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

Pentazocine Capsules

General Notices

Action and use

Opioid receptor agonist; analgesic.

DEFINITION

Pentazocine Capsules contain Pentazocine Hydrochloride.

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

Content of pentazocine hydrochloride, $C_{19}H_{27}NO,HCl$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. Shake a quantity of the contents of the capsules containing 50 mg of Pentazocine Hydrochloride with 3 mL of 0.1M *sodium hydroxide* and 3 mL of *dichloromethane* and allow to separate. Filter the dichloromethane layer through a phase separation paper (Whatman 1PS is suitable) and evaporate the filtrate using a rotary evaporator at a temperature of 40°. The *infrared absorption spectrum* of the residue, Appendix II A, is concordant with the *reference spectrum* of pentazocine (form B) (*RS 261*).
B. Yields the reactions characteristic of *chlorides*, Appendix VI.

TESTS

Dissolution

Comply with the requirements for Monographs of the British Pharmacopoeia in the *dissolution test for tablets and capsules*, Appendix XII B1,

TEST CONDITIONS

(a) Use Apparatus 1, rotating the basket at 100 revolutions per minute.
(b) Use 900 mL of *water*, at a temperature of 37°, as the medium.

PROCEDURE

After 45 minutes withdraw a 10 mL sample of the medium and measure the *absorbance* of the filtered sample, suitably diluted with the dissolution medium if necessary, at the maximum at 278 nm, Appendix II B, using *water* in the reference cell.

DETERMINATION OF CONTENT

Calculate the total content of pentazocine hydrochloride, $C_{19}H_{27}NO,HCl$, in the medium taking 61.2 as the value of A(1%, 1 cm) at the maximum at 278 nm.

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 0.2 g of Pentazocine Hydrochloride with 10 mL of 0.1M *methanolic ammonia*, centrifuge and use the clear supernatant liquid.
(2) Dilute 1 volume of solution (1) to 100 volumes with the same solvent.
(3) Dilute 1 volume of solution (1) to 200 volumes with the same solvent.
(4) Dilute 1 volume of solution (1) to 400 volumes with the same solvent.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating silica gel F_{254} (Merck silica gel 60 F_{254} plates are suitable).
(b) Use the mobile phase as described below.
(c) Apply 10 µL of each solution.
(d) Develop the plate to 15 cm.
(e) After removal of the plate, allow it to dry in air and examine under *ultraviolet light (254 nm)*. Heat the plate at 105° for 15 minutes, allow to cool, expose to iodine vapour and re-examine under *ultraviolet light (254 nm)*.

MOBILE PHASE

3 volumes of *isopropylamine*, 3 volumes of *methanol* and 94 volumes of *chloroform*.

LIMITS

By each method of visualisation, in the chromatogram obtained with solution (1):

any *secondary spot* is not more intense than the spot in the chromatogram obtained with solution (2)(1%);

not more than one such spot is more intense than the spot in the chromatogram obtained with solution (3)(0.5%);

and not more than four such spots are more intense than the spot in the chromatogram obtained with solution (4)(0.25%).

Disregard any spot remaining on the line of application.

ASSAY

Shake a quantity of the mixed contents of 20 capsules containing 50 mg of Pentazocine Hydrochloride with 200 mL of *water* for 15 minutes, add 5 mL of 1M *hydrochloric acid* and sufficient *water* to produce 500 mL, mix and filter. Measure the *absorbance* of the filtrate at the maximum at 278 nm, Appendix II B. Calculate the content of $C_{19}H_{27}NO,HCl$ taking 61.2 as the value of A(1%, 1 cm) at the maximum at 278 nm.