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Dipyridamole Compounded Oral Suspension

DEFINITION

Dipyridamole Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of dipyridamole ($C_{24}H_{40}N_8O_4$).

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

Dipyridamole	1 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

Place the required number of tablets into a suitable mortar and comminute to a fine powder, or add *Dipyridamole* powder to the mortar. Add 20 mL of *Vehicle*, and mix to a uniform paste. Add *Vehicle* in small portions, and mix well after each addition. Transfer, stepwise and quantitatively, to a graduated or calibrated bottle. Add *Vehicle* in portions to rinse the mortar, add sufficient *Vehicle* to bring to final volume, and mix well.

ASSAY

• **Procedure**

Solution A: 1 mg/mL of dibasic sodium phosphate. Adjust with dilute phosphoric acid (1 in 3) to a pH of 4.6.

Mobile phase: Methanol and *Solution A* (75:25). Pass through a membrane filter of a 0.5-µm pore size, and degas.

Standard solution: 100 µg/mL of USP Dipyridamole RS in *Mobile phase*

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 on 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 288 nm

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

Flow rate: 1.3 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for dipyridamole is about 7.3 min.]

Suitability requirements

Relative standard deviation: NMT 2.3% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of dipyridamole ($C_{24}H_{40}N_8O_4$) in the portion of Oral Suspension taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

C_U = nominal concentration of dipyridamole in the *Sample solution* (µg/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 controlled room temperature, or in a refrigerator.

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

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

• **USP Reference Standards** ⟨11⟩

USP Dipyridamole RS

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

Topic/Question	Contact	Expert Committee
DIPYRIDAMOLE COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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