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Bretylium Tosylate Injection

» Bretylium Tosylate Injection is a sterile solution of Bretylium Tosylate in Water for Injection. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{18}H_{24}BrNO_3S$.

Packaging and storage—Preserve in single-dose containers, preferably of Type I glass.

USP Reference standards ⟨11⟩—
USP Bretylium Tosylate RS

Identification—The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that of the *Standard preparation,* both relative to the internal standard, as obtained in the *Assay*.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 0.20 USP Endotoxin Unit per mg of bretylium tosylate.

pH ⟨791⟩: between 3.5 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—

pH 3.1 Tetramethylammonium phosphate buffer—Dissolve 1.38 g of monobasic sodium phosphate and 2.0 mL of 25% tetra-methylammonium hydroxide solution in methanol in 800 mL of water, adjust with phosphoric acid to a pH of 3.1 ± 0.1, dilute with water to 1000 mL, and mix.

Mobile phase—Transfer 15 mL of tetrahydrofuran and 75 mL of acetonitrile to a 1000-mL volumetric flask, and dilute with *pH 3.1 Tetramethylammonium phosphate buffer* to volume.

Standard preparation—Dissolve an accurately weighed quantity of USP Bretylium Tosylate RS in water, and dilute quantitatively, and stepwise if necessary, with water to obtain a solution having a known concentration of about 0.2 mg per mL.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 10 mg of bretylium tosylate, to a 50-mL volumetric flask, dilute with water to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 220-nm detector and a 3.9-mm × 30-cm column that contains packing L1. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the relative retention times are about 0.7 for tosylate and 1.0 for bretylium; the resolution, *R,* between the bretylium and tosylate peaks is not less than 3.0; and the relative standard deviation for replicate injections is not more than 1.4%.

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 $C_{18}H_{24}BrNO_3S$ in each mL of the Injection taken by the formula:

$$50(C/V)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Bretylium Tosylate RS in the *Standard preparation; V* is the volume, in mL, of Injection taken; and r_U and r_S are the bretylium 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
BRETYLIUM TOSYLATE INJECTION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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