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Xylazine Hydrochloride

$C_{12}H_{16}N_2S \cdot HCl$ 256.79

4*H*-1,3-Thiazin-2-amine, *N*-(2,6-dimethylphenyl)-5,6-dihydro-, monohydrochloride.

5,6-Dihydro-2-(2,6-xylidino)-4*H*-1,3-thiazine hydrochloride CAS RN®: 23076-35-9; UNII: NGC3S0882S.

» Xylazine Hydrochloride contains not less than 98.0 percent and not more than 102.0 percent of $C_{12}H_{16}N_2S \cdot HCl$.

Packaging and storage—Preserve in tight containers. Store at 25°, excursions permitted between 15° and 30°.

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⟩, Infrared Spectroscopy: 197K*▲ (CN 1-May-2020) ·

B: *Thin-Layer Chromatographic Identification Test ⟨201⟩*—

Test solution: 5 mg per mL, in methanol.

Developing solvent system: methanol and ammonium hydroxide (98.5:1.5).

Procedure—Separately apply 1 µL of the *Test solution* and the *Standard solution.* Allow the applications to dry with the aid of a stream of nitrogen, develop in a saturated chromatographic chamber, and dry the plate in a current of air: the size, intensity, and R_F value of the principal spot obtained from the *Test solution* correspond to those of the principal spot obtained from the *Standard solution.*

Melting range ⟨741⟩: between 164° and 168°.

pH ⟨791⟩: between 4.0 and 6.0, in a solution (1 in 100).

Loss on drying ⟨731⟩—Dry it at 105° for 4 hours: it loses not more than 1.0% of its weight.

Residue on ignition ⟨281⟩: not more than 0.1%.

Chromatographic purity—Examine the chromatogram obtained from the *Assay preparation.* Calculate the percentage of impurities in the Xylazine Hydrochloride taken by the formula:

$$100r_s/(r_U + r_s)$$

in which r_s is the sum of the areas of all the impurity peaks observed; and r_U is the area of the xylazine peak: the sum of the impurity responses is not greater than 2.0%.

Assay—

Mobile phase—Dissolve 6.0 g of sodium 1-heptanesulfo nate in 2500 mL of water, add 60 mL of glacial acetic acid, dilute with water to 3000 mL, and mix. Prepare a mixture of 2200 mL of this solution and 1800 mL of methanol, 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—Prepare a solution of USP Xylazine Hydrochloride RS in *Mobile phase* having a known concentration of about 1 mg per mL.

Assay preparation—Transfer about 25 mg of Xylazine Hydrochloride, accurately weighed, to a 25-mL volumetric flask, dissolve in and dilute with *Mobile phase* to volume, and mix.

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 L1, and a 3.9-mm × 30-cm analytical column that contains packing L1 and is maintained at a constant temperature of about 40°. The flow rate is about 2.5 mL per minute. 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 acetonitrile 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 $C_{12}H_{16}N_2S \cdot HCl$ in the portion of Xylazine Hydrochloride taken by the formula:

$$25C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Xylazine Hydrochloride RS in the *Standard 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 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

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