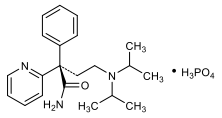
Disopyramide Phosphate

ジソピラミドリン酸塩



and enantiomer

$C_{21}H_{29}N_3O.H_3PO_4$: 437.47

(2*RS*)-4-Di(propan-2-yl)amino-2-phenyl-2-(pyridin-2-yl) butanamide monophosphate

[*22059-60-5*]

Disopyramide Phosphate, when dried, contains not less than 98.0% and not more than 102.0% of disopyramide phosphate ($C_{21}H_{29}N_3O.H_3PO_4$).

Description Disopyramide Phosphate occurs as a white crystalline powder.

It is freely soluble in water and in acetic acid (100), soluble in methanol, and very slightly soluble in ethanol (99.5).

A solution of Disopyramide Phosphate (1 in 20) shows no optical rotation.

Melting point: about 204℃ (with decomposition).

Identification **(1)** Determine the absorption spectrum of a solution of Disopyramide Phosphate in 0.05 mol/L Sulfuric acid-methanol TS (1 in 25,000) as directed under Ultraviolet-visible Spectrophotometry *<2.24>*, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelengths.

(2) Determine the infrared absorption spectrum of Disopyramide Phosphate as directed in the potassium bromide disk method under Infrared Spectrophotometry *<2.25>*, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wave numbers.

(3) A solution of Disopyramide Phosphate (1 in 20) responds to Qualitative Tests *<1.09>* for phosphate.

pH *<2.54>* Dissolve 1.0 g of Disopyramide Phosphate in 20 mL of water: the pH of the solution is between 4.0 and 5.0.

Purity **(1)** Clarity and color of solution—Dissolve 1.0 g of Disopyramide Phosphate in 20 mL of water: the solution is clear and colorless.

(2) Related substances—Dissolve 50 mg of Disopyramide Phosphate in 5 mL of methanol, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add methanol to make exactly 100 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under Thin-layer Chromatography *<2.03>*. Spot 10 μL each of the sample solution and standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of toluene, ethanol (99.5) and ammonia solution (28) (85:14:1) to a distance of about 15 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

Loss on drying *<2.41>* Not more than 0.5% (1 g, 105℃, 4 hours).

Assay Weigh accurately about 0.1 g of Disopyramide Phosphate, previously dried, dissolve in 30 mL of acetic acid (100), and titrate *<2.50>* with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination in the same manner, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS
=21.87 mg $C_{21}H_{29}N_3O.H_3PO_4$

Containers and storage Containers—Tight containers.