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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 as described in *Packaging and Storage Requirements* ⟨659⟩, *Injection Packaging*. 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, *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.

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 spots in the chromatograms obtained from the *Test solution* and the *Mixed solution* correspond to those characteristics of the principal spot in the chromatogram obtained from the *Standard solution*.

Bacterial Endotoxins Test ⟨85⟩—It contains not more than 45.5 USP Endotoxin Units per mg of yohimbine.

Sterility Tests ⟨71⟩—It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined.*

pH ⟨791⟩: between 3.7 and 4.3.

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

Assay—

Diluent—Prepare a mixture of acetonitrile, water, and glacial acetic acid (49:49:2).

Mobile phase—Prepare a mixture of water, acetonitrile, and glacial acetic acid (603:377:20) containing 3.5 g of sodium 1-decanesulfonate in each 1000 mL. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Transfer about 55 mg of USP Yohimbine Hydrochloride RS, accurately weighed, to a 25-mL volumetric flask, add 20 mL of water, warm, and swirl to dissolve. Add 84 mg of anhydrous citric acid, and swirl to dissolve. Allow the solution to cool, adjust with 1 N sodium hydroxide to a pH of 4.0, dilute with water to volume, and mix. Transfer 125.0 µL of this stock solution to a second 25-mL volumetric flask, dilute with *Diluent* to volume, and mix. This solution contains about 0.011 mg of USP Yohimbine Hydrochloride RS per mL.

Resolution solution—Prepare a solution in methanol containing about 0.56 mg of methylparaben and 0.06 mg of propylparaben per mL. Transfer 200 µL of this solution to a 25-mL volumetric flask, add 125.0 µL of the stock solution used to prepare the *Standard preparation,* dilute with *Diluent* to volume, and mix.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 0.25 mg of yohimbine, to a 25-mL volumetric flask, dilute with *Diluent* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 3.9-mm × 15-cm column that contains 5-µm packing L1. The flow rate is about 1 mL per minute. Chromatograph the *Resolution solution*, and record the peak responses as directed for *Procedure:* the relative retention times are about 0.4 for methylparaben, 0.7 for propylparaben, and 1.0 for yohimbine; and the resolution, *R,* between methylparaben and propylparaben and between propylparaben and yohimbine is not less than 2.0. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 25 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 yohimbine ($C_{21}H_{26}N_2O_3$) in each mL of the Injection taken by the formula:

$$(354.45/390.90)(25{,}000C/V)(r_U/r_S)$$

in which 354.45 and 390.90 are the molecular weights of yohimbine and yohimbine hydrochloride, respectively; C is the concentration, in mg per mL, of USP Yohimbine Hydrochloride RS in the *Standard preparation; V* is the volume, in µL, of Injection taken to prepare the *Assay 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 INJECTION	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

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