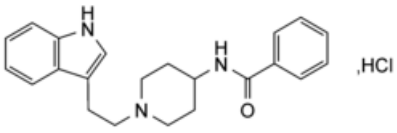
Edition: BP 2025 (Ph. Eur. 11.6 update)

Indoramin Hydrochloride

General Notices



$C_{22}H_{25}N_3O$,HCl 383.9 *33124-53-7*

Action and use

Alpha$_1$-adrenoceptor antagonist.

Preparation

Indoramin Tablets

DEFINITION

Indoramin Hydrochloride is *N*-1-[2-(indol-3-yl)ethyl]-4-piperidylbenzamide hydrochloride. It contains not less than 98.5% and not more than 100.5% of $C_{22}H_{25}N_3O$,HCl, calculated with reference to the dried substance.

CHARACTERISTICS

A white or almost white powder. It exhibits polymorphism.

Slightly soluble in *water*; sparingly soluble in *ethanol (96%)*; soluble in *methanol*; very slightly soluble in *ether*.

IDENTIFICATION

A. The *light absorption*, Appendix II B, in the range 230 to 350 nm of a 0.0045% w/v solution in *ethanol (96%)* exhibits three maxima, at 273, 280 and 290 nm. The *absorbances* at the maxima are about 0.76, 0.77 and 0.64, respectively.
B. Dissolve 50 mg in 30 mL of *water*, make the solution alkaline by the addition of 5M *ammonia* and shake with 50 mL of *dichloromethane*. Dry the dichloromethane layer with *anhydrous sodium sulfate*, filter and evaporate the filtrate 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)*.
C. Yields reaction A characteristic of *chlorides*, Appendix VI.

TESTS

Acidity

pH of a 2% w/v suspension in *water*, 4.0 to 5.5, Appendix V L.

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 three solutions of the substance being examined in *ethanol (96%)* containing (1) 1.0% w/v, (2) 0.0050% w/v and (3) 0.0010% w/v. After removal of the plate, allow it to dry in a current of warm air and examine 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%).

Loss on drying

When dried at 100° to 105° for 4 hours, loses not more than 0.5% of its weight. Use 1 g.

Sulfated ash

Not more than 0.1%, Appendix IX A.

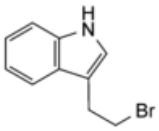
ASSAY

Dissolve 0.2 g in 30 mL of *anhydrous acetic acid*, add 6 mL of *acetic anhydride* and 6 mL of *mercury(II) acetate* solution. Titrate with *0.1M perchloric acid VS* determining the end point potentiometrically. Each mL of *0.1M perchloric acid VS* is equivalent to 38.39 mg of $C_{22}H_{25}N_3O$,HCl.

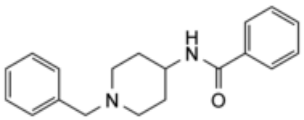
STORAGE

Indoramin Hydrochloride should be protected from light.

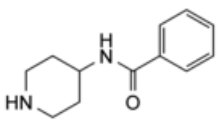
IMPURITIES



A. 3-(2-bromoethyl)indole



B. *N*-(1-benzyl-4-piperidyl)benzamide



C. *N*-(4-piperidyl)benzamide