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Trimethoprim Tablets

» Trimethoprim Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{14}H_{18}N_4O_3$.

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

USP Reference standards ⟨11⟩—

USP Trimethoprim RS

Identification—Triturate a quantity of finely powdered Tablets, equivalent to about 100 mg of trimethoprim, with 2.5 mL of methanol. Add 2.5 mL of chloroform, triturate again, and centrifuge. Apply 25 µL of this test solution and 25 µL of a Standard solution of USP Trimethoprim RS in a mixture of methanol and chloroform (1:1) containing 20 mg per mL to a suitable thin-layer chromatographic plate (see *Chromatography ⟨621⟩*) coated with a 0.25-mm layer of chromatographic silica gel mixture. Allow the spots to dry, and develop the chromatogram in an unsaturated chamber with a solvent system consisting of a mixture of chloroform, methanol, and ammonium hydroxide (95:7.5:1), until the solvent front has moved approximately 15 cm from the origin. Remove the plate from the developing chamber, mark the solvent front, and allow the solvent to evaporate. Locate the spots on the plate by viewing under short-wavelength UV light: the R_F value of the principal spot obtained from the test solution corresponds to that obtained from the Standard solution.

Dissolution ⟨711⟩—

Medium: 0.01 N hydrochloric acid; 900 mL.

Apparatus 2: 50 rpm.

Time: 45 minutes.

Procedure—Determine the amount of $C_{14}H_{18}N_4O_3$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 271 nm of filtered portions of the solution under test, suitably diluted with 0.01 N hydrochloric acid to a concentration of about 20 µg per mL, in comparison with a Standard solution having a known concentration of USP Trimethoprim RS in the same *Medium*.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{14}H_{18}N_4O_3$ is dissolved in 45 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of 1% glacial acetic acid in water (v/v) and acetonitrile (21:4). Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard preparation—Using an accurately weighed quantity of USP Trimethoprim RS, prepare a solution in methanol having a known concentration of about 0.2 mg per mL.

Assay preparation—Weigh and finely powder not less than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 100 mg of trimethoprim, to a 100-mL volumetric flask, add 50 mL of methanol, and sonicate for 5 minutes, with intermittent swirling. Dilute with methanol to volume, and mix. Centrifuge, pipet 10 mL of the supernatant into a 50-mL volumetric flask, dilute with methanol to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 254-nm detector and a 4.2-mm × 25-cm column that contains packing L1. The flow rate is about 2 mL per minute. Chromatograph five replicate injections of the *Standard preparation*, and measure the peak responses as directed for *Procedure:* the relative standard deviation is not more than 2.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the analyte peak. Calculate the quantity, in mg, of $C_{14}H_{18}N_4O_3$, in the portion of Tablets taken by the formula:

$$500C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Trimethoprim 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
TRIMETHOPRIM TABLETS	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

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