone RS](#), and dilute quantitatively, and stepwise if necessary, with acetonitrile to obtain a solution having a concentration of about 1 mg per mL.

Working standard solution—For Tablets labeled to contain 2.5 mg: combine 100 μ L of the *Standard solution*, 400 μ L of the *Internal standard solution*, and 1500 μ L of acetonitrile. For Tablets labeled to contain 10 mg: combine 100 μ L of the *Standard solution*, 100 μ L of the *Internal standard solution*, and 1800 μ L of acetonitrile.

Test solution—Withdraw 25 mL of the solution under test from the vessel. Pass through a 0.45- μ m polytetrafluoroethylene filter. Transfer 20 mL of the filtrate to a separatory funnel, add 400 μ L of the *Internal standard solution*, 40 mL of a 10% potassium chloride solution, and 8 mL of chloroform. In separate separatory funnels, prepare an extraction blank and an internal standard blank in a similar manner using 20 mL of filtered *Medium* in place of the solution under test and excluding the *Internal standard solution* from the extraction blank. Shake each funnel, and allow the layers to separate. Collect the lower chloroform layer. Repeat the extraction procedure one more time. Evaporate the solvents under a stream of nitrogen at 45° until just dry. Reconstitute the dried residue with 2 mL of acetonitrile (for Tablets with a 2.5-mg label claim) or with 8 mL of acetonitrile (for Tablets with a 10-mg label claim), and sonicate for 10 minutes.

CHROMATOGRAPHY (621)—The gas chromatograph is equipped with a flame ionization detector and a 0.53-mm $\times$ 30-m column coated with a 0.5- μ m phase G27. The carrier gas is helium, flowing at a rate of about 16.8 mL per minute. The injection port

Error preparing HTML-CSS output (postProcess)

and detector temperatures are maintained at 190° and 320°, respectively. The chromatograph is programmed as follows. The column temperature is initially 180°. Upon injection, the column temperature is increased at a rate of 25° per minute to 280°, and maintained at 280° for 3 minutes. Then the column temperature is increased at a rate of 10° per minute to 320°, and maintained at 320° for 3 minutes. Chromatograph the acetonitrile, the extraction blank, and the internal standard blank, and record the peak responses as directed for *Procedure*: the tailing factor is not more than 1.5. Make two injections of the *Working standard solution*, and record the peak responses. The average oxandrolone/*Internal standard solution* peak area percent comparison is between 98.0% and 102.0%. The resolution, *R*, between the oxandrolone peak and the nearest eluting peak is equal to or greater than 1.5.

Procedure—Separately inject equal volumes (0.5 µL) of the *Working standard solution* and the *Test solution* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the percentage of $C_{19}H_{30}O_3$ released by the formula:

in which C_s is the concentration, in mg per mL, of oxandrolone in the *Standard solution*; $r_U \times C_s \times D \times 500 \times 100$ is the area ratio of oxandrolone to 17α-methyltestosterone in the sample injection for each *Test solution*; V_{UF} is the final volume, in mL, of the sample after reconstitution of the dry residue; 500 is the volume, in mL, of *Medium*; 100 is the conversion factor to percentage; standard ratio is the mean area ratio of oxandrolone to 17α-methyltestosterone in all injections of the *Standard solution*; V_{UI} is the initial sample volume, in mL, used in the extraction; and *LC* is the Tablet label claim, in mg.

Tolerances—Not less than 75% (*Q*) of the labeled amount of oxandrolone ($C_{19}H_{30}O_3$) is dissolved in 60 minutes.

TEST 2—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: 1% polysorbate 80 in water; 500 mL, deaerated.

Apparatus 2: 100 rpm.

Time: 120 minutes.

Determine the amount of $C_{19}H_{30}O_3$ dissolved by employing the following method.

Mobile phase—Prepare a filtered and degassed mixture of water and acetonitrile (55:45). Make adjustments if necessary (see *System Suitability* under [Chromatography \(621\)](#)).

Standard stock solution—Transfer about 20 mg of [USP Oxandrolone RS](#), accurately weighed, to a 200-mL volumetric flask. Add about 20 mL of acetonitrile, and sonicate to dissolve. Dilute with *Medium* to volume, and mix.

Working standard solution—Quantitatively dilute the *Standard stock solution* with *Medium* to obtain a solution having a final concentration of about 5 µg per mL for Tablets with a label claim of 2.5 mg, or a final concentration of about 20 µg per mL for Tablets with a label claim of 10 mg.

Test solution—Withdraw about 10 mL of the solution under test from the vessel. Centrifuge in a glass tube at 2000 rpm for 10 minutes.

Chromatographic system (see [CHROMATOGRAPHY \(621\)](#))—The liquid chromatograph is equipped with a refractive index detector and a 4.6-mm × 25-cm column that contains 5-µm packing L1. The column is maintained at 30°, and the detector is maintained at 50°. The flow rate is about 1.5 mL per minute. Chromatograph the *Working standard solution*, and record the peak responses as directed for *Procedure*: the tailing factor is not more than 2.0; the column efficiency is not less than 4000 theoretical plates; and the relative standard deviation for replicate injections is not more than 5.0%.

Procedure—Separately inject equal volumes (about 100 µL) of the *Working standard solution* and the *Test solution* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the percentage of $C_{19}H_{30}O_3$ released by the formula:

in which r_U and r_s are the peak responses obtained from the *Test solution* and *Working standard solution*, respectively; C_s is the concentration, in mg per mL, of the *Working standard solution*; *D* is the dilution factor of the *Test solution*; 500 is the volume, in mL, of *Medium*; 100 is the conversion factor to percentage; and *LC* is the Tablet label claim, in mg.

Tolerances—Not less than 65% (*Q*) of the labeled amount of $C_{19}H_{30}O_3$ is dissolved in 120 minutes.

TEST 3—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 3*.

Medium: 0.1 N hydrochloric acid containing 0.75% of sodium lauryl sulfate; 500 mL for Tablets labeled to contain 2.5 mg, 900 mL for Tablets labeled to contain 10 mg, deaerated with helium.

Apparatus 2: 75 rpm.

Time: 90 minutes.

Error preparing HTML-CSS output (postProcess) $C_{19}H_{30}O_3$ released by employing the following method.