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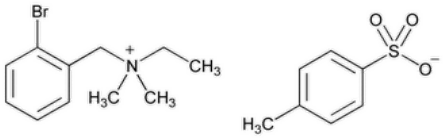
Bretylium Tosylate



$C_{18}H_{24}BrNO_3S$ 414.36

Benzenemethanaminium, 2-bromo-*N*-ethyl-*N*,*N*-dimethyl-, salt with 4-methylbenzenesulfonic acid (1:1).

(*o*-Bromobenzyl)ethyldimethylammonium *p*-toluenesulfonate CAS RN®: 61-75-6; UNII: 78ZP3YR353.

» Bretylium Tosylate contains not less than 98.0 percent and not more than 101.0 percent of $C_{18}H_{24}BrNO_3S$, calculated on the dried basis.

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

USP Reference standards ⟨11⟩—

USP Bretylium Tosylate RS

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Infrared Spectroscopy: 197K.*▲ (CN 1-May-2020)

B: The retention time of the major peak in the chromatogram of the *Test solution* corresponds to that in the chromatogram of the *Standard solution,* as obtained in the test for *Related compounds.*

Loss on drying ⟨731⟩—Dry it in vacuum at 75° for 2 hours: it loses not more than 3.0% of its weight.

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

Related compounds—

0.01 M Sodium 1-octanesulfonate solution—Dissolve 1.0814 g of 1-sodium octanesulfonate in 500 mL of water.

Mobile phase—Prepare a mixture of *0.01 M Sodium 1-octanesulfonate solution,* acetonitrile, glacial acetic acid, and triethylamine (81:19:2:0.5). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard solution—Dissolve an accurately weighed quantity of USP Bretylium Tosylate RS in *Mobile phase,* and dilute quantitatively, and stepwise if necessary, to obtain a solution having a known concentration of about 20 µg per mL.

Test solution—Transfer about 200 mg of Bretylium Tosylate, accurately weighed, to a 100-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 265-nm detector and a 4.6-mm × 25-cm column that contains packing L11. The flow rate is about 1.9 mL per minute. Chromatograph the *Standard solution,* record the chromatograms, and record the peak responses as directed for *Procedure:* the relative standard deviation for replicate injections is not more than 3.0%.

Procedure—Separately inject equal volumes (about 30 µL) of the *Test solution* and the *Standard solution* into the chromatograph, record the chromatograms, and measure the peak responses. The relative retention times are about 0.25, 0.74, 1.0, 1.27, 1.40 for tosylate ion, *o*-bromobenzyldimethylamine, bretylium, *m*-bromobenzyldimethylamine, and *p*-bromobenzyldimethylamine, respectively. The sum of the responses for all the peaks, excluding those of the bretylium and tosylate peaks, from the *Test solution* is not more than two times the bretylium response from the *Standard solution* (2%); and no individual peak response is greater than that of the bretylium peak from the *Standard solution* (1%).

Assay—Dissolve about 300 mg of Bretylium Tosylate, accurately weighed, in 50 mL of dioxane in a conical flask. Add 2 drops of crystal violet TS, and titrate with 0.025 N perchloric acid in dioxane to a blue-green endpoint. Perform a blank determination (see *Titrimetry* ⟨541⟩), and make any necessary correction. Each mL of 0.025 N perchloric acid is equivalent to 10.36 mg of $C_{18}H_{24}BrNO_3S$.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
BRETYLIUM TOSYLATE	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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