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Azathioprine Compounded Oral Suspension

DEFINITION

Azathioprine Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of azathioprine ($C_9H_7N_7O_2S$).

Prepare Azathioprine Compounded Oral Suspension 50 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Azathioprine	5 g
Vehicle: a 1:1 mixture of Vehicle for Oral Solution, (regular or sugar-free), *NF* and Vehicle for Oral Suspension, *NF*, a sufficient quantity to make	100 mL

If using tablets, comminute them to a fine powder in a suitable mortar, or add *Azathioprine* powder to the mortar. Add about 10 mL of the *Vehicle*, and mix to a uniform paste. Add the *Vehicle* in small portions almost to volume, and mix thoroughly after each addition. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add sufficient *Vehicle* to bring to final volume, and mix well.

[**Caution—**Avoid skin contact or inhalation of azathioprine by using protective gloves and a fume hood or surgical mask.]

ASSAY

• **Procedure**

Mobile phase: Dissolve 1.1 g of sodium-1-heptanesulfonate in 700 mL of water, and add 300 mL of methanol. Adjust with 1 N hydrochloric acid to a pH of 3.5.

Standard solution: Transfer 25 mg of USP Azathioprine RS to a 50-mL volumetric flask. Add 15 mL of methanol and 0.5 mL of ammonium hydroxide to the flask, swirl, and sonicate for 2 min. Dilute with methanol to volume. Transfer 10 mL of this solution to a 50-mL volumetric flask, and dilute with water to volume.

Sample solution: Agitate the container of Oral Suspension for 30 min on a rotating mixer, remove a 5-mL sample, and store in a clear glass vial at −70° until analyzed. At the time of analysis, remove the sample from the freezer, allow it to reach room temperature, and mix with a vortex mixer for 30 s. Pipet 1.0 mL of the sample into a 100-mL volumetric flask, and dilute with *Mobile phase* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 2 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for the azathioprine peak is about 4 min.]

Suitability requirements

Relative standard deviation: NMT 1.3% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of azathioprine ($C_9H_7N_7O_2S$) in the portion of Oral Suspension taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.8–4.8

ADDITIONAL REQUIREMENTS

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

• **Beyond-Use Date:** NMT 60 days after the day on which it was compounded when stored at room temperature, or in a refrigerator

• **Labeling:** Label it to state that it is to be well shaken before use, and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Azathioprine RS

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

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

Chromatographic Database Information: Chromatographic Database

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