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Sulfadoxine and Pyrimethamine Tablets

DEFINITION

Sulfadoxine and Pyrimethamine Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of sulfadoxine ($C_{12}H_{14}N_4O_4S$) and NLT 90.0% and NMT 110.0% of the labeled amount of pyrimethamine ($C_{12}H_{13}ClN_4$).

IDENTIFICATION

• **A.** The retention times of the major peaks of the *Sample solution* correspond to those of the *Standard solution* for pyrimethamine and sulfadoxine, as obtained in the *Assay*.

• **B.**

Diluent: Ammonium hydroxide and methanol (1 in 50)

Standard solution A: 10 mg/mL of USP Sulfadoxine RS in *Diluent*

Standard solution B: 0.5 mg/mL of USP Pyrimethamine RS in *Diluent*

Sample solution: Vigorously shake 700 mg of finely ground Tablet powder with 50 mL of *Diluent* for 3 min, and filter.

Chromatographic system

(See *Chromatography ⟨621⟩, Thin-Layer Chromatography*.)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 10 µL

Developing solvent system: Heptane, chloroform, solution of methanol in alcohol (1 in 20), and glacial acetic acid (4:4:4:1)

Analysis

Samples: *Standard solution A*, *Standard solution B*, and *Sample solution*

Allow the solvent front to move about two-thirds of the length of the plate, remove the plate, dry, and examine under short-wavelength UV light.

Acceptance criteria: The R_F values of the principal spots from the *Sample solution* correspond to the R_F values of the principal spots from the corresponding *Standard solution*.

ASSAY

• **Procedure**

Solution A: 1 mL of phosphoric acid in 1000 mL of water

Mobile phase: Acetonitrile and *Solution A* (17:83)

Standard solution: 0.4 mg/mL of USP Sulfadoxine RS and 0.02 mg/mL of USP Pyrimethamine RS prepared as follows. Transfer suitable amounts of USP Sulfadoxine RS and USP Pyrimethamine RS to a suitable volumetric flask. Dissolve in acetonitrile using about 17% of the final flask volume, then dilute with *Solution A* to volume.

Sample stock solution: Transfer an equivalent of about 200 mg of sulfadoxine and 10 mg of pyrimethamine from NLT 10 finely powdered Tablets to a 100-mL volumetric flask. Add about 28 mL of acetonitrile and sonicate for about 30 min. Allow to cool and dilute with *Solution A* to volume.

Sample solution: Nominally 0.4 mg/mL of sulfadoxine and 0.02 mg/mL of pyrimethamine in *Mobile phase* from *Sample stock solution*. Pass through a PVDF filter of 0.45-µm pore size. Discard the first 5 mL and use the remaining filtrate.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 230 nm

Column: 2.0-mm × 10-cm; 3-µm packing L11

Flow rate: 0.3 mL/min

Injection volume: 5 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 1.5 between pyrimethamine and sulfadoxine

Tailing factor: NMT 1.6 for sulfadoxine; NMT 2.0 for pyrimethamine

Relative standard deviation: NMT 2.0% for both sulfadoxine and pyrimethamine

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amounts of sulfadoxine ($C_{12}H_{14}N_4O_4S$) and pyrimethamine ($C_{12}H_{13}ClN_4$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of sulfadoxine or pyrimethamine from the *Sample solution*

r_S = peak response of sulfadoxine or pyrimethamine from the *Standard solution*

C_S = concentration of USP Sulfadoxine RS or USP Pyrimethamine RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of sulfadoxine or pyrimethamine in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0% each for sulfadoxine and pyrimethamine

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Medium: *pH 6.8 Phosphate Buffer*, prepared as directed in *Reagents, Indicators, and Solutions—Buffer Solutions*; 1000 mL

Apparatus 2: 75 rpm

Time: 30 min

Analysis: Determine the percentage of the labeled amounts of sulfadoxine ($C_{12}H_{14}N_4O_4S$) and pyrimethamine ($C_{12}H_{13}ClN_4$) dissolved, using the procedure set forth in the *Assay*, making any necessary modifications.

Tolerances: NLT 60% (*Q*) of the labeled amounts each of sulfadoxine ($C_{12}H_{14}N_4O_4S$) and pyrimethamine ($C_{12}H_{13}ClN_4$) is dissolved.

• **Uniformity of Dosage Units** ⟨905⟩, *Content Uniformity*: Meet the requirements with respect to sulfadoxine and to pyrimethamine

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed, light-resistant containers.

• **USP Reference Standards** ⟨11⟩

USP Pyrimethamine RS

USP Sulfadoxine RS

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

Topic/Question	Contact	Expert Committee
SULFADOXINE AND PYRIMETHAMINE 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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