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Disopyramide Phosphate Capsules

» Disopyramide Phosphate Capsules contain an amount of Disopyramide Phosphate equivalent to not less than 90.0 percent and not more than 110.0 percent of the labeled amount of disopyramide ($C_{21}H_{29}N_3O$).

Packaging and storage—Preserve in well-closed containers.

USP REFERENCE STANDARDS (11)—

[USP Disopyramide Phosphate RS](#)

Identification—Transfer a portion of Capsule contents, equivalent to about 125 mg of disopyramide phosphate, to a 25-mL volumetric flask, add 20 mL of methanol, and shake by mechanical means for 20 minutes. Dilute with methanol to volume, mix, and filter through paper (Whatman No. 2 or equivalent), discarding the first 10 mL of the filtrate. Apply 10 µL each of the subsequent filtrate and of a solution of [USP Disopyramide Phosphate RS](#) in methanol containing 6.2 mg per mL to a suitable thin-layer chromatographic plate (see [Chromatography \(621\)](#)) coated with a 0.25-mm layer of chromatographic silica gel mixture. Allow the spots to dry, and develop the chromatogram in a solvent system consisting of a mixture of toluene, 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 developing chamber, mark the solvent front, and allow the solvent to evaporate. Locate the spots on the plate by viewing under short-wavelength UV light: the R_f value of the principal spot obtained from the test solution corresponds to that obtained from the Standard solution.

DISSOLUTION (711)—

Medium: water; 1000 mL.

Apparatus 2: 50 rpm.

Time: 20 minutes.

Procedure—Filter 15 mL of the solution under test, and transfer 10.0 mL of the filtrate to a 25-mL volumetric flask. Dilute with 2 N sulfuric acid to volume, and mix. Determine the amount of disopyramide ($C_{21}H_{29}N_3O$) dissolved from UV absorbances at the wavelength of maximum absorbance at about 268 nm of this solution, using water as the blank, in comparison with a Standard solution having a known concentration of [USP Disopyramide Phosphate RS](#) in the same medium.

Tolerances—Not less than 80% (Q) of the labeled amount of $C_{21}H_{29}N_3O$ is dissolved in 20 minutes.

UNIFORMITY OF DOSAGE UNITS (905): meet the requirements.

Assay—

Methanolic sulfuric acid—Cautiously add 5.4 mL of sulfuric acid to about 1800 mL of methanol with stirring, dilute with methanol to 2000 mL, and mix.

Procedure—Weigh the contents of not fewer than 20 Phosphate Capsules, and calculate the average weight per Capsule. Mix the combined contents of the Capsules, and transfer an accurately weighed portion, equivalent to about 125 mg of disopyramide phosphate, to a glass-stoppered, 125-mL flask. Add 50 mL of *Methanolic sulfuric acid*, and stir for 30 minutes. Filter through a medium-porosity, sintered-glass filter, and rinse thoroughly with *Methanolic sulfuric acid*. Transfer the combined filtrate and rinsings to a 100-mL volumetric flask, dilute with *Methanolic sulfuric acid* to volume, and mix. Dilute an accurately measured portion of this solution quantitatively and stepwise with the same solvent to obtain a solution having a concentration of about 40 µg per mL. Dissolve an accurately weighed portion of [USP Disopyramide Phosphate RS](#) in *Methanolic sulfuric acid*, and dilute quantitatively and stepwise with the same solvent to obtain a solution having a known concentration of about 40 µg per mL. Concomitantly determine the absorbances of both solutions in 1-cm cells at the wavelength of maximum absorbance at about 268 nm, with a suitable spectrophotometer, using *Methanolic sulfuric acid* as the blank. Calculate the quantity, in mg, of $C_{21}H_{29}N_3O$ in the portion of Capsules taken by the formula:

$$3.125(339.48/437.47)C(A_u/A_s)$$

in which 339.48 and 437.47 are the molecular weights of disopyramide and disopyramide phosphate, respectively; C is the concentration, in µg per mL, of [USP Disopyramide Phosphate RS](#) in the Standard solution; and A_u and A_s are the absorbances of the solution from the Capsules and the Standard solution, respectively.

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

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:
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