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

Ergocalciferol Tablets

General Notices

Action and use

Vitamin D analogue (Vitamin D_2).

DEFINITION

Ergocalciferol Tablets contain Ergocalciferol.

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

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

90.0 to 125.0% of the stated amount.

IDENTIFICATION

A. In the test for Uniformity of content, the chromatogram obtained with solution (2) shows a peak with the same retention time as the principal peak in the chromatogram obtained with solution (1).
B. Extract one powdered tablet with 5 mL of *dichloromethane*, filter and to 1 mL of the filtrate add 9 mL of *antimony trichloride solution*. A brownish red colour is produced.

TESTS

Uniformity of content

Ergocalciferol Tablets comply with the requirements stated under Tablets using the following method of analysis. Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions, protected from light.

(1) 0.001% w/v of *ergocalciferol BPCRS* in *hexane*.
(2) For tablets containing more than 0.25 mg of Ergocalciferol prepare the solution in the following manner. Add 4 mL of *water* to one tablet in an amber flask and disperse with the aid of ultrasound. Add 12 mL of *dimethyl sulfoxide*, mix, extract with 100 mL of *hexane* by shaking for 30 minutes, centrifuge the hexane layer and use the clear supernatant liquid.

For tablets containing 0.25 mg of Ergocalciferol or less carry out the same procedure but using 2 mL of *water*, 6 mL of *dimethyl sulfoxide* and 25 mL of *hexane*.

(3) Dissolve 5 mg of *colecalciferol BPCRS* in *hexane* and dilute to 20 mL with the same solvent. Heat in a water-bath at 90° under a reflux condenser for 45 minutes and cool (formation of pre-colecalciferol). Dissolve the contents of a vial of *cholecalciferol impurity A EPCRS* in 1.0 mL of this solution.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (20 cm × 4.6 mm) packed with *silica gel for chromatography* (5 µm) (Partisil is suitable).
(b) Use isocratic elution and the mobile phase described below.

(c) Use a flow rate of 2 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 254 nm.
(f) Inject 20 µL of each solution.
(g) Allow the chromatography to proceed for twice the retention time of the principal peak.

MOBILE PHASE

8 volumes of *pentan-1-ol* and 992 volumes of *hexane*.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the peaks corresponding to pre-colecalciferol and *trans*-colecalciferol is at least 1.0.

DETERMINATION OF CONTENT

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

ASSAY

Use the average of the individual results obtained in the test for Uniformity of content.

LABELLING

The label states the equivalent number of IU (International Units) of antirachitic activity (vitamin D) per tablet.

Each µg of ergocalciferol is equivalent to 40 IU of antirachitic activity (vitamin D).

When calciferol tablets are prescribed or demanded, Colecalciferol Tablets or Ergocalciferol Tablets shall be dispensed or supplied.