Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-08F94515-406F-4168-8B4C-DEF827921432_3_en-US
DOI: https://doi.org/10.31003/USPNF_M27575_03_01
DOI Ref: 2zt6y

Dipyridamole Injection

» Dipyridamole Injection is a sterile solution of Dipyridamole in Water for Injection. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of dipyridamole ($C_{24}H_{40}N_8O_4$).

Packaging and storage—Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging*. Protect from light, and avoid freezing.

USP Reference standards ⟨11⟩—
USP Dipyridamole RS

Identification—

A: *Thin-Layer Chromatographic Identification Test ⟨201⟩*—

Test solution—Use the Injection.

Standard solution: 5 mg per mL in a mixture of methanol, water, and 0.1 N hydrochloric acid (5:4:1).

Developing solvent system: a mixture of butyl alcohol, water, and glacial acetic acid (34:10:5).

Procedure—Proceed as directed in the chapter. Locate the yellow spots on the plate: the R_F value of the principal spot obtained from the *Test solution* corresponds to that of the principal spot obtained from the *Standard solution.* Spray the plate lightly with a spray reagent prepared as follows. Transfer 1 g of iodine and 3 g of potassium iodide to a 100-mL volumetric flask. Add 10 mL of alcohol to dissolve (heat gently). Add 20 mL of 2 N sulfuric acid, dilute with water to volume, and mix. Store in a dark place. Observe the plate, and locate the brown spots: the R_F value of the principal spot obtained from the *Test solution* corresponds to that of the principal spot obtained from the *Standard solution.*

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay.*

Bacterial Endotoxins Test ⟨85⟩—It contains not more than 8.8 USP Endotoxin Units per mg of dipyridamole.

pH ⟨791⟩: between 2.2 and 3.2.

Chromatographic purity— [Note—Protect dipyridamole solutions from exposure to light.]

Mobile phase and *Chromatographic system*—Proceed as directed in the *Assay.*

Test solution—Use the *Assay preparation* prepared as directed in the *Assay.*

Procedure—Inject a volume (about 10 µL) of the *Test solution* into the chromatograph, record the chromatogram, and measure the peak responses. Calculate the percentage of each impurity in the portion of Injection taken by the formula:

$$100(r_i/r_s)$$

in which r_i is the peak response for each impurity; and r_s is the sum of the responses of all of the peaks: not more than 2.0% of any individual impurity is found; and not more than 4.5% of total impurities is found.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*.

Assay—

[Note—Protect dipyridamole solutions from exposure to light.]

Acetate buffer—Dissolve a quantity of sodium acetate in water to obtain a concentration of about 6.8 mg per mL. Adjust with acetic acid to a pH of 5.1 ± 0.1.

Mobile phase—Prepare a filtered and degassed mixture of methanol and *Acetate buffer* (65:35). Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard preparation—Dissolve an accurately weighed quantity of USP Dipyridamole RS in *Mobile phase*, and dilute quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution having a known concentration of about 1.0 mg per mL.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 25 mg of dipyridamole, to a 25-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 276-nm detector and a 3.9-mm × 30-cm column that contains packing L1. The flow rate is about 1.0 mL per minute. Chromatograph the *Standard preparation,* and record the peak

responses as directed for *Procedure:* the column efficiency is not less than 2000 theoretical plates; the tailing factor is not greater than 1.7; and the relative standard deviation for replicate injections is not greater than 2.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of dipyridamole ($C_{24}H_{40}N_8O_4$) in the portion of Injection taken by the formula:

$$25C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Dipyridamole RS in the *Standard preparation;* and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

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

Topic/Question	Contact	Expert Committee
DIPYRIDAMOLE INJECTION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 28(4)

Current DocID: GUID-08F94515-406F-4168-8B4C-DEF827921432_3_en-US
Previous DocID: GUID-08F94515-406F-4168-8B4C-DEF827921432_1_en-US
DOI: https://doi.org/10.31003/USPNF_M27575_03_01
DOI ref: 2zt6y