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

Mianserin Tablets

General Notices

Action and use

Monoamine reuptake inhibitor; tetracyclic antidepressant.

DEFINITION

Mianserin Tablets contain Mianserin Hydrochloride.

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

Content of mianserin hydrochloride, $C_{18}H_{20}N_2$,HCl

90.0 to 110.0% of the stated amount.

IDENTIFICATION

A. Shake a quantity of the powdered tablets containing 20 mg of Mianserin Hydrochloride with 10 mL of *methanol*, filter and evaporate the filtrate to dryness. The *infrared absorption spectrum* of the residue, Appendix II A, is concordant with the *reference spectrum* of mianserin hydrochloride *(RS 234)*.
B. In the Assay, the chromatogram obtained with solution (2) shows a peak with the same retention time as that due to mianserin in the chromatogram obtained with solution (1).
C. The residue obtained in test A yields the reactions characteristic of *chlorides*, Appendix VI.

TESTS

Related substances

Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions prepared in a mixture of 1 volume of 13.5M *ammonia* and 4 volumes of *methanol*.

(1) Triturate a quantity of the powdered tablets containing 40 mg of Mianserin Hydrochloride with 2 mL of a mixture of 4 volumes of *methanol* and 1 volume of 13.5M *ammonia* and centrifuge. Use the supernatant.
(2) Dilute 1 volume of solution (1) to 200 volumes.
(3) Dilute 2 volumes of solution (2) to 5 volumes.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel*.
(b) Use the mobile phase as described below.
(c) Apply 5 µL of each solution.
(d) Develop the plate to 15 cm.
(e) After removal of the plate, dry in a current of cold air for 5 minutes and then expose to iodine vapour for 20 minutes.

MOBILE PHASE

10 volumes of *methanol* and 90 volumes of *dichloromethane*.

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) (0.5%) and not more than two such spots are more intense than the spot in the chromatogram obtained with solution (3) (0.2%).

Disregard any spot with an Rf value lower than 0.15.

ASSAY

Weigh and powder 20 tablets. Carry out the method for *gas chromatography*, Appendix III B. Use a 0.2% w/v solution of *triphenylamine* in *toluene* as the internal standard solution.

(1) Shake a quantity of the powdered tablets containing 60 mg of Mianserin Hydrochloride with 30 mL of 0.2M *hydrochloric acid* for 1 hour and filter. To 10 mL of the filtrate add 3 mL of 1M *sodium hydroxide* and 10 mL of internal standard solution, mix for 5 minutes, centrifuge and use the clear upper layer.
(2) Add 3 mL of 1M *sodium hydroxide* and 10 mL of internal standard solution to 10 mL of a solution containing 0.2% w/v of *mianserin hydrochloride BPCRS* in 0.2M *hydrochloric acid*, mix for 5 minutes, centrifuge and use the clear upper layer.

CHROMATOGRAPHIC CONDITIONS

(a) Use a fused silica column (30 m × 0.32 mm) bonded with a 0.25 µm film of *phenyl(5)methyl(95)polysiloxane* (HP-5 is suitable).
(b) Use *helium* as the carrier gas at 1.0 mL per minute.
(c) Use isothermal conditions maintained at 255°.
(d) Use an inlet temperature of 280°.
(e) Use a flame ionisation detector at a temperature of 300°.
(f) Inject 1 µL of each solution.
(g) Use a split ratio of 1:5.

When the chromatograms are recorded under the prescribed conditions the retention time of triphenylamine relative to mianserin (retention time about 5 minutes) is about 0.7.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (2), the *resolution* between the peaks due to triphenylamine and mianserin is at least 10.

DETERMINATION OF CONTENT

Calculate the content of $C_{18}H_{20}N_2$,HCl in the tablets using the declared content of $C_{18}H_{20}N_2$,HCl in *mianserin hydrochloride BPCRS*.

STORAGE

Mianserin Tablets should be protected from light.