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

Acebutolol Tablets

General Notices

Action and use

Beta-adrenoceptor antagonist.

DEFINITION

Acebutolol Tablets contain Acebutolol Hydrochloride.

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

Content of acebutolol, $C_{18}H_{28}N_2O_4$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

The *infrared absorption spectrum* of a 0.7% w/w dispersion of the powdered tablets in *potassium bromide*, Appendix II A, is concordant with the *reference spectrum* of acebutolol hydrochloride *(RS 380)*.

TESTS

Related substances

Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions in a solvent mixture of equal volumes of *chloroform* and *methanol*.

(1) A quantity of the powdered tablets containing the equivalent of 0.4 g of Acebutolol in 20 mL of the solvent mixture, shaken for 2 minutes and centrifuged. Use the supernatant liquid.
(2) Dilute 3 volumes of solution (1) to 100 volumes with the solvent mixture. Further dilute 1 volume of the resulting solution to 10 volumes with the solvent mixture.
(3) Dilute 1 volume of solution (1) to 100 volumes with the solvent mixture. Further dilute 1 volume of the resulting solution to 10 volumes with the solvent mixture.

CHROMATOGRAPHIC CONDITIONS

(a) Use a precoated *silica gel F_{254}* plate (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)*.

MOBILE PHASE

20 volumes of *glacial acetic acid*, 20 volumes of *dimethylformamide* and 60 volumes of *chloroform*.

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) (0.3%);

not more than two such spots are more intense than the spot in the chromatogram obtained with solution (3) (0.1%).

Disregard any spot remaining on the line of application.

ASSAY

Shake a number of whole tablets containing the equivalent of 4 g of Acebutolol with 250 mL of *water* until completely disintegrated, add sufficient *water* to produce 1000 mL, filter and dilute 10 mL of the filtrate to 250 mL with *water*. To 10 mL of this solution add 20 mL of 0.1M *hydrochloric acid* and sufficient *water* to produce 200 mL. Measure the *absorbance* of this solution, Appendix II B, at the maximum at 233 nm and calculate the content of $C_{18}H_{28}N_2O_4$ in the tablets taking 643 as the value of A (1%, 1 cm) at the maximum at 233 nm.

LABELLING

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