Quality standards

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

Calcium Chloride Dihydrate

General Notices

(Ph. Eur. monograph 0015)

CaCl₂,2H₂O 147.0 10035-04-8

Preparations

Calcium Chloride Injection

Compound Sodium Lactate Infusion

Ph Eur

DEFINITION

Content

97.0 per cent to 103.0 per cent of CaCl₂,2H₂O.

CHARACTERS

Appearance

White or almost white, crystalline powder, hygroscopic.

Solubility

Freely soluble in water, soluble in ethanol (96 per cent).

IDENTIFICATION

- A. Solution S (see Tests) gives reaction (a) of chlorides (2.3.1).
- B. It gives reaction (b) of calcium (2.3.1).
- C. It complies with the limits of the assay.

TESTS

Solution S

Dissolve 10.0 g in *carbon dioxide-free water R* prepared from *distilled water R* and dilute to 100 mL with the same solvent.

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Appearance of solution

Solution S is clear (2.2.1) and not more intensely coloured than reference solution Y₆ (2.2.2, Method II).

Acidity or alkalinity

To 10 mL of freshly prepared solution S add 0.1 mL of <u>phenolphthalein solution R</u>. If the solution is pink, not more than 0.2 mL of <u>0.01 M hydrochloric acid</u> is required to discharge the colour and if the solution is colourless, not more than 0.2 mL of <u>0.01 M sodium hydroxide</u> is required to turn it pink.

Sulfates (2.4.13)

Maximum 300 ppm.

Dilute 5 mL of solution S to 15 mL with distilled water R.

Aluminium

To 10 mL of solution S add 2 mL of <u>ammonium chloride solution R</u> and 1 mL of <u>dilute ammonia R1</u> and boil the solution. No turbidity or precipitate is formed.

If intended for use in the manufacture of dialysis solutions, the above test is replaced by the following test for aluminium (2.4.17): maximum 1 ppm.

Prescribed solution Dissolve 4 g in 100 mL of water R and add 10 mL of acetate buffer solution pH 6.0 R.

Reference solution Mix 2 mL of <u>aluminium standard solution (2 ppm Al) R</u>, 10 mL of <u>acetate buffer solution pH 6.0 R</u> and 98 mL of <u>water R</u>.

Blank solution Mix 10 mL of acetate buffer solution pH 6.0 R and 100 mL of water R.

Iron (<u>2.4.9</u>)

Maximum 10 ppm, determined on solution S.

Magnesium and alkali metals

Maximum 0.5 per cent.

To a mixture of 20 mL of solution S and 80 mL of <u>water R</u> add 2 g of <u>ammonium chloride R</u> and 2 mL of <u>dilute ammonia R1</u>, heat to boiling and pour into the boiling solution a hot solution of 5 g of <u>ammonium oxalate R</u> in 75 mL of <u>water R</u>. Allow to stand for 4 h, dilute to 200 mL with <u>water R</u> and filter through a suitable filter. To 100 mL of the filtrate add 0.5 mL of <u>sulfuric acid R</u>. Evaporate to dryness on a water-bath and ignite to constant mass at 600 ± 50 °C. The residue weighs a maximum of 5 mg.

ASSAY

Dissolve 0.280 g in 100 mL of water R and carry out the complexometric titration of calcium (2.5.11).

1 mL of <u>0.1 M sodium edetate</u> is equivalent to 14.70 mg of CaCl₂,2H₂O.

LABELLING

The label states, where applicable, that the substance is suitable for use in the manufacture of dialysis solutions.

STORAGE

https://nhathuocngocanh.com/bp/ In an airtight container.

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