



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

Celiprolol Tablets

[General Notices](#)

Action and use

Beta-adrenoceptor antagonist.

DEFINITION

Celiprolol Tablets contain Celiprolol Hydrochloride.

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

Content of celiprolol hydrochloride, $C_{20}H_{33}N_3O_4 \cdot HCl$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

Mix with the aid of ultrasound a quantity of the powdered tablets containing 200 mg of Celiprolol Hydrochloride with 100 mL of [dichloromethane](#) for 30 minutes, filter (Whatman filter paper No. 42 is suitable), remove the dichloromethane using a rotary evaporator and dry the residue over [phosphorus pentoxide](#) at 110° at a pressure not exceeding 2 kPa for 1 hour. The [infrared absorption spectrum](#) of the dried residue, [Appendix II A](#), is concordant with the *reference spectrum* of celiprolol hydrochloride ([RS 420](#)).

TESTS

Dissolution

Comply with 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 [water](#) at a temperature of 37° as the medium.

PROCEDURE

- (1) Withdraw a sample of 10 mL of the medium and filter; to 1 volume of the filtrate add sufficient [water](#) to produce 20 volumes and filter using a 0.45 µm membrane filter. Measure the [absorbance](#) of the filtrate, suitably diluted with [water](#) if necessary, at the maximum at 231 nm, [Appendix II B](#), using [water](#) in the reference cell.
- (2) Measure the [absorbance](#) of a 0.011% w/v solution of [celiprolol hydrochloride BPCRS](#) in the dissolution medium at the maximum at 231 nm, [Appendix II B](#), using [water](#) in the reference cell.

DETERMINATION OF CONTENT

Calculate the total content of celiprolol hydrochloride, $C_{20}H_{33}N_3O_4 \cdot HCl$, in the medium using the declared content of $C_{20}H_{33}N_3O_4 \cdot HCl$ in [celiprolol hydrochloride BPCRS](#).

Related substances

Carry out method for [liquid chromatography, Appendix III D](#), using the following solutions.

- (1) Disperse with the aid of ultrasound a quantity of the powdered tablets containing 0.1 g of Celiprolol Hydrochloride in 100 mL of the mobile phase for 15 minutes with occasional shaking, cool and filter using a 0.45- μ m membrane filter.
- (2) Dilute 1 volume of solution (1) to 50 volumes with the mobile phase and further dilute 1 volume of this solution to 20 volumes with the mobile phase.
- (3) Prepare a solution containing 0.1% w/v of [celiprolol hydrochloride BPCRS](#) in [water](#), add 5 drops of 5M [sodium hydroxide](#) and heat at 70° for 20 minutes (generation of impurity A).

CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (30 cm \times 3.9 mm) packed with [octadecylsilyl silica gel for chromatography](#) (10 μ m) (Waters μ Bondapak is suitable).
- (b) Use isocratic elution and the mobile phase described below.
- (c) Use a flow rate of 1.5 mL per minute.
- (d) Use ambient column temperature.
- (e) Use a detection wavelength of 233 nm.
- (f) Inject 20 μ L of each solution.
- (g) For solution (1) allow the chromatography to proceed for twice the retention time of the principal peak.

MOBILE PHASE

A mixture of 25 volumes of [acetonitrile](#) and 75 volumes of 0.025M [sodium dihydrogen phosphate monohydrate](#) adjusted to pH 3.0 with 3M [orthophosphoric acid](#). If necessary adjust the composition of the mobile phase so that, in the chromatogram obtained with solution (3), the peak due to celiprolol impurity A is resolved from the solvent front.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the peak due to celiprolol impurity A is resolved from the solvent front.

LIMITS

In the chromatogram obtained with solution (1):

the area of any peak due to celiprolol impurity A is not greater than twice the area of the principal peak in the chromatogram obtained with solution (2) (0.2%);

the area of any other [secondary peak](#) is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (0.1%);

not more than one such peak has an area not greater than 3 times the area of the principal peak in the chromatogram obtained with solution (2) (0.3%);

the sum of the areas of any [secondary peaks](#) is not greater than 5 times the area of the principal peak in the chromatogram obtained with solution (2) (0.5%).

Disregard any peak with an area of less than a fifth of the area of the peak in the chromatogram obtained with solution (2) (0.02%).

ASSAY

Carry out method for [liquid chromatography, Appendix III D](#), using the following solutions.

- (1) Disperse with the aid of ultrasound a quantity of the powdered tablets containing 0.1 g of Celiprolol Hydrochloride in 100 mL of the mobile phase for 15 minutes, cool and filter. Dilute 1 volume of the filtrate to 50 volumes with the mobile phase and filter using a 0.45 μ m membrane filter.
- (2) 0.002% w/v solution of [celiprolol hydrochloride BPCRS](#) in the mobile phase.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used.

DETERMINATION OF CONTENT

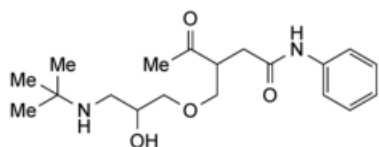
Calculate the content of $C_{20}H_{33}N_3O_4 \cdot HCl$ in the tablets using the declared content of $C_{20}H_{33}N_3O_4 \cdot HCl$ in [celiprolol hydrochloride BPCRS](#).

STORAGE

Celiprolol Tablets should be protected from light.

IMPURITIES

The impurities limited by the requirements of this monograph include those listed under Celiprolol Hydrochloride and the following:



1. 3-acetyl-4-{3-(1,1-dimethyl-ethylamino)-2-hydroxy}propoxybutyranilide