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

Calcium Phosphate

General Notices

Tribasic Calcium Phosphate

(Ph. Eur. monograph 1052)

Action and use

Excipient.

Preparations

Calcium and Ergocalciferol Tablets

Calcium Phosphate for Homoeopathic Preparations

Calcium and Ergocalciferol Chewable Tablets

Ph Eur

DEFINITION

Mixture of calcium phosphates.

Content

35.0 per cent to 40.0 per cent of Ca (A_r 40.08).

CHARACTERS

Appearance

White or almost white powder.

Solubility

Practically insoluble in water. It dissolves in dilute hydrochloric acid and in dilute nitric acid.

IDENTIFICATION

A. Dissolve 0.1 g in 5 mL of a 25 per cent *V/V* solution of *nitric acid R*. The solution gives reaction (b) of phosphates (*2.3.1*).
B. It gives reaction (b) of calcium (*2.3.1*). Filter before adding *potassium ferrocyanide solution R*.
C. It complies with the limits of the assay.

TESTS

Solution S

Dissolve 1.00 g in 8 mL of *dilute hydrochloric acid R*. If the solution is not clear, filter it. Add *dilute ammonia R1* dropwise until a precipitate is formed. Dissolve the precipitate by adding *dilute hydrochloric acid R* and dilute to 20 mL with *distilled water R*.

Chlorides (*2.4.4*)

Maximum 0.15 per cent.

Dissolve 0.22 g in a mixture of 1 mL of *nitric acid R* and 10 mL of *water R* and dilute to 100 mL with *water R*.

Fluorides

Maximum 75 ppm.

Potentiometry (*2.2.36, Method II*).

Test solution Dissolve 0.250 g in *0.1 M hydrochloric acid*, add 5.0 mL of *fluoride standard solution (1 ppm F) R* and dilute to 50.0 mL with *0.1 M hydrochloric acid*. To 20.0 mL of this solution add 20.0 mL of *total-ionic-strength-adjustment buffer R* and 3 mL of an 82 g/L solution of *anhydrous sodium acetate R*. Adjust to pH 5.2 with *ammonia R* and dilute to 50.0 mL with *distilled water R*.

Reference solution *Fluoride standard solution (10 ppm F) R*.

Indicator electrode Fluoride-selective.

Reference electrode Silver-silver chloride.

Carry out the measurements on the test solution, then add at least 3 quantities, each of 0.5 mL, of the reference solution, carrying out a measurement after each addition. Calculate the concentration of fluorides using the calibration curve, taking into account the addition of fluoride to the test solution.

Sulfates (*2.4.13*)

Maximum 0.5 per cent.

Dilute 1 mL of solution S to 25 mL with *distilled water R*.

Elemental impurities

Any method that fulfils the requirements of general chapter *2.4.20*. *Determination of elemental impurities* may be used.

Element	Maximum content (ppm)
Arsenic	2
Lead	1

Iron (*2.4.9*)

Maximum 400 ppm.

Dilute 0.5 mL of solution S to 10 mL with *water R*.

Acid-insoluble matter

Maximum 0.2 per cent.

Dissolve 5.0 g in a mixture of 10 mL of *hydrochloric acid R* and 30 mL of *water R*. Filter, wash the residue with *water R* and dry to constant mass at 100-105 °C. The residue weighs a maximum of 10 mg.

Loss on ignition

Maximum 8.0 per cent, determined on 1.000 g by ignition at 800 ± 50 °C for 30 min.

ASSAY

Dissolve 0.200 g in a mixture of 1 mL of *hydrochloric acid R1* and 5 mL of *water R*. Add 25.0 mL of *0.1 M sodium edetate* and dilute to 200 mL with *water R*. Adjust to about pH 10 with *concentrated ammonia R*. Add 10 mL of *ammonium chloride buffer solution pH 10.0 R* and a few milligrams of *mordant black 11 triturate R*. Titrate the excess sodium edetate with *0.1 M zinc sulfate* until the colour changes from blue to violet.

1 mL of *0.1 M sodium edetate* is equivalent to 4.008 mg of Ca.

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 phosphate is used as a filler in tablets and capsules.

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

Bulk density of powders (*2.9.34*)

Powder flow (*2.9.36*)