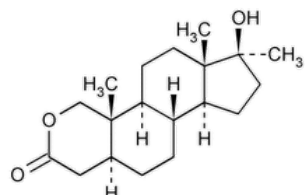


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Oxandrolone



$C_{19}H_{30}O_3$ 306.44

2-Oxaandrost-3-one, 17-hydroxy-17-methyl-, (5 α ,17 β)-.

17 β -Hydroxy-17-methyl-2-oxa-5 α -androst-3-one CAS RN[®]: 53-39-4; UNII: 7H6TM3CT4L.

» Oxandrolone contains not less than 98.0 percent and not more than 102.0 percent of $C_{19}H_{30}O_3$, calculated on the dried basis.

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

USP REFERENCE STANDARDS (11)—

[USP Oxandrolone RS](#)

[USP Oxandrolone Related Compound A RS](#)

(7,8-Didehydro-oxandrolone) or (17 β -hydroxy-17 α -methyl-2-oxa-5 α -androst-7-en-3-one).

[USP Oxandrolone Related Compound B RS](#)

(4-Oxa-isomer) or (17 β -hydroxy-17 α -methyl-4-oxa-5 α -androst-3-one).

[USP Oxandrolone Related Compound C RS](#)

Anhydro-oxandrolone or (17,17-dimethyl-18-nor-2-oxa-5 α -androst-13-en-3-one).

Identification—

Change to read:

A: ▲ [Spectroscopic Identification Tests \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-May-2020) ·

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.

SPECIFIC ROTATION (781S): between -18° and -24° .

Test solution: 10 mg per mL, in chloroform.

LOSS ON DRYING (731)—Dry it at 105° for 3 hours: it loses not more than 1.0% of its weight.

RESIDUE ON IGNITION (281): not more than 0.2%.

Related compounds—

Solution A: acetonitrile.

Solution B: water.

Mobile phase—Use variable mixtures of *Solution A* and *Solution B* as directed for *Chromatographic system*. Make adjustments if necessary (see *System Suitability* under [Chromatography \(621\)](#)).

Blank solution—Prepare a mixture of *Solution A* and *Solution B* (50:50).

Standard stock solution—Dissolve accurately weighed quantities of [USP Oxandrolone Related Compound A RS](#), [USP Oxandrolone Related Compound B RS](#), [USP Oxandrolone Related Compound C RS](#), and [USP Oxandrolone RS](#) in acetonitrile, and dilute quantitatively, and stepwise if necessary, with acetonitrile to obtain a solution having known concentrations of about 4 μ g of [USP Oxandrolone Related Compound A RS](#) per mL, 120 μ g of [USP Oxandrolone Related Compound B RS](#) per mL, 4 μ g of [USP Oxandrolone Related Compound C RS](#) per mL, and 200 μ g of [USP Oxandrolone RS](#) per mL. [NOTE—Sonicate if necessary to dissolve.]

Standard solution—Dilute 1.0 mL of the *Standard stock solution* with 4.0 mL of acetonitrile and 5.0 mL of water, and mix.

Test solution—Weigh accurately 40 mg of Oxandrolone into a 10-mL volumetric flask, dissolve in 5.0 mL of acetonitrile using an ultrasonic bath, dilute with water to volume, and mix.

[NOTE—The *Test solution*, the *Standard solution*, and the *Blank solution* are made up fresh and injected immediately.]

Chromatographic system—The liquid chromatograph is equipped with a 210-nm detector and a 4.6-mm × 25-cm column that contains 5-μm packing L1. The column temperature is maintained at 40°. The flow rate is about 0.7 mL per minute. The chromatograph is programmed as follows.

Time (minutes)	Solution A (%)	Solution B (%)	Elution
0	50	50	equilibration
0–30	50→100	50→0	linear gradient
30–32	100→50	0→50	linear gradient
32–40	50	50	re-equilibration

Chromatograph the *Standard solution*, and record the peak responses as directed for *Procedure*: the resolution, R , between oxandrolone related compound A and oxandrolone related compound B is not less than 1.5, and the resolution, R , between oxandrolone related compound B and oxandrolone is not less than 2.0; the tailing factor is not more than 1.5; and the relative standard deviation for replicate injections is not more than 5.0%.

Change to read:

Procedure—Separately inject equal volumes (about 50 μL) of the *Blank solution*, the *Standard solution*, and the *Test solution* into the chromatograph, record the chromatograms, and measure the peak responses. Calculate the percentage of oxandrolone related compound A in the portion of Oxandrolone taken by the formula:

$$(C/W)(r_U/r_S)$$

in which C is the concentration, in μg per mL, of oxandrolone related compound A in the *Standard solution*; W is the weight, in mg, of Oxandrolone taken to prepare the *Test solution*; r_U is the peak area of oxandrolone related compound A in the chromatogram of the *Test solution*; and r_S is the peak area obtained for oxandrolone related compound A in the chromatogram of the *Standard solution*.

Calculate the percentage of oxandrolone related compound C, methyltestosterone, Δ1-mestalone, specified unknown impurity 1, and each impurity eluting at a relative retention time greater than or equal to 2.2 (relative to retention time of oxandrolone) by the formula:

$$(1/F)(C/W)(r_U/r_S)$$

in which F is the relative response factor (see accompanying table for values); C is the concentration, in μg per mL, of oxandrolone related compound C in the *Standard solution*; W is the weight, in mg, of Oxandrolone taken to prepare the *Test solution*; r_U is the peak area of oxandrolone related compound C, methyltestosterone, Δ1-mestalone, specified unknown impurity 1, or each impurity eluting at a relative retention time greater than or equal to 2.2 in the chromatogram of the *Test solution*; and r_S is the peak area obtained for oxandrolone related compound C in the chromatogram of the *Standard solution*.

Calculate the percentage of each impurity, except oxandrolone related compound A, oxandrolone related compound C, methyltestosterone, Δ1-mestalone, specified unknown impurity 1, and other impurities eluting at relative retention times greater than or equal to 2.2 by the formula:

$$(1/F)(C/W)(r_U/r_S)$$

in which F is the relative response factor for each impurity (see accompanying table for values); C is the concentration, in μg per mL, of [USP Oxandrolone RS](#) in the *Standard solution*; W is the weight, in mg, of Oxandrolone taken to prepare the *Test solution*; r_U is the peak area of each impurity, in the chromatogram of the *Test solution*, other than peak areas of oxandrolone related compound A, oxandrolone related compound C, methyltestosterone, Δ1-mestalone, specified unknown impurity 1, and other impurities eluting at relative retention times greater than or equal to 2.2; and r_S is the peak area obtained for oxandrolone in *Standard solution*. Disregard any peak observed in the chromatogram obtained from the *Blank solution*. Disregard any impurity peak that is less than 0.05%. The impurities meet the requirements specified in the accompanying table.

Compound	Relative Retention Time	Relative Response Factor (F)	Limit (%)
Secodicarboxylic acid ¹	0.46	4.1	0.1