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Tripelennamine Hydrochloride Injection

» Tripelennamine Hydrochloride Injection is a sterile solution of Tripelennamine 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 tripelennamine hydrochloride ($C_{16}H_{21}N_3 \cdot HCl$).

Packaging and storage—Preserve in tight, single-dose or multiple-dose containers as described in *Packaging and Storage Requirements* ⟨659⟩, *Injection Packaging*. Store at a controlled room temperature, and protect from light.

Labeling—Label it to indicate that it is for veterinary use only.

USP Reference standards ⟨11⟩—
USP Tripelennamine Hydrochloride RS

Identification—

A: *Identification—Organic Nitrogenous Bases* ⟨181⟩.

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay*.

Bacterial Endotoxins Test ⟨85⟩—It contains not more than 4.6 USP Endotoxin Units per mg of tripelennamine hydrochloride.

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 6.0 and 7.0.

Particulate Matter in Injections ⟨788⟩: meets the requirements for small-volume injections.

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

Assay—

Mobile phase—Dissolve 4.8 g of monobasic potassium phosphate in 880 mL of water in a 2-liter cylinder. Add 720 mL of methanol and 400 mL of acetonitrile, mix, filter, and degas. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed quantity of USP Tripelennamine Hydrochloride RS quantitatively in water to obtain a solution having a known concentration of about 0.02 mg per mL. Protect this solution from light.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 4 mg of tripelennamine hydrochloride, to a 200-mL volumetric flask, dilute with water to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector, a 3.9-mm × 30-mm guard column that contains packing L1, and a 3.9-mm × 30-cm analytical column that contains packing L1. The flow rate is about 1 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%.

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 tripelennamine peaks. Calculate the quantity, in mg, of tripelennamine hydrochloride ($C_{16}H_{21}N_3 \cdot HCl$) in each mL of the Injection taken by the formula:

$$200(C/V)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Tripelennamine 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 peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Topic/Question	Contact	Expert Committee
TRIPELENNAMINE HYDROCHLORIDE 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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