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

Indoramin Tablets

General Notices

Action and use

Alpha$_1$-adrenoceptor antagonist.

DEFINITION

Indoramin Tablets contain Indoramin Hydrochloride. They are coated.

The tablets comply with the requirements stated under Tablets and with the following requirements.

Content of indoramin, $C_{22}H_{25}N_3O$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

Shake a quantity of the powdered tablets containing the equivalent of 0.1 g of indoramin with 25 mL of *water* for 5 minutes, filter (Whatman GF/C paper is suitable), make the filtrate alkaline with 2M *sodium hydroxide* and extract with 20 mL of *dichloromethane*. Wash the extracts with two 10 mL quantities of *water*, dry by shaking with *anhydrous sodium sulfate* and evaporate to dryness using a rotary evaporator. The *infrared absorption spectrum* of the residue, Appendix II A, is concordant with the *reference spectrum* of indoramin *(RS 188)*.

TESTS

Related substances

Carry out the method for *thin-layer chromatography*, Appendix III A, using a silica gel F_{254} precoated plate (Merck silica gel 60 F_{254} plates are suitable) and a mixture of 1 volume of 18M *ammonia*, 20 volumes of *absolute ethanol* and 79 volumes of *toluene* as the mobile phase. Apply separately to the plate 10 µL of each of the following solutions. For solution (1) add 10 mL of *ethanol (96%)* to a quantity of the powdered tablets containing the equivalent of 0.1 g of indoramin, shake for 30 minutes and filter. For solution (2) dilute 1 volume of solution (1) to 200 volumes with *ethanol (96%)*. For solution (3) dilute 1 volume of solution (2) to 5 volumes with *ethanol (96%)*. After removal of the plate, allow it to dry in a current of warm air and examine it under *ultraviolet light (254 nm)*. Any *secondary spot* in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (2) (0.5%) and not more than one such spot is more intense than the spot in the chromatogram obtained with solution (3) (0.1%). Disregard any spot remaining on the line of application.

Dissolution

Comply with the requirements for Monographs of the British Pharmacopoeia in the *dissolution test for tablets and capsules*, Appendix XII B1, using Apparatus 2. Use 900 mL of *0.1M hydrochloric acid* as the medium and rotate the paddle

at 50 revolutions per minute. Withdraw a sample of 10 mL of the medium. Measure the *absorbance* of a layer of suitable thickness of the filtered sample, suitably diluted if necessary, at the maximum at 280 nm, Appendix II B. Calculate the total content of indoramin, $C_{22}H_{25}N_3O$, in the medium taking 186 as the value of A(1%, 1 cm) at the maximum at 280 nm.

ASSAY

Shake 10 whole tablets with 50 mL of 0.1M *hydrochloric acid* until the tablets have disintegrated, add 300 mL of *ethanol (96%)* and mix with the aid of ultrasound for 10 minutes, shaking occasionally. Add sufficient *ethanol (96%)* to produce 500 mL, filter (Whatman GF/C paper is suitable), dilute the filtrate with *ethanol (96%)* to contain 0.005% w/v of indoramin and measure the *absorbance* of the resulting solution at the maximum at 280 nm, Appendix II B. Calculate the content of $C_{22}H_{25}N_3O$ taking 186 as the value of A(1%, 1 cm) at the maximum at 280 nm.

STORAGE

Indoramin Tablets should be protected from light.

LABELLING

The quantity of active ingredient is stated in terms of the equivalent amount of indoramin.