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Pyrazinamide Compounded Oral Suspension

DEFINITION

Pyrazinamide Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of pyrazinamide ($C_5H_5N_3O$).

Prepare Pyrazinamide Compounded Oral Suspension 10 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Pyrazinamide tablets[a] equivalent to	1 g of pyrazinamide
Vehicle: a 1:1 mixture of Ora-Sweet[b] (regular or sugar-free) and Ora-Plus,[b] a sufficient quantity to make	100 mL

[a] Pyrazinamide 500-mg tablets, Mikart Inc., Atlanta, GA.

[b] Paddock Laboratories, Minneapolis, MN.

Calculate the required quantity of each ingredient for the total amount to be prepared. Place the required number of *Pyrazinamide tablets* in a suitable mortar, and comminute to a fine powder. Add the *Vehicle* in small portions, and triturate to make a smooth paste. Add increasing volumes of the *Vehicle* to make a pyrazinamide liquid that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough of the *Vehicle* to bring to final volume, and mix well.

ASSAY

• **Procedure**

Solution A: 10 mM monobasic sodium phosphate, adjusted with phosphoric acid to a pH of 3.5

Mobile phase: Acetonitrile and *Solution A* (10:90). Filter and degas.

Standard stock solution: 1.0 mg/mL of USP Pyrazinamide RS in methanol

Standard solution: Pipet 1.0 mL of the *Standard stock solution* into a 10-mL volumetric flask, and dilute with methanol to volume to obtain a solution with a nominal concentration of 0.1 mg/mL of pyrazinamide.

Sample solution: Shake thoroughly by hand each bottle of Oral Suspension. Pipet 1.0 mL of sample into a 100-mL volumetric flask, and dilute with methanol to volume to obtain a solution having a nominal concentration of 0.1 mg/mL.

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm × 25-cm; 5-µm packing L7

Flow rate: 0.8 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for pyrazinamide is about 6.5 min.]

Suitability requirements

Column efficiency: NLT 8000 theoretical plates

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of pyrazinamide ($C_5H_5N_3O$) in the portion of Oral Suspension taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.9–5.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store at controlled room temperature or in a refrigerator.

• **Beyond-Use Date:** NMT 60 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, and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩
USP Pyrazinamide RS

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

Topic/Question	Contact	Expert Committee
PYRAZINAMIDE 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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