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Calcium and Ergocalciferol Tablets

General Notices

DEFINITION

Calcium and Ergocalciferol Tablets contain Calcium Lactate Pentahydrate, Calcium Phosphate and Ergocalciferol.

The tablets comply with the requirements stated under Tablets and with the following requirements.

Content of calcium

85.0 to 115.0% of the stated amount.

Content of ergocalciferol, $C_{28}H_{44}O$

90.0 to 120.0% of the stated amount.

IDENTIFICATION

A. Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.
(1) Shake a quantity of the powdered tablets containing 20 µg of Ergocalciferol with 20 mL of the mobile phase with the aid of ultrasound for 15 minutes, cool to room temperature, centrifuge and use the supernatant liquid.
(2) 0.0001% w/v each of *colecalciferol BPCRS* and *ergocalciferol BPCRS* in the mobile phase.
(3) 0.0001% w/v of *ergocalciferol BPCRS* in the mobile phase.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm) (Spherisorb ODS 1 is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 265 nm.
(f) Inject 50 µL of each solution.

MOBILE PHASE

10 volumes of *water* and 90 volumes of *methanol*.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (2), the *resolution factor* between the two principal peaks is at least 1.4. If necessary, adjust the composition of the mobile phase to obtain the required resolution.

CONFIRMATION

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The chromatogram obtained with solution (1) shows a peak with the same retention time as the peak due to ergocalciferol in the chromatogram obtained with solution (3).

B. Disperse a quantity of the powdered tablets containing the equivalent of 10 mg of calcium in 5 mL of *water* and filter. The filtrate yields reaction A characteristic of *lactates*, Appendix VI.
C. Warm a quantity of the powdered tablets containing the equivalent of 90 mg of calcium with 10 mL of 2M *nitric acid*, cool and filter. Add 10 mL of *ammonium molybdate solution* to the filtrate. A yellow precipitate is produced, characteristic of phosphates.
D. Shake a quantity of the powdered tablets containing the equivalent of 10 mg of calcium with 50 mL of *water* and filter. The solution yields reaction A characteristic of *calcium salts*, Appendix VI.

TESTS

Uniformity of content

Tablets containing less than 2 mg and/or less than 2% w/w of Ergocalciferol comply with the requirements stated under Tablets, with respect to the content of Ergocalciferol, using the following method of analysis. Carry out the following procedure protected from light. Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Add 15 mL of *methanol (90%)*, mix with the aid of ultrasound until the tablet is dispersed and then for a further 5 minutes, dilute to 20 mL with *methanol (90%)*, mix, centrifuge and filter through a glass-fibre filter (Whatman GF/C is suitable).
(2) 0.00005% w/v of *ergocalciferol BPCRS* in *methanol (90%)*.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Assay for ergocalciferol may be used.

DETERMINATION OF CONTENT

Calculate the content of $C_{28}H_{44}O$ in each tablet using the declared content of $C_{28}H_{44}O$ in *ergocalciferol BPCRS*.

ASSAY

For calcium

Weigh and powder 20 tablets. To a quantity of the powder containing the equivalent of 50 mg of calcium add 50 mL of *water* and 5 mL of *hydrochloric acid*. Heat the dispersion gently to boiling and continue for about 2 minutes. Allow to cool and add 50 mL of 0.05M *disodium edetate VS*. Neutralise the solution using 2M *sodium hydroxide*, add 10 mL of *ammonia buffer pH 10.9* and 50 mL of *water*. Titrate the excess of disodium edetate with 0.05M *zinc chloride VS* using *mordant black II solution* as indicator. Each mL of 0.05M *disodium edetate VS* is equivalent to 2.004 mg of Ca.

For ergocalciferol

Carry out the following procedure protected from light. Weigh and powder 20 tablets. Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Shake a quantity of the powdered tablets containing 0.1 mg of Ergocalciferol with about 170 mL of *methanol (90%)* for 5 minutes. Mix with the aid of ultrasound for a further 5 minutes, dilute to 200 mL with *methanol (90%)*, centrifuge and filter through a glass fibre filter (Whatman GF/C is suitable).
(2) 0.00005% w/v of *ergocalciferol BPCRS* in *methanol*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (10 cm × 4.6 mm) packed with *end-capped octadecylsilyl silica gel for chromatography* (5 µm) (Hypersil 5 ODS is suitable).
(b) Use isocratic elution and the mobile phase described below.

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(c) Use a flow rate of 1 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 264 nm.
(f) Inject 50 µL of each solution.

MOBILE PHASE

3 volumes of *water* and 97 volumes of *methanol*.

DETERMINATION OF CONTENT

Calculate the content of $C_{28}H_{44}O$ in the tablets using the declared content of $C_{28}H_{44}O$ in *ergocalciferol BPCRS*.

LABELLING

The label states (1) the equivalent number of IU (Units) of antirachitic activity (vitamin D); (2) the equivalent amount of calcium.

Each microgram of Ergocalciferol is equivalent to 40 IU of antirachitic activity (vitamin D).

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