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Meptazinol Tablets

General Notices

Action and use

Opioid receptor partial agonist; analgesic.

DEFINITION

Meptazinol Tablets contain Meptazinol Hydrochloride.

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

Content of meptazinol, $C_{15}H_{23}NO$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. The *light absorption*, Appendix II B, in the range 220 to 330 nm of the solution obtained in the Assay exhibits a maximum at 273 nm.
B. Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions in *ethanol (96%)*.
(1) Shake a quantity of the powdered tablets containing the equivalent of 50 mg of meptazinol with 5 mL of *ethanol (96%)*, centrifuge and dilute 1 volume of the supernatant liquid to 50 volumes with *ethanol (96%)*.
(2) 0.02% w/v of *meptazinol hydrochloride BPCRS* in *ethanol (96%)*.

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, dry in air and examine under *ultraviolet light (254 nm)*.

MOBILE PHASE

1 volume of 18M *ammonia*, 20 volumes of *absolute ethanol* and 79 volumes of *toluene*.

CONFIRMATION

The principal spot in the chromatogram obtained with solution (1) corresponds in intensity, position and size to that in the chromatogram obtained with solution (2).

TESTS

Related substances

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Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions in *ethanol (96%)*.

(1) Shake a quantity of the powdered tablets containing the equivalent of 0.2 g of meptazinol with 20 mL of *ethanol (96%)*, centrifuge and use the supernatant liquid.
(2) Dilute 1 volume of solution (1) to 100 volumes.
(3) Dilute 1 volume of solution (2) to 2 volumes.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel* (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, dry in air, examine under *ultraviolet light (254 nm)*, expose to iodine vapour for 2 hours and examine again.

MOBILE PHASE

1 volume of 18M *ammonia*, 30 volumes of *chloroform* and 70 volumes of *ethyl acetate*.

LIMITS

By each method of visualisation, any *secondary spot* in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (2) (1%) and not more than one such spot is more intense than the spot in the chromatogram obtained with solution (3) (0.5%).

ASSAY

To a quantity of the powdered tablets containing the equivalent of 0.2 g of meptazinol add 40 mL of 0.06M *hydrochloric acid*, shake, dilute to 50 mL with the same solvent, filter through a glass-fibre paper (Whatman GF/C paper is suitable); dilute 5 mL of the filtrate to 250 mL with 0.06M *hydrochloric acid* and measure the *absorbance* of the resulting solution at the maximum at 273 nm, Appendix II B. Calculate the content of $C_{15}H_{23}NO$ from the *absorbance* obtained using a 0.0080% w/v solution of *meptazinol hydrochloride BPCRS* in 0.06M *hydrochloric acid* and from the declared content of $C_{15}H_{23}NO$ in *meptazinol hydrochloride BPCRS*.

LABELLING

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

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