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Pyrimethamine Compounded Oral Suspension

DEFINITION

Pyrimethamine Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of pyrimethamine ($C_{12}H_{13}ClN_4$).

Prepare Pyrimethamine Compounded Oral Suspension 2 mg/mL as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).

Pyrimethamine powder	200 mg
Vehicle: a 1:1 mixture of Methylcellulose 1% Solution, and Syrup, NF, a sufficient quantity to make	100 mL

Calculate the required quantity of each ingredient for the total amount to be prepared. Place *Pyrimethamine powder* in a suitable mortar. Add 2 mL of the *Vehicle*, and triturate to make a smooth paste. Add an additional 10 mL of the *Vehicle* to the paste, and levigate to form a suspension. Add increasing volumes of *Vehicle* to make a liquid that is pourable. Transfer the contents of the mortar to a calibrated bottle. Add enough of the *Vehicle* to bring to final volume, and mix well.

ASSAY

• PROCEDURE

Mobile phase: Acetonitrile and 50 mM anhydrous sodium acetate (40:60). Pass through a PVDF membrane filter of 0.45- μ m pore size, and degas.

System suitability solution: 0.20 mg/mL of [USP Pyrimethamine RS](#) (previously dried) and 0.10 mg/mL of [USP Phenacetin RS](#) (previously dried) in methanol

Standard solution: 0.20 mg/mL of [USP Pyrimethamine RS](#) (previously dried) in methanol

Sample solution: Shake thoroughly by hand each bottle of Oral Suspension. Prepare 0.20 mg/mL of pyrimethamine from Oral Suspension in methanol. Sonicate, and mix on a vortex mixer.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 230 nm

Column: 4.6-mm \times 15-cm; 5- μ m packing L1

Autosampler temperature: 10°

Flow rate: 1.5 mL/min

Injection volume: 10 μ L

System suitability

Samples: System suitability solution and Standard solution

[**NOTE**—The relative retention times for phenacetin and pyrimethamine are about 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 6.0 between the pyrimethamine and phenacetin peaks, System suitability solution

Column efficiency: NLT 8000 theoretical plates, System suitability solution

Tailing factor: NMT 1.5, System suitability solution

Relative standard deviation: NMT 2.0% for replicate injections, Standard solution

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 Oral Suspension taken:

$$\text{Result} = (r_u/r_s) \times (C_s/C_u) \times 100$$

r_u = peak response of pyrimethamine from the *Sample solution* r_s = peak response of pyrimethamine from 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:** 90.0%–110.0%**SPECIFIC TESTS**

- [pH \(791\)](#): 6.6–7.6

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store in a refrigerator or at controlled room temperature.
- **BEYOND-USE DATE:** NMT 90 days after the date on which it was compounded, when stored in a refrigerator or at controlled room temperature
- **LABELING:** Label it to indicate that it is to be well shaken before use, protect from light, and to state the *Beyond-Use Date*.
- [USP Reference Standards \(11\)](#).

[USP Phenacetin RS](#)[USP Pyrimethamine RS](#)**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
PYRIMETHAMINE COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

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