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Pyrimethamine Tablets

(*This monograph has been updated to the current USP style. No revisions or changes to tests have been made.*)

DEFINITION
Pyrimethamine Tablets contain NLT 93.0% and NMT 107.0% of the labeled amount of pyrimethamine ($C_{12}H_{13}ClN_4$).

IDENTIFICATION

• **A.** The UV absorption spectrum of the *Sample solution* exhibits maxima at the same wavelengths as that of a similar solution of USP Pyrimethamine RS, as obtained in the *Assay*.

• **B. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197K

Sample: Nominally equivalent to about 250 mg of pyrimethamine from powdered Tablets

Analysis: Add 25 mL of acetone to the *Sample*, boil for 2 min, and filter through a sintered-glass crucible. Repeat this treatment three times with 25-mL portions of acetone. Evaporate the combined filtrates carefully on a steam bath with the aid of a current of air to dryness.

Acceptance criteria: The residue meets the requirements in 197K, and melts at 237°–242° (see *Melting Range or Temperature ⟨741⟩*).

ASSAY

• **Procedure**

Standard stock solution: Prepare as directed for the *Standard preparation* in *Salts of Organic Nitrogenous Bases ⟨501⟩*.

Standard solution: Transfer 5.0 mL of the *Standard stock solution* to a 200-mL volumetric flask and dilute with 0.5 N sulfuric acid to volume.

Sample stock solution: Prepare as directed for the *Assay preparation* in *Salts of Organic Nitrogenous Bases ⟨501⟩*.

Sample solution: Transfer 5.0 mL of the *Sample stock solution* to a 200-mL volumetric flask and dilute with 0.5 N sulfuric acid to volume.

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum absorbance at about 273 nm

Cell: 1 cm

Blank: 0.5 N sulfuric acid

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of pyrimethamine ($C_{12}H_{13}ClN_4$) in the portion of Tablets taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

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

Acceptance criteria: 93.0%–107.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 2: 50 rpm

Time: 45 min

Standard solution: A known concentration of USP Pyrimethamine RS in *Medium*

Sample solution: Filter portions of the solution under test, and suitably dilute with *Medium* if necessary.

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum absorbance at about 273 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the labeled amount of pyrimethamine ($C_{12}H_{13}ClN_4$) dissolved.

Tolerances: NLT 75% (*Q*) of the labeled amount of pyrimethamine ($C_{12}H_{13}ClN_4$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩**

Procedure for content uniformity

Standard solution: 10 µg/mL of USP Pyrimethamine RS in 0.1 N hydrochloric acid

Sample solution: Nominally 10 µg/mL of pyrimethamine, prepared as follows. Transfer 1 Tablet to a 100-mL volumetric flask, add 25 mL of 0.1 N hydrochloric acid, warm the flask on a steam bath for 5 min, cool, dilute with 0.1 N hydrochloric acid to volume, mix, and filter, discarding the first few milliliters of the filtrate. Pipet a portion of the clear filtrate, equivalent to about 2.5 mg of pyrimethamine, into a 250-mL volumetric flask, and dilute with 0.1 N hydrochloric acid to volume.

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum absorbance at about 273 nm

Cell: 1 cm

Blank: 0.1 N hydrochloric acid

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of pyrimethamine ($C_{12}H_{13}ClN_4$) in the Tablet taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

C_U = nominal concentration of pyrimethamine in the *Sample solution* (µg/mL)

Acceptance criteria: Meet the requirements

ADDITIONAL REQUIREMENTS

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

• **USP Reference Standards ⟨11⟩**

USP Pyrimethamine RS

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

Topic/Question	Contact	Expert Committee
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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