



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

## Carbimazole Tablets

### [General Notices](#)

### Action and use

Thionamide antithyroid drug.

### DEFINITION

Carbimazole Tablets contain Carbimazole.

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

### Content of carbimazole, $C_7H_{10}N_2O_2S$

90.0 to 110.0% of the stated amount.

### IDENTIFICATION

Extract a quantity of the powdered tablets containing 50 mg of Carbimazole with two 5-mL quantities of [dichloromethane](#). Combine the dichloromethane extracts, filter and evaporate the filtrate to dryness. The [infrared absorption spectrum](#), [Appendix II A](#), of the residue after drying at 60° at a pressure not exceeding 0.7 kPa for 30 minutes is concordant with the *reference spectrum* of carbimazole ([RS 042](#)).

### Thiamazole and other related substances

*Carry out the test protected from light and prepare the solutions immediately before use.*

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

- (1) Disperse a quantity of the powdered tablets containing 20 mg of Carbimazole in 10 mL of [acetonitrile](#) with the aid of ultrasound for 5 minutes, filter through a nylon syringe, filter and dilute 1 volume of the filtrate to 20 volumes with [water](#).
- (2) Dilute 1 volume of solution (1) to 200 volumes with mobile phase A.
- (3) 0.00025% w/v of *thiamazole* in mobile phase A.
- (4) 0.002% w/v of [carbimazole BPCRS](#) and 0.0001% w/v of *thiamazole* in mobile phase A.

### CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (15 cm × 3.9 mm) packed with [base-deactivated octadecylsilyl silica gel for chromatography](#) (5 µm) (Waters Symmetry C18 is suitable).
- (b) Use gradient elution and the mobile phase described below.
- (c) Use a flow rate of 1 mL per minute.
- (d) Use an ambient column temperature.
- (e) Use a detection wavelength of 254 nm.
- (f) Inject 100 µL of each solution.

### MOBILE PHASE

Mobile phase A 5 volumes of [acetonitrile](#) and 95 volumes of [water](#).

Mobile phase B 20 volumes of [acetonitrile](#) and 80 volumes of [water](#).

Time (Minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
0-4.5	100	0	isocratic
4.5-4.6	100→0	0→100	linear gradient
4.6-30	0	100	isocratic
30-30.1	0→100	100→0	linear gradient
30.1-40	100	0	re-equilibration

#### SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (4), the [resolution](#) between the peaks due to carbimazole and thiamazole is at least 5.0.

#### LIMITS

In the chromatogram obtained with solution (1):

the area of any peak corresponding to thiamazole is not greater than the area of the principal peak in the chromatogram obtained with solution (3) (2.5%);

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

## ASSAY

*Carry out the test protected from light and prepare the solutions immediately before use.*

Weigh and powder 20 tablets. Carry out the method for [liquid chromatography](#), [Appendix III D](#), using the following solutions.

- (1) Disperse a quantity of the powdered tablets containing 20 mg of Carbimazole in 10 mL of [acetonitrile](#) with the aid of ultrasound for 5 minutes, filter through a nylon syringe filter and dilute 1 volume of this solution to 40 volumes with a 5% v/v solution of [acetonitrile](#).
- (2) 0.005% w/v of [carbimazole BPCRS](#) in mobile phase A.
- (3) 0.01% w/v of [carbimazole BPCRS](#) and 0.0005% w/v of *thiamazole* in mobile phase A.

#### CHROMATOGRAPHIC CONDITIONS

The chromatographic procedure described under Related substances may be used.

#### SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the [resolution](#) between the peaks due to carbimazole and thiamazole is at least 5.0.

#### DETERMINATION OF CONTENT

Calculate the content of  $C_7H_{10}N_2O_2S$  in the tablets using the declared content of  $C_7H_{10}N_2O_2S$  in [carbimazole BPCRS](#).

## IMPURITIES

The impurities limited by the requirements of this monograph include those listed under Carbimazole.

