



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

Acebutolol Capsules

[General Notices](#)

Action and use

Beta-adrenoceptor antagonist.

DEFINITION

Acebutolol Capsules contain Acebutolol Hydrochloride.

The capsules comply with the requirements stated under Capsules 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 contents of the capsules in [potassium chloride](#), [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.

- (1) Add to a quantity of the contents of the capsules containing the equivalent of 0.4 g of Acebutolol 20 mL of a mixture of equal volumes of [chloroform](#) and [methanol](#), shake for 2 minutes, centrifuge and use the supernatant liquid.
- (2) Dilute 3 volumes of solution (1) to 100 volumes with a mixture of equal volumes of [chloroform](#) and [methanol](#) and further dilute 1 volume of this solution to 10 volumes with the same mixture of solvents.
- (3) Dilute 1 volume of solution (1) to 100 volumes with a mixture of equal volumes of [chloroform](#) and [methanol](#) and further dilute 1 volume of this solution to 10 volumes with the same mixture of solvents.

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 μ L 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

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

To a quantity of the mixed contents of 20 capsules containing the equivalent of 0.15 g of Acebutolol add 150 mL of [water](#), shake for 10 minutes, add sufficient [water](#) to produce 250 mL, centrifuge and dilute 10 mL of the supernatant liquid to 100 mL with [water](#). To 10 mL of this solution add 10 mL of 0.1M [hydrochloric acid](#) and sufficient [water](#) to produce 100 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 capsules taking 643 as the value of A(1%, 1 cm) at the maximum at 233 nm.

STORAGE

Acebutolol Capsules should be protected from light.

LABELLING

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