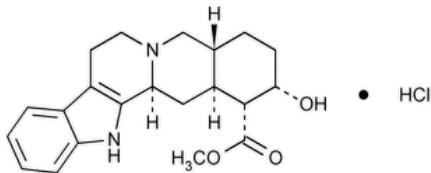


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Yohimbine Hydrochloride



$C_{21}H_{26}N_2O_3 \cdot HCl$ 390.90

17 α -Hydroxy-20- α -yohimban-16- β -carboxylic acid, methyl ester, hydrochloride CAS RN[®]: 65-19-0; UNII: NB2E1YP49F.

» Yohimbine Hydrochloride contains not less than 98.0 percent and not more than 102.0 percent of $C_{21}H_{26}N_2O_3 \cdot HCl$, calculated on the dried basis.

Packaging and storage—Preserve in tight containers, and store at controlled room temperature.

Labeling—Where it is intended for veterinary use only, it is so labeled.

USP REFERENCE STANDARDS (11)—

[USP Yohimbine Hydrochloride RS](#)

Identification—

Change to read:

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

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

Test solution—Dissolve 10 mg of it in 1 mL of methanol, add 1 drop of ammonium hydroxide, and mix.

Application volume: 1 μ L.

Developing solvent system: methylene chloride, methanol, and ammonium hydroxide (90:14:1), in a saturated chamber.

Procedure—Allow the plate to air-dry in a hood. Expose the dry plate for 30 minutes to short-wavelength UV light, then examine under long-wavelength UV light: the size, intensity, and R_f value of the principal spot in the chromatogram obtained from the *Test solution* correspond to those characteristics of the principal spot in the chromatogram obtained from the Standard solution.

Change to read:

C: [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Ultraviolet-Visible Spectroscopy: 197U](#)▲ (CN 1-May-2020) —

Solution: 10 μ g per mL.

Medium: 0.1 N hydrochloric acid in methanol.

D: To 10 mg of it add 3 drops of sulfuric acid. Mix, and add 50 mg of ammonium vanadate: a violet color is produced (differentiation from *strychnine*, which produces a red color). Add 1 mL of water: no color change occurs.

SPECIFIC ROTATION (781S): between +100° and +105°.

Test solution: 10 mg per mL, in water, prepared by warming on a steam bath and allowing to cool.

LOSS ON DRYING (731)—Dry it at 105° for 2 hours: it loses not more than 1.0% of its weight.

Chromatographic purity—Use the chromatogram of the *Assay preparation* obtained as directed in the *Assay*. Calculate the percentage of each impurity in the portion of Yohimbine Hydrochloride taken by the formula:

$$100(r_i/r_s)$$

in which r_i is the response of the individual impurity; and r_s is the sum of all the responses in the chromatogram: not more than 1.0% of any individual impurity is found, and the sum of all the impurities found is not more than 2.0%.

Assay—

Mobile phase—Prepare a mixture of water, dibasic sodium phosphate dihydrate solution (11.88 g per L), and monobasic potassium phosphate solution (9.08 g per L) (355:100:50). Add 4 g of sodium dodecyl sulfate, and mix. Add 285 mL of acetonitrile, and mix. Make adjustments if necessary (see *System Suitability* under [Chromatography \(621\)](#)).

Standard preparation—Quantitatively dissolve an accurately weighed quantity of [USP Yohimbine Hydrochloride RS](#) in methanol to obtain a solution having a known concentration of about 0.2 mg per mL.

Assay preparation—Transfer about 50 mg of Yohimbine Hydrochloride, accurately weighed, to a 100-mL volumetric flask, dilute with methanol to volume, and mix. Transfer 10.0 mL of this solution to a 25-mL volumetric flask, dilute with methanol to volume, and mix.

System suitability solution—Quantitatively dilute an accurately measured volume of the *Standard preparation* with methanol to obtain a solution having a concentration of 0.40 µg of [USP Yohimbine Hydrochloride RS](#) per mL.

Chromatographic system (see [CHROMATOGRAPHY \(621\)](#))—The liquid chromatograph is equipped with a 229-nm detector and a 4-mm × 12.5-cm column that contains 4-µm packing L7. The flow rate is about 2 mL per minute. Chromatograph the *System suitability solution*, and record the peak responses as directed for *Procedure*: the main yohimbine peak gives a measurable response. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure*: the tailing factor is not more than 2.5; and the relative standard deviation for replicate injections is not more than 1%.

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 areas for the major peaks. Calculate the quantity, in mg, of $C_{21}H_{26}N_2O_3 \cdot HCl$ in the portion of Yohimbine Hydrochloride taken by the formula:

$$250C(r_u/r_s)$$

in which C is the concentration, in mg per mL, of [USP Yohimbine Hydrochloride RS](#) in the *Standard preparation*; and r_u and r_s are the yohimbine 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
YOHIMBINE HYDROCHLORIDE	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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