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Tromethamine for Injection

» Tromethamine for Injection is a sterile, lyophilized mixture of tromethamine with Potassium Chloride and Sodium Chloride. It contains not less than 93.0 percent and not more than 107.0 percent of the labeled amount of tromethamine ($C_4H_{11}NO_3$), and not less than 90.0 percent and not more than 110.0 percent of the labeled amounts of potassium chloride (KCl) and of sodium chloride (NaCl).

Packaging and storage—Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging, Packaging for constitution*.

Constituted solution—At the time of use, it meets the requirements for *Injections and Implanted Drug Products ⟨1⟩, Specific Tests, Completeness and clarity of solutions*.

Identification—

A: The IR absorption spectrum of a mineral oil dispersion of it exhibits maxima only at the same wavelengths as that of a similar preparation of USP Tromethamine RS.

B: A solution, prepared as directed in the labeling, responds to the tests for *Chloride ⟨191⟩*, for *Sodium ⟨191⟩*, and for *Potassium ⟨191⟩*.

Bacterial Endotoxins Test ⟨85⟩—It contains not more than 0.03 USP Endotoxin Unit per mg of tromethamine.

pH ⟨791⟩: between 10.0 and 11.5, in a solution prepared as directed in the labeling.

Water Determination, *Method I* ⟨921⟩—Add 5 mL of glacial acetic acid prior to the titration: the content is not more than 1.0%.

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

Potassium chloride content—

Standard solutions—Prepare five standard solutions (*1*, *2*, *3*, *4*, and *5*) each containing 0.60 mEq of sodium (35 mg of sodium chloride) per liter, and to the solutions add, respectively, 0-, 2-, 4-, 6-, and 8-mg supplements of potassium, in the form of the chloride, per L. If necessary, because of changes in the sensitivity of the photometer, vary the levels of concentration of the potassium, keeping the ratios between solutions approximately as given.

Standard graph—Set a suitable flame photometer for maximum emittance at a wavelength of 766 nm to 767 nm. (The exact wavelength setting will vary slightly with the instrument.) Adjust the instrument to zero emittance with solution *1*. Then adjust the instrument to 100% emittance with solution *5*. Read the percentage emittance of solutions *2*, *3*, and *4*. Plot the observed emittance of solutions *2*, *3*, *4*, and *5* as the ordinate and the concentration, in µg per mL, of potassium as the abscissa on arithmetic coordinate paper.

Procedure—Dissolve the entire contents of 1 container of Tromethamine for Injection in sufficient water, and dilute quantitatively and stepwise with water to obtain a solution containing about 4 µg of potassium per mL, or a quantity corresponding to the concentration of the *Standard solutions.* Adjust the instrument to zero emittance with solution *1* and to 100% emittance with solution *5*. Read the percentage emittance of the test solution. By reference to the *Standard graph*, determine the concentration, in µg per mL, of potassium in the test solution, apply the dilution factor, and calculate the quantity, in mg, of potassium in the container of Tromethamine for Injection. Each mg of potassium is equivalent to 1.907 mg of potassium chloride (KCl).

Sodium chloride content—Proceed as directed under *Potassium chloride content*, with the following modifications: (1) Prepare the *Standard solutions* to contain 0, 2, 4, 6, and 8 mg of sodium, in the form of the chloride, per 1000 mL, without added potassium; (2) prepare the *Standard graph* with the flame photometer set at 588 nm to 589 nm; and (3) under *Procedure* read “sodium” for “potassium” throughout. Each mg of sodium is equivalent to 2.542 mg of sodium chloride (NaCl).

Other requirements—It meets the requirements for *Sterility Tests ⟨71⟩*, *Uniformity of Dosage Units ⟨905⟩*, and *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*.

Assay for tromethamine—Dissolve the entire contents of 1 container of Tromethamine for Injection in sufficient water, diluting with water to an accurately measured volume to obtain a solution containing about 36 mg of tromethamine per mL. Transfer to a beaker an accurately measured volume of the solution, equivalent to about 180 mg of tromethamine, dilute with water to about 100 mL, add bromocresol purple TS, and titrate with 0.1 N hydrochloric acid VS to a yellow endpoint. Each mL of 0.1 N hydrochloric acid is equivalent to 12.11 mg of $C_4H_{11}NO_3$.

Topic/Question	Contact	Expert Committee
TROMETHAMINE FOR 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

Most Recently Appeared In:
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