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

Oxazepam Tablets

General Notices

Action and use

Benzodiazepine.

DEFINITION

Oxazepam Tablets contain Oxazepam.

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

Content of oxazepam, $C_{15}H_{11}ClN_2O_2$

90.0 to 110.0% of the stated amount.

IDENTIFICATION

A. Extract a quantity of the powdered tablets containing 20 mg of Oxazepam with 25 mL of *chloroform*, filter, evaporate to dryness and dry the residue at 60° at a pressure not exceeding 0.7 kPa. The *infrared absorption spectrum* of the residue, Appendix II A, is concordant with the *reference spectrum* of oxazepam (*RS 253*).
B. The *light absorption*, Appendix II B, in the range 210 to 350 nm of the solution obtained in the Assay exhibits two maxima, at 230 nm and 316 nm.

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 2, rotating the paddle at 50 revolutions per minute.
(b) Use 900 mL of 0.01M *hydrochloric acid*, at a temperature of 37°, as the medium.

PROCEDURE

(1) After 45 minutes withdraw a sample of the medium and measure the *absorbance* of a layer of suitable thickness of the filtered sample, suitably diluted with the dissolution medium if necessary, at the maximum at 236 nm, Appendix II B using 0.01M *hydrochloric acid* in the reference cell.

DETERMINATION OF CONTENT

Calculate the total content of oxazepam, $C_{15}H_{11}ClN_2O_2$, in the medium taking 1080 as the value of A(1%, 1 cm) at the maximum at 236 nm.

Related substances

Carry out the following procedure protected from light. Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.

(1) Shake a quantity of the powdered tablets containing 30 mg of Oxazepam with 6 mL of *acetone* and centrifuge.
(2) Dilute 1 volume of solution (1) to 100 volumes with *acetone*.
(3) Dilute 1 volume of solution (1) to 500 volumes with *acetone*.
(4) 0.10% w/v of each of *oxazepam BPCRS* and *bromazepam EPCRS* in *acetone*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel* F_{254} (Merck silica gel 60 F_{254} is suitable). Before use, wash the plate with *methanol* allowing the solvent front to ascend 17 cm above the line of application.
(b) Use the mobile phase as described below.
(c) Apply 20 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)*.

MOBILE PHASE

10 volumes of *methanol* and 100 volumes of *dichloromethane*.

SYSTEM SUITABILITY

The test is not valid unless the chromatogram obtained with solution (4) shows two clearly separated spots.

LIMITS

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) (0.2%).

ASSAY

Weigh and powder 20 tablets. To a quantity of the powder containing 25 mg of Oxazepam add 150 mL of *ethanol* (*96%*) and shake for 30 minutes. Add sufficient *ethanol* (*96%*) to produce 250 mL, centrifuge, dilute 5 mL of the supernatant liquid to 100 mL with the same solvent and measure the *absorbance* of the resulting solution at the maximum at 230 nm, Appendix II B. Calculate the content of $C_{15}H_{11}ClN_2O_2$ taking 1250 as the value of A(1%, 1 cm) at the maximum at 230 nm.

STORAGE

Oxazepam Tablets should be protected from light.