Status: Currently Official on 14-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-52AF9F2D-E3D5-4A7E-A50C-DBE827FC4CE0_1_en-US
DOI: https://doi.org/10.31003/USPNF_M27580_01_01
DOI Ref: waq7v

Dipyridamole Tablets

» Dipyridamole Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{24}H_{40}N_8O_4$.

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards ⟨11⟩—

USP Dipyridamole RS

Identification—Triturate a quantity of finely powdered Tablets, equivalent to about 100 mg of dipyridamole, with 10 mL of 0.1 N hydrochloric acid, and filter, collecting the filtrate in a beaker. Add 0.1 N sodium hydroxide until the solution is basic and a precipitate forms. Heat the mixture on a steam bath for 1 minute, cool, and filter. Dry the residue at 105° for 1 hour: the residue so obtained responds to the *Identification* test under *Dipyridamole*.

Dissolution ⟨711⟩—

Medium: 0.1 N hydrochloric acid; 900 mL.

Apparatus 2: 50 rpm.

Time: 30 minutes.

Procedure—Determine the amount of $C_{24}H_{40}N_8O_4$ dissolved by employing UV absorption at the wavelength of maximum absorbance at about 282 nm on filtered portions of the solution under test, suitably diluted with *Medium*, if necessary, in comparison with a Standard solution having a known concentration of USP Dipyridamole RS in the same *Medium*.

Tolerances—Not less than 70% *(Q)* of the labeled amount of $C_{24}H_{40}N_8O_4$ is dissolved in 30 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Procedure for content uniformity—Transfer 1 Tablet to a 100-mL volumetric flask, add 50 mL of 1 N hydrochloric acid, heat in a steam bath for 5 minutes, and shake by mechanical means for 30 minutes. Cool to room temperature, dilute with 1 N hydrochloric acid to volume, and mix. Filter, discarding the first 25 mL of the filtrate. Dilute an accurately measured portion of the subsequent filtrate with 1 N hydrochloric acid to provide a solution containing about 10 µg of dipyridamole per mL. Concomitantly determine the absorbances of this solution and of a solution of USP Dipyridamole RS in the same medium having a known concentration of about 10 µg per mL, in 1-cm cells at the wavelength of maximum absorbance at about 282 nm using 1 N hydrochloric acid as the blank. Calculate the quantity, in mg, of $C_{24}H_{40}N_8O_4$ in the Tablet taken by the formula:

$$(TC/D)(A_U/A_S)$$

in which T is the labeled quantity, in mg, of dipyridamole in the Tablet; C is the concentration, in µg per mL, of USP Dipyridamole RS in the *Standard solution; D* is the concentration, in µg per mL, of dipyridamole in the solution from the Tablet based upon the labeled quantity per Tablet and the extent of dilution; and A_U and A_S are the absorbances of the solution from the Tablet and the *Standard solution*, respectively.

Assay—

Mobile phase—Dissolve 250 mg of dibasic sodium phosphate in 250 mL of water, and adjust with dilute phosphoric acid (1 in 3) to a pH of 4.6. Add 750 mL of methanol, mix, filter through a 0.5-µm membrane filter, and degas. Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard preparation—Using an accurately weighed quantity of USP Dipyridamole RS, prepare a solution in *Mobile phase* having a known concentration of about 15 µg per mL.

Assay preparation—Transfer not less than 20 Tablets to a 1000-mL volumetric flask, add 100 mL of water, and sonicate for 15 minutes. Add about 750 mL of methanol, and shake by mechanical means for 30 minutes. Dilute with methanol to volume, mix, and centrifuge. Dilute an accurately measured volume (V_S mL) of the clear supernatant quantitatively with *Mobile phase* to obtain a solution (V_A mL) containing about 15 µg of dipyridamole per mL.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 288-nm detector and a 3.9-mm × 30-cm column that contains packing L1. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard preparation,* and record the peak

responses as directed for *Procedure:* the column efficiency determined from the analyte peak is not less than 1000 theoretical plates, the tailing factor for the analyte peak is not more than 2.0, and the relative standard deviation for replicate injections is not more than 2.0%. *Procedure*—Separately inject equal volumes (about 50 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 $C_{24}H_{40}N_8O_4$ in the Tablets taken by the formula:

$$C(V_A/V_S)(r_U/r_S)$$

in which C is the concentration, in µg per mL, of USP Dipyridamole RS in the *Standard preparation;* V_A is the volume, in mL, of the *Assay preparation;* V_S is the volume, in mL, of supernatant taken for the *Assay 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 TABLETS	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 41(3)

Current DocID: GUID-52AF9F2D-E3D5-4A7E-A50C-DBE827FC4CE0_1_en-US
DOI: https://doi.org/10.31003/USPNF_M27580_01_01
DOI ref: waq7v