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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<sub>12</sub>H<sub>13</sub>ClN<sub>4</sub>).  
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, <i>NF</i> , 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-µm 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 × 15-cm; 5-µm packing L1

**Autosampler temperature:** 10°

**Flow rate:** 1.5 mL/min

**Injection volume:** 10 µL

**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<sub>12</sub>H<sub>13</sub>ClN<sub>4</sub>) in the portion of Oral Suspension taken:

Result = (r<sub>U</sub>/r<sub>S</sub>) × (C<sub>S</sub>/C<sub>U</sub>) × 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	<a href="#">Brian Serumaga</a> Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	CMP2020 Compounding 2020

**Chromatographic Database Information:** [Chromatographic Database](#)

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