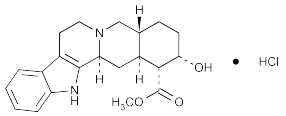
## Yohimbine Hydrochloride



$C_{21}H_{26}N_2O_3 \cdot HCl$ 390.91
17α-Hydroxy-20-α-yohimban-16-β-carboxylic acid, methyl ester, hydrochloride [65-19-0].

» 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—**

**A:** *Infrared Absorption* ⟨197K⟩.

**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 µL.

*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.

**C:** *Ultraviolet Absorption* ⟨197U⟩—

*Solution:* 10 µg 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.

## Yohimbine Injection

» Yohimbine Injection is a sterile solution of Yohimbine Hydrochloride in Water for Injection. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of yohimbine ($C_{21}H_{26}N_2O_3$).

**Packaging and storage—**Preserve in single-dose or multiple-dose *Containers for Injections* as described under *Injections* ⟨1⟩, and store at controlled room temperature.

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

**USP Reference standards** ⟨11⟩**—**
USP Endotoxin RS
USP Yohimbine Hydrochloride RS

**Identification,** *Thin-Layer Chromatographic Identification Test* ⟨201⟩**—**

*Test solution*—Transfer a volume of Injection, equivalent to about 40 mg of yohimbine, to a separator, add 5 mL of a sodium carbonate solution (1 in 20), and extract with four 10-mL portions of chloroform, combining the chloroform extracts in a beaker and evaporating to dryness. Add 20 mL of methanol to the beaker, and swirl to dissolve the residue.

*Standard solution*—Prepare a solution of USP Yohimbine Hydrochloride RS in methanol containing 2 mg per mL.

*Mixed solution:* a mixture of the *Test solution* and the *Standard solution* (1:1).

*Application volume:* 1 µL.

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