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Xylazine Injection

» Xylazine Injection is a sterile solution of Xylazine in Water for Injection prepared with the aid of Hydrochloric Acid or a sterile solution of Xylazine Hydrochloride in Water for Injection. It contains the equivalent of not less than 90.0 percent and not more than 110.0 percent of the labeled amount of xylazine ($C_{12}H_{16}N_2S$).

Packaging and storage—Preserve in single-dose or multiple-dose containers.

Labeling—Where it is intended for veterinary use only, the label so states.

USP Reference standards ⟨11⟩—
USP Xylazine Hydrochloride RS

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests ⟨197⟩, Ultraviolet-Visible Spectroscopy: 197U*▲ (CN 1-May-2020) —

Solution: 5 µg per mL.

Medium: 0.1 N hydrochloric acid.

B: Transfer a volume of Injection equivalent to about 50 mg of xylazine to a separator, add 1 mL of sodium carbonate solution (1 in 20), and extract with four 10-mL portions of methylene chloride, combining the methylene chloride extracts in a beaker and evaporating to dryness. Add 10 mL of methanol to the beaker, and swirl to dissolve the residue. The test solution thus obtained responds to *Identification* test *B* under *Xylazine Hydrochloride*.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 1.7 USP Endotoxin Units per mg of xylazine.

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 4.5 and 5.5.

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

Assay—

Mobile phase—Dissolve 6.0 g of sodium 1-heptanesulfonate in 3000 mL of water, adjust to a pH of 3.0 by dropwise addition of phosphoric acid. Add 1000 mL of acetonitrile, mix, and pass through a filter having a 0.5-µm or finer porosity. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed portion of USP Xylazine Hydrochloride RS quantitatively in *Mobile phase* to obtain a solution having a known concentration of about 1.2 mg per mL. Transfer 5.0 mL of this solution to a 50-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. Pass a portion of this solution through a filter having a 0.5-µm or finer porosity, discarding the first 3 mL of the filtrate. Use the clear filtrate as the *Standard preparation*. This solution contains about 0.12 mg of USP Xylazine Hydrochloride RS per mL.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 200 mg of xylazine, to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. Transfer 5.0 mL of this solution to a second 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. Pass a portion of this solution through a filter having a 0.5-µm or finer porosity, discarding the first 3 mL of the filtrate. Use the clear filtrate as the *Assay preparation*.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector, a 2-mm × 2-cm guard column that contains packing L2, and a 4.6-mm × 25-cm analytical column that contains packing L1 and is maintained at a constant temperature of about 40°. The flow rate is about 1 mL per minute. Chromatograph the *Assay preparation*, and record the peak responses as directed for *Procedure:* the resolution, *R*, between the main xylazine peak and the closest eluting other peak, if any, is not less than 2.5; and the tailing factor for the xylazine peak is not more 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%. [Note—After daily use, rinse the column with 100 mL of water and with 100 mL of methanol, and store the column containing methanol.]

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of xylazine ($C_{12}H_{16}N_2S$) in each mL of the Injection taken by the formula:

$$(220.34/256.80)(2000C/V)(r_U/r_S)$$

in which 220.34 and 256.80 are the molecular weights of xylazine and xylazine hydrochloride, respectively; C is the concentration, in mg per mL, of USP Xylazine Hydrochloride RS in the *Standard preparation; V* is the volume, in mL, of Injection taken to prepare the *Assay preparation;*

and r_U and r_S are the areas of the xylazine peak responses in the chromatograms 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
XYLAZINE 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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