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Trimethobenzamide Hydrochloride Injection

» Trimethobenzamide Hydrochloride Injection is a sterile solution of Trimethobenzamide Hydrochloride in Water for Injection. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of $C_{21}H_{28}N_2O_5 \cdot HCl$.

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

USP Reference standards ⟨11⟩—
USP Trimethobenzamide Hydrochloride RS

Identification—

A: It meets the requirements of *Identification* test *A* under *Trimethobenzamide Hydrochloride Capsules*.

B: Transfer a volume of Injection, equivalent to about 100 mg of trimethobenzamide hydrochloride, to a separator containing 20 mL of water. Add 2 mL of 1 N sodium hydroxide, and proceed as directed in *Identification* test *B* under *Trimethobenzamide Hydrochloride Capsules*, beginning with "Extract with 15 mL of chloroform."

C: Dilute a portion of Injection quantitatively and stepwise with methanol to obtain a solution containing 2.5 mg of trimethobenzamide hydrochloride per mL: this solution meets the requirements of the *Thin-layer Chromatographic Identification Test ⟨201⟩*, a solvent system consisting of a mixture of ethyl acetate, alcohol, and ammonium hydroxide (90:10:5) being used.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 1.80 USP Endotoxin Units per mg of trimethobenzamide hydrochloride.

pH ⟨791⟩: between 4.5 and 5.5.

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

Assay—Transfer to a suitable separator an accurately measured volume of Injection, equivalent to about 200 mg of trimethobenzamide hydrochloride. Add 5 mL of water and 3 mL of dilute hydrochloric acid (1 in 12), and extract with four 20-mL portions of ether, collecting the ether extracts in a second separator, and transferring the aqueous layer to a 500-mL volumetric flask. Wash the combined ether extracts with one 20-mL portion of water, transfer the aqueous layer to the 500-mL volumetric flask, dilute with water to volume, and mix. Dilute 5.0 mL of the solution with dilute hydrochloric acid (1 in 120) to 100.0 mL, and mix. Concomitantly determine the absorbances of this solution and a Standard solution of USP Trimethobenzamide Hydrochloride RS in the same medium having a known concentration of about 20 µg per mL, in 1-cm cells at the wavelength of maximum absorbance at about 258 nm, with a suitable spectrophotometer, using dilute hydrochloric acid (1 in 120) as the blank. Calculate the quantity, in mg, of $C_{21}H_{28}N_2O_5 \cdot HCl$ in each mL of the Injection taken by the formula:

$$(10C/V)(A_U/A_S)$$

in which C is the concentration, in µg per mL, of USP Trimethobenzamide Hydrochloride RS in the Standard solution, V is the volume, in mL, of Injection taken, and A_U and A_S are the absorbances of the solution from the Injection and the Standard solution, respectively.

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

Topic/Question	Contact	Expert Committee
TRIMETHOBENZAMIDE 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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