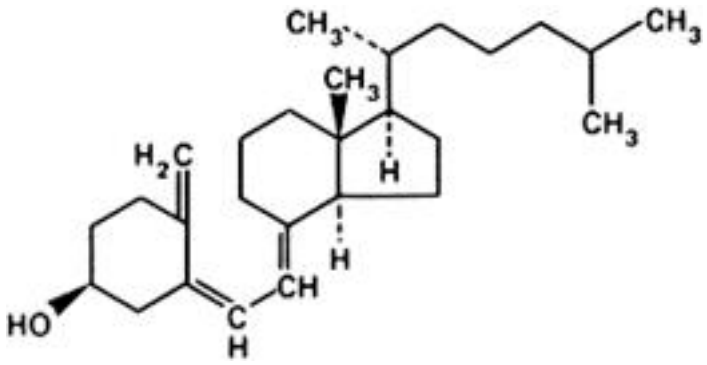
Colecalciferol (Colecalciferolum)

Molecular formula. $C_{27}H_{44}O$

Relative molecular mass. 384.7

Graphic formula.



Chemical name. (5*Z*,7*E*)-9,10-Secocholesta-5,7,10(19)-trien-3*β*-ol; CAS Reg. No. 67-97-0.

Other name. Cholecalciferol.

Description. Colourless crystals or a white, crystalline powder; odourless.

Solubility. Practically insoluble in water; soluble in ethanol (~750 g/l) TS, ether R.

Category. Vitamin, antirachitic.

Storage. Colecalciferol should be kept in a hermetically closed container, in an inert atmosphere, protected from light and stored at a temperature between 2° and 8°C.

Additional information. Even in the absence of light, Colecalciferol is gradually degraded on exposure to a humid atmosphere, the decomposition being faster at higher temperatures.

Requirements

Definition. Colecalciferol contains not less than 95.0% and not more than 105.0% of $C_{27}H_{44}O$.

Identity tests

• Either test A alone or tests B and C may be applied.

A. Carry out the examination as described under 1.7 Spectrophotometry in the infrared region. The infrared absorption spectrum is concordant with the spectrum obtained from colecalciferol RS or with the *reference spectrum* of colecalciferol.

B. Dissolve 1 mg in 1 mL of dichloroethane R and add 4 mL of antimony trichloride TS; a yellowish orange colour is produced.

C. Dissolve 5 mg in 5 mL of chloroform R, add 0.3 mL of acetic anhydride R and 0.1 mL of sulfuric acid (~1760 g/l) TS, and shake vigorously; a bright red colour is produced which changes rapidly through violet to blue and finally to green.

Specific optical rotation. Use a freshly prepared 10 mg/mL solution in aldehyde-free ethanol (~750 g/l) TS; $[\alpha]_D^{20\,°C}$ = +105° to +112°.

7-Dehydrocholesterol. Dissolve 0.04 g in 2 mL of ethanol (~750 g/l) TS, using a glass-stoppered test-tube, and add 1 mL of digitonin TS; the solution produced remains clear for 12 hours.

Assay. With the aid of heat, dissolve about 20 mg, accurately weighed, in sufficient aldehyde-free ethanol (~750 g/l) TS to produce 100 mL; dilute 5.0 mL of this solution to 100 mL with the same solvent. Measure without delay the absorbance of a 1-cm layer of the diluted solution at the maximum at about 265 nm. Calculate the amount of $C_{27}H_{44}O$ in the substance being examined by comparison with colecalciferol RS, similarly and concurrently examined. In an adequately calibrated spectrophotometer the absorbance of the reference solution should be 0.48 ± 0.03.