

75 ml of *water R*. Allow to stand for 4 h, dilute to 200 ml with *water R* and filter through a suitable filter. To 100 ml of the filtrate add 0.5 ml of *sulphuric acid R*. Evaporate to dryness on a water-bath and ignite to constant mass at 600 ± 50 °C. The residue weighs a maximum of 5 mg.

Heavy metals (2.4.8): maximum 15 ppm.

12 ml of solution S complies with test A. Prepare the reference solution using *lead standard solution (2 ppm Pb) R*.

ASSAY

Dissolve 0.200 g in 100 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 21.91 mg of $\text{CaCl}_2 \cdot 6\text{H}_2\text{O}$.

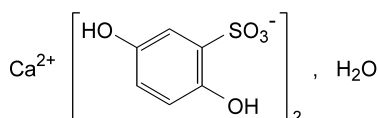
LABELLING

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

01/2008:1183

CALCIUM DOBESILATE MONOHYDRATE

Calcii dobesilas monohydricus



$\text{C}_{12}\text{H}_{10}\text{CaO}_{10}\text{S}_2 \cdot \text{H}_2\text{O}$

M_r 436.4

DEFINITION

Calcium dobesilate monohydrate contains not less than 99.0 per cent and not more than the equivalent of 102.0 per cent of calcium di(2,5-dihydroxybenzenesulphonate), calculated with reference to the anhydrous substance.

CHARACTERS

A white or almost white, hygroscopic powder, very soluble in water, freely soluble in ethanol, very slightly soluble in 2-propanol, practically insoluble in methylene chloride.

IDENTIFICATION

- Dissolve 0.100 g in *water R* and dilute to 200.0 ml with the same solvent. Dilute 5.0 ml of the solution to 100.0 ml with *water R*. Examined between 210 nm and 350 nm (2.2.25), the solution shows two absorption maxima, at 221 nm and 301 nm. The specific absorbance at the maximum at 301 nm is 174 to 181.
- Mix 1 ml of *ferric chloride solution R2*, 1 ml of a freshly prepared 10 g/l solution of *potassium ferricyanide R* and 0.1 ml of *nitric acid R*. To this mixture add 5 ml of freshly prepared solution S (see Tests): a blue colour and a precipitate are immediately produced.
- 2 ml of freshly prepared solution S (see Tests) gives reaction (b) of calcium (2.3.1).

TESTS

Solution S. Dissolve 10.0 g in *carbon dioxide-free water R* and dilute to 100 ml with the same solvent.

Appearance of solution. Solution S, when freshly prepared, is clear (2.2.1) and colourless (2.2.2, *Method II*).

pH (2.2.3). The pH of solution S is 4.5 to 6.0.

Hydroquinone. Examine by thin-layer chromatography (2.2.27), using as the coating substance a suitable silica gel with a fluorescent indicator having an optimal intensity at 254 nm.

Test solution. Dissolve 2.0 g of the substance to be examined in *water R* and dilute to 10 ml with the same solvent.

Reference solution. Dissolve 10 mg of *hydroquinone R* in *water R* and dilute to 50 ml with the same solvent.

Apply to the plate 10 µl of each solution and dry the starting points in a current of cool air. Develop over a path of 15 cm using a mixture of 20 volumes of *methylene chloride R*, 30 volumes of *methyl acetate R* and 50 volumes of *ethyl acetate R*. Dry the plate in a current of hot air and examine in ultraviolet light at 254 nm. Any spot corresponding to hydroquinone in the chromatogram obtained with the test solution is not more intense than the principal spot in the chromatogram obtained with the reference solution (0.1 per cent).

Heavy metals (2.4.8). 1.0 g complies with limit test C for heavy metals (15 ppm). Prepare the standard using 1.5 ml of *lead standard solution (10 ppm Pb) R*.

Iron (2.4.9). 10 ml of solution S complies with the limit test for iron (10 ppm).

Water (2.5.12): 4.0 per cent to 6.0 per cent, determined on 0.500 g by the semi-micro determination of water.

ASSAY

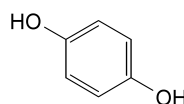
Dissolve 0.200 g in a mixture of 10 ml of *water R* and 40 ml of *dilute sulphuric acid R*. Titrate with 0.1 M *cerium sulphate*, determining the end-point potentiometrically (2.2.20).

1 ml of 0.1 M *cerium sulphate* is equivalent to 10.45 mg of $\text{C}_{12}\text{H}_{10}\text{CaO}_{10}\text{S}_2$.

STORAGE

Store in an airtight container, protected from light.

IMPURITIES

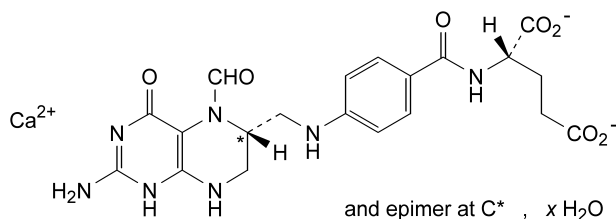


A. benzene-1,4-diol (hydroquinone).

01/2008:0978
corrected 6.0

CALCIUM FOLINATE

Calcii folinas



$\text{C}_{20}\text{H}_{21}\text{CaN}_7\text{O}_7 \cdot x\text{H}_2\text{O}$

M_r 511.5 (anhydrous substance)

DEFINITION

Calcium (2S)-2-[[4-[[[(6RS)-2-amino-5-formyl-4-oxo-1,4,5,6,7,8-hexahydropteridin-6-yl]methyl]amino]benzoyl]amino]pentanedioate.