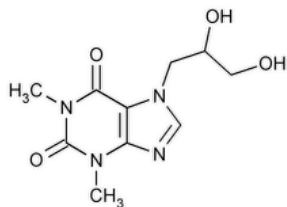


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Dyphylline



$C_{10}H_{14}N_4O_4$ 254.24

1*H*-Purine-2,6-dione, 7-(2,3-dihydroxypropyl)-3,7-dihydro-1,3-dimethyl-, (±)-.

(±)-7-(2,3-Dihydroxypropyl)theophylline CAS RN®: 479-18-5; UNII: 263T0E9RR9.

» Dyphylline contains not less than 98.0 percent and not more than 102.0 percent of $C_{10}H_{14}N_4O_4$, calculated on the dried basis.

Packaging and storage—Preserve in tight containers.

USP REFERENCE STANDARDS (11)—

USP Dyphylline RS

Identification—

Change to read:

A: ▲ [Spectroscopic Identification Tests \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-May-2020) ·

Change to read:

B: ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Ultraviolet-Visible Spectroscopy: 197U](#) ▲ (CN 1-May-2020) —

Solution: 10 µg per mL.

Medium: water.

MELTING RANGE (741): between 160° and 164°.

pH (791): between 5.0 and 7.5, in a solution (1 in 100).

LOSS ON DRYING (731)—Dry about 1 g, accurately weighed, at 105° for 3 hours: it loses not more than 0.5% of its weight.

RESIDUE ON IGNITION (281): not more than 0.15%.

CHLORIDE (221): A 1.0-g portion shows no more chloride than corresponds to 0.50 mL of 0.020 N hydrochloric acid (0.035%).

SULFATE (221): A 1.0-g portion shows no more sulfate than corresponds to 0.10 mL of 0.020 N sulfuric acid (0.010%).

Limit of theophylline—Dissolve 2.0 g in 10 mL of hot water. Cool, add 10 drops of bromothymol blue TS and 5.0 mL of silver nitrate TS, and mix. Not more than 0.50 mL of 0.10 N sodium hydroxide is required to change the color of the solution to blue (0.5%).

Related compounds—Dissolve about 200 mg in a mixture of 30 volumes of methanol and 20 volumes of water in a 10-mL volumetric flask, dilute with the same mixture to volume, and mix (*Test solution*). Dilute 1 mL of the *Test solution* with methanol to 100 mL (*Diluted test solution*). Separately apply 10 µL of each solution to a suitable thin-layer chromatographic plate (see [Chromatography \(621\)](#)) coated with a 0.25-mm layer of binder-free chromatographic silica gel mixture. Develop the plate in a suitable chamber containing a mixture of chloroform, dehydrated alcohol, and ammonium hydroxide (90:10:1) until the solvent front has moved about 15 cm. Remove the plate, air-dry at room temperature, and examine under short-wavelength UV light: no spot in the chromatogram of the *Test solution* other than the principal spot is larger or more intense than the principal spot from the *Diluted test solution* (1.0%).

Assay—Dissolve about 200 mg of Dyphylline, accurately weighed, in 2 mL of formic acid, and carefully add, with stirring, 50 mL of acetic anhydride. Add 0.2 mL of Sudan IV TS, and titrate with 0.1 N perchloric acid VS to a deep violet endpoint. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 25.42 mg of $C_{10}H_{14}N_4O_4$.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
DYPHYLLINE	Documentary Standards Support	SM52020 Small Molecules & Documents

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 29(5)

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