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

Calcium Sulfate Dihydrate

General Notices

Calcium Sulphate

(Ph. Eur. monograph 0982)

$CaSO_4,2H_2O$ 172.2 *10101-41-4*

Action and use

Excipient.

Ph Eur

DEFINITION

Content

98.0 per cent to 102.0 per cent of $CaSO_4,2H_2O$.

CHARACTERS

Appearance

White or almost white fine powder.

Solubility

Very slightly soluble in water, practically insoluble in ethanol (96 per cent).

IDENTIFICATION

A. Loss on ignition (see Tests).
B. Solution S (see Tests) gives reaction (a) of sulfates (*2.3.1*).
C. Solution S gives reaction (a) of calcium (*2.3.1*); use *methylene chloride R* instead of *chloroform R* for the extraction.

TESTS

Solution S

Dissolve 1.0 g in 50 mL of a 10 per cent *V/V* solution of *hydrochloric acid R* by heating at 50 °C for 5 min. Allow to cool.

Acidity or alkalinity

Shake 1.5 g with 15 mL of *carbon dioxide-free water R* for 5 min. Allow to stand for 5 min and filter. To 10 mL of the filtrate add 0.1 mL of *phenolphthalein solution R* and 0.25 mL of *0.01 M sodium hydroxide*. The solution is red. Add 0.30 mL of *0.01 M hydrochloric acid*. The solution is colourless. Add 0.2 mL of *methyl red solution R*. The solution is reddish-orange.

Chlorides (*2.4.4*)

Maximum 300 ppm.

Shake 0.5 g with 15 mL of *water R* for 5 min. Allow to stand for 15 min and filter. Dilute 5 mL of the filtrate to 15 mL with *water R*.

Iron (*2.4.9*)

Maximum 100 ppm.

To 0.25 g add a mixture of 5 mL of *hydrochloric acid R* and 20 mL of *water R*. Heat to boiling, cool and filter.

Loss on ignition

18.0 per cent to 22.0 per cent, determined on 1.000 g by ignition to constant mass at 800 ± 50 °C.

ASSAY

Dissolve 0.150 g in 120 mL of *water R*. Carry out the complexometric titration of calcium (*2.5.11*).

1 mL of *0.1 M sodium edetate* is equivalent to 17.22 mg of $CaSO_4,2H_2O$.

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 sulfate dihydrate used as 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*)