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Bretylium Tosylate in Dextrose Injection

» Bretylium Tosylate in Dextrose Injection is a sterile solution of Bretylium Tosylate and Dextrose in Water for Injection. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amounts of bretylium tosylate ($C_{18}H_{24}BrNO_3S$) and dextrose ($C_6H_{12}O_6 \cdot H_2O$). It contains no antimicrobial agents.

Packaging and storage—Preserve in single-dose glass or plastic containers. Glass containers are preferably of Type I or Type II glass.

USP REFERENCE STANDARDS (11)—
[USP Bretylium Tosylate RS](#)

Identification—

- A:** 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 for bretylium tosylate*.
- B:** Add a few drops of a solution (1 in 20) to 5 mL of hot alkaline cupric tartrate TS. A copious red precipitate of cuprous oxide is formed.

BACTERIAL ENDOTOXINS TEST (85)—It contains not more than 0.20 USP Endotoxin Unit per mg of bretylium tosylate.

pH (791): between 3.0 and 6.5.

Other requirements—It meets the requirements under [Injections and Implanted Drug Products \(1\)](#).

Assay for bretylium tosylate—

pH 3.1 Tetramethylammonium phosphate buffer, Mobile phase, Standard preparation, and Chromatographic system—Proceed as directed in the Assay under [Bretylium Tosylate Injection](#).

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.

Procedure—Separately inject equal volumes (about 20 μ L) 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 bretylium tosylate ($C_{18}H_{24}BrNO_3S$) 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 from the *Assay preparation* and the *Standard preparation*, respectively.

Assay for dextrose—Transfer an accurately measured volume of Injection, containing 2 to 5 g of dextrose, to a 100-mL volumetric flask. Add 0.2 mL of 6 N ammonium hydroxide, dilute with water to volume, and mix. Determine the angular rotation in a suitable polarimeter tube (see [Optical Rotation \(781\)](#)). Calculate the percentage (g per 100 mL) of dextrose ($C_6H_{12}O_6 \cdot H_2O$) in the portion of Injection taken by the formula:

$$(100/52.9)(198.17/180.16)AR$$

in which 100 is the percentage; 52.9 is the midpoint of the specific rotation range for anhydrous dextrose, in degrees; 198.17 and 180.16 are the molecular weights for dextrose monohydrate and anhydrous dextrose, respectively; *A* is 100 mm divided by the length of the polarimeter tube, in mm; and *R* is the observed rotation, in degrees.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
BRETYLIUM TOSYLATE IN DEXTROSE INJECTION	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: [Chromatographic Database](#)

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