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

# Calcium Carbonate

General Notices

*(Ph. Eur. monograph 0014)*

$CaCO_3$ 100.1 *471-34-1*

**Action and use**

Antacid.

**Preparations**

Calcium Carbonate Chewable Tablets

Calcium Carbonate Oral Suspension

Calcium and Colecalciferol Tablets

Calcium and Colecalciferol Chewable Tablets

Ph Eur

## DEFINITION

**Content**

98.5 per cent to 100.5 per cent (dried substance).

## CHARACTERS

**Appearance**

White or almost white powder.

**Solubility**

Practically insoluble in water.

## IDENTIFICATION

A. It gives the reaction of carbonates (*2.3.1*).
B. 0.2 mL of solution S (see Tests) gives reaction (b) of calcium (*2.3.1*).

## TESTS

**Solution S**

Dissolve 5.0 g in 80 mL of *dilute acetic acid R*. When the effervescence ceases, boil for 2 min. Allow to cool, dilute to 100 mL with *dilute acetic acid R* and filter, if necessary, through a sintered-glass filter (2.1.2). Keep the residue for the test for substances insoluble in acetic acid.

**Substances insoluble in acetic acid**

Maximum 0.2 per cent.

Wash any residue obtained during the preparation of solution S with 4 quantities, each of 5 mL, of hot *water R* and dry at 100-105 °C for 1 h. The residue weighs a maximum of 10 mg.

**Chlorides** (2.4.4)

Maximum 330 ppm.

Dilute 3 mL of solution S to 15 mL with *water R*.

**Sulfates** (2.4.13)

Maximum 0.25 per cent.

Dilute 1.2 mL of solution S to 15 mL with *distilled water R*.

**Iron** (2.4.9)

Maximum 200 ppm.

Dissolve 50 mg in 5 mL of *dilute hydrochloric acid R* and dilute to 10 mL with *water R*.

**Magnesium and alkali metals**

Maximum 1.5 per cent.

Dissolve 1.0 g in 12 mL of *dilute hydrochloric acid R*. Boil the solution for about 2 min and add 20 mL of *water R*, 1 g of *ammonium chloride R* and 0.1 mL of *methyl red solution R*. Add *dilute ammonia R1* until the colour of the indicator changes and then add 2 mL in excess. Heat to boiling and add 50 mL of hot *ammonium oxalate solution R*. Allow to stand for 4 h, dilute to 100 mL with *water R* and filter through a suitable filter. To 50 mL of the filtrate add 0.25 mL of *sulfuric acid R*. Evaporate to dryness on a water-bath and ignite to constant mass at 600 ± 50 °C. The residue weighs a maximum of 7.5 mg.

**Loss on drying** (2.2.32)

Maximum 2.0 per cent, determined on 1.000 g by drying in an oven at 200 ± 10 °C.

## ASSAY

Dissolve 0.150 g in a mixture of 3 mL of *dilute hydrochloric acid R* and 20 mL of *water R*. Boil for 2 min, allow to cool and dilute to 50 mL with *water R*. Carry out the complexometric titration of calcium (2.5.11).

1 mL of *0.1 M sodium edetate* is equivalent to 10.01 mg of $CaCO_3$.

## FUNCTIONALITY-RELATED CHARACTERISTICS

*This section provides information on characteristics that are recognised as being relevant control parameters for one or more functions of the substance when used as an excipient (see chapter 5.15). Some of the characteristics described in the Functionality-related characteristics section may also be present in the mandatory part of the monograph since they*

*also represent mandatory quality criteria. In such cases, a cross-reference to the tests described in the mandatory part is included in the Functionality-related characteristics section. Control of the characteristics can contribute to the quality of a medicinal product by improving the consistency of the manufacturing process and the performance of the medicinal product during use. Where control methods are cited, they are recognised as being suitable for the purpose, but other methods can also be used. Wherever results for a particular characteristic are reported, the control method must be indicated.*

*The following characteristics may be relevant for calcium carbonate used as filler in tablets and capsules.*

**Particle-size distribution** (*2.9.31* or *2.9.38*)

**Powder flow** (*2.9.36*)

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