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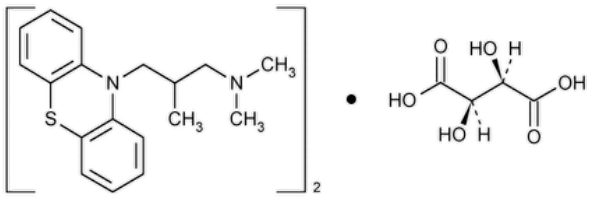
Trimeprazine Tartrate



$(C_{18}H_{22}N_2S)_2 \cdot C_4H_6O_6$ 746.98

10*H*-Phenothiazine-10-propanamine *N*,*N*,β-trimethyl-, [*R*-(*R**,*R**)]-2,3-dihydroxybutanedioate (2:1).

10-[3-(Dimethylamino)-2-methylpropyl]phenothiazine tartrate (2:1) CAS RN®: 4330-99-8; 41375-66-0; UNII: 362NW1LD6Z.

» Trimeprazine Tartrate contains not less than 98.0 percent and not more than 101.0 percent of $(C_{18}H_{22}N_2S)_2 \cdot C_4H_6O_6$, calculated on the dried basis.

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards ⟨11⟩—

USP Trimeprazine Tartrate RS

[Note—Throughout the following procedures, protect test or assay specimens, the Reference Standard, and solutions containing them, by conducting the procedures without delay, under subdued light, or using low-actinic glassware.]

Identification—

Change to read:

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

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation* obtained as directed in the *Assay*.

C: Prepare a solution of it in methanol containing 6 mg in each 5 mL. Proceed as directed under *Thin-layer Chromatographic Identification Test* ⟨201⟩, applying 5 µL of this solution and 5 µL of a similar solution of USP Trimeprazine Tartrate RS, using as the solvent system a mixture of 0.15 mL of ammonium hydroxide and 100 mL of acetone. Locate the spots on the plate by lightly spraying with iodoplatinic acid solution [prepared by dissolving 100 mg of chloroplatinic acid in 1 mL of 1 N hydrochloric acid, adding 25 mL of potassium iodide solution (1 in 25), diluting with water to 100 mL, and adding 0.5 mL of formic acid]: the R_F value of the principal spot obtained from the test solution corresponds to that obtained from the Standard solution.

Loss on drying ⟨731⟩—Dry it in vacuum at 60° for 4 hours: it loses not more than 0.5% of its weight.

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

Ordinary impurities ⟨466⟩—

Test solution: methanol.

Standard solution: methanol.

Eluant: a mixture of ethyl acetate saturated with ammonium hydroxide and ether (1:1).

Visualization: 1.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of 0.005 M sodium 1-heptanesulfonate in methanol, water, and acetic acid (65:34:1). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed quantity of USP Trimeprazine Tartrate RS in *Mobile phase*, and dilute quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution having a known concentration of about 0.031 mg per mL.

Assay preparation—Transfer about 62 mg of Trimeprazine Tartrate, accurately weighed, to a 100-mL volumetric flask, dissolve in and dilute with *Mobile phase* to volume. Transfer 5 mL of this solution into a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 3.9-mm × 30-cm column that contains packing L1. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the capacity factor, *k'*, is not less than 2.0 and not more than 5.0, the column efficiency is not less than 1200 theoretical plates, the tailing factor is not more than 3.5, and the relative standard deviation for replicate injections is not more than 0.6%.

Procedure—Separately inject equal volumes (about 25 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 $(C_{18}H_{22}N_2S)_2 \cdot C_4H_6O_6$ in the portion of Trimeprazine Tartrate taken by the formula:

$$2000C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Trimeprazine Tartrate RS in the *Standard preparation*, and r_U and r_S are the 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
TRIMEPRAZINE TARTRATE	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:
Pharmacopeial Forum: Volume No. Information currently unavailable

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