



Edition: BP 2025 (Ph. Eur. 11.6 update)

Disopyramide Capsules

[General Notices](#)

Action and use

Class I antiarrhythmic.

DEFINITION

Disopyramide Capsules contain Disopyramide.

The capsules comply with the requirements stated under Capsules and with the following requirements.

Content of disopyramide, $C_{21}H_{29}N_3O$

92.5 to 107.5% of the stated amount.

IDENTIFICATION

- A. Shake a quantity of the contents of the capsules containing 0.2 g of Disopyramide with 50 mL of [chloroform](#) for 15 minutes, filter, evaporate the filtrate to dryness using a rotary evaporator and dissolve the residue in 2 mL of [chloroform](#). The [infrared absorption spectrum, Appendix II A](#), is concordant with the *reference spectrum* of disopyramide ([RS 110](#)).
- B. The [light absorption, Appendix II B](#), in the range 230 to 350 nm of the solution obtained in the Assay exhibits a maximum only at 269 nm.

TESTS

Related substances

Carry out the method for [thin-layer chromatography, Appendix III A](#), using the following solutions.

- (1) Shake a quantity of the contents of the capsules containing 0.20 g of Disopyramide with 20 mL of [methanol](#) for 30 minutes and filter.
- (2) Dilute 1 volume of solution (1) to 400 volumes with [methanol](#).

CHROMATOGRAPHIC CONDITIONS

- (a) Use a TLC [silica gel](#) GF_{254} plate.
- (b) Use the mobile phase as described below.
- (c) Apply 10 μ L of each solution.
- (d) Develop the plate to 15 cm.
- (e) After removal of the plate, dry in a current of air and examine under [ultraviolet light \(254 nm\)](#).

MOBILE PHASE

1 volume of 18M [ammonia](#), 30 volumes of [acetone](#) and 30 volumes of [cyclohexane](#).

LIMITS

Any secondary spot in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (2) (0.25%).

ASSAY

To a quantity of the mixed contents of 20 capsules containing 40 mg of Disopyramide, add 40 mL of 0.05M methanolic sulfuric acid, shake for 15 minutes, dilute to 100 mL with the same solvent and filter. Dilute 5 mL of the filtrate to 100 mL with 0.05M methanolic sulfuric acid and measure the absorbance of the resulting solution at the maximum at 269 nm, Appendix II B. Calculate the content of $C_{21}H_{29}N_3O$ taking 198.5 as the value of A(1%, 1 cm) at the maximum at 269 nm.