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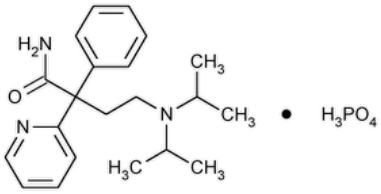
Disopyramide Phosphate



$C_{21}H_{29}N_3O \cdot H_3PO_4$ 437.47

2-Pyridineacetamide, α-[2-[bis(1-methylethyl)amino]ethyl]-α-phenyl-, (±)-, phosphate (1:1).

(±)-α-[2-(Diisopropylamino)ethyl]-α-phenyl-2-pyridineacetamide phosphate (1:1) CAS RN®: 22059-60-5; UNII: N6BOM1935W.

» Disopyramide Phosphate contains not less than 98.0 percent and not more than 102.0 percent of $C_{21}H_{29}N_3O \cdot H_3PO_4$, calculated on the dried basis.

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

USP Reference standards ⟨11⟩—

USP Disopyramide Phosphate RS

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests* ⟨197⟩, *Infrared Spectroscopy: 197M*▲ (CN 1-May-2020) ·

B: A solution (1 in 200) meets the requirements of the tests for *Phosphate* ⟨191⟩.

pH ⟨791⟩**:** between 4.0 and 5.0 in a solution (1 in 20).

Loss on drying ⟨731⟩—Dry it at 105° for 4 hours: it loses not more than 0.5% of its weight.

Chromatographic purity—

Standard solutions—Prepare solutions *A* and *B* of USP Disopyramide Phosphate RS in methanol having concentrations of about 50 and 100 µg per mL, respectively.

Test solution—Prepare a solution of Disopyramide Phosphate in methanol having a concentration of about 10 mg per mL.

Procedure—Separately apply 10-µL portions of *Standard solutions A* and *B* and the *Test solution* to a suitable thin-layer chromatographic plate (see *Chromatography* ⟨621⟩), coated with a 0.25-mm layer of chromatographic silica gel. Allow the spots to dry, and develop the chromatogram in a solvent system consisting of a mixture of toluene, dehydrated alcohol, and ammonium hydroxide (170:28:2) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chamber, allow to air-dry, and spray with potassium bismuth iodide TS: the R_F value of the principal spot obtained from the *Test solution* corresponds to that obtained from *Standard solution B.* Estimate the levels of any additional spots observed in the chromatogram of the *Test solution* by comparison with the principal spots in the chromatograms of *Standard solutions A* and *B:* the sum of the intensities of any additional spots observed is not greater than that obtained from *Standard solution B* (equivalent to 1%).

Assay—Dissolve about 160 mg of Disopyramide Phosphate, accurately weighed, in 50 mL of glacial acetic acid, and titrate with 0.1 N perchloric acid VS, determining the endpoint potentiometrically. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 21.87 mg of $C_{21}H_{29}N_3O \cdot H_3PO_4$.

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

Topic/Question	Contact	Expert Committee
DISOPYRAMIDE PHOSPHATE	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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