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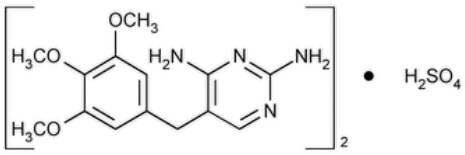
Trimethoprim Sulfate



$(C_{14}H_{18}N_4O_3)_2 \cdot H_2SO_4$ 678.71

2,4-Pyrimidinediamine, 5-[(3,4,5-trimethoxyphenyl)methyl]-, sulfate (2:1) (salt).

2,4-Diamino-5-[(3,4,5-trimethoxybenzyl)pyrimidine]-, sulfate (2:1) (salt) CAS RN®: 56585-33-2; UNII: E377MF8EQ8.

» Trimethoprim Sulfate contains not less than 98.5 percent and not more than 101.0 percent of $(C_{14}H_{18}N_4O_3)_2 \cdot H_2SO_4$, calculated on the anhydrous basis.

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

USP Reference standards ⟨11⟩—

USP Trimethoprim RS

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests* ⟨197⟩, *Ultraviolet-Visible Spectroscopy: 197U*▲ (CN 1-May-2020) —

Solution—Transfer about 100 mg of it, accurately weighed, to a 100-mL volumetric flask, dissolve in 25 mL of alcohol, dilute with 0.1 N sodium hydroxide to volume, and mix.

Medium—Dilute the *Solution* quantitatively and stepwise with 0.1 N sodium hydroxide to obtain a solution containing a known concentration of about 20 µg per mL.

Absorptivity, at about 287 nm, calculated on the anhydrous basis, is between 83.0% and 86.4% of USP Trimethoprim RS.

B: It responds to the tests for *Sulfate* ⟨191⟩.

Melting range ⟨741⟩**:** between 210° and 215°.

pH ⟨791⟩**:** between 7.5 and 8.5, in a solution (0.5 mg per mL).

Water Determination, *Method I* ⟨921⟩ **:** not more than 3.0%.

Chromatographic purity—

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture.

Diluent—Prepare a mixture of chloroform and methanol (9:1).

Test solution—Transfer about 20 mg of Trimethoprim Sulfate, accurately weighed, to a 10-mL volumetric flask, add 4 mL of glacial acetic acid, and swirl to dissolve. Dilute with *Diluent* to volume, and mix.

Standard solution—Dissolve an accurately weighed quantity of USP Trimethoprim RS in *Diluent.* Dilute an accurately measured volume of this solution quantitatively, and stepwise if necessary, with *Diluent* to obtain a solution having a known concentration of 0.02 mg per mL.

Application volume: 10 µL.

Developing solvent system: a mixture of chloroform, methanol, and 6 N ammonium hydroxide (95:7.5:1).

Procedure—Proceed as directed for *Thin-Layer Chromatography* under *Chromatography* ⟨621⟩. Spray the plate with a freshly prepared mixture of 1.9 g of ferric chloride in 20 mL of water and 0.5 g of potassium ferricyanide in 10 mL of water. Compare the intensities of any secondary spots observed in the chromatogram of the *Test solution* with that of the principal spot in the chromatogram of the *Standard solution:* no secondary spot in the chromatogram obtained from the *Test solution* is larger or more intense than the principal spot obtained from the *Standard solution* (0.1%); and the sum of the intensities of the secondary spots obtained from the *Test solution* corresponds to not more than 0.5%.

Assay—Transfer about 800 mg of Trimethoprim Sulfate, accurately weighed, to a 50-mL conical flask, add about 60 mL of glacial acetic acid, and titrate with 0.1 N perchloric acid VS, determining the endpoint potentiometrically. Perform a blank determination, and make any necessary

correction. Each mL of 0.1 N perchloric acid is equivalent to 67.87 mg of $(C_{14}H_{18}N_4O_3)_2 \cdot H_2SO_4$.

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

Topic/Question	Contact	Expert Committee
TRIMETHOPRIM SULFATE	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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