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

Calcitriol Capsules

General Notices

Action and use

Vitamin D analogue.

DEFINITION

Calcitriol Capsules contain a solution of Calcitriol in a suitable fixed oil.

The capsules comply with the requirements stated under Capsules and with the following requirements.

Content of calcitriol, $C_{27}H_{44}O_3$

90.0 to 110.0% of the stated amount.

A reversible isomerisation to pre-calcitriol takes place in solution, depending on temperature and time. The activity is due to both compounds.

IDENTIFICATION

In the Assay, the chromatogram obtained with solution (1) shows a peak with the same retention time as the peak due to calcitriol in the chromatogram obtained with solution (2).

ASSAY

Mix the contents of 20 capsules. Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

For capsules containing 0.25 µg of Calcitriol or less, prepare solution (1) in the following manner:

(1) Use an undiluted quantity of the mixed capsule content.

For capsules containing more than 0.25 µg of Calcitriol, prepare solution (1) in the following manner:

(1) To a quantity of the mixed capsule content containing 1.5 µg of Calcitriol, add sufficient mobile phase to produce 1 mL.
(2) 0.00015% w/v of *calcitriol EPCRS* in the mobile phase.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *silica gel for chromatography* (5 µm) (Lichrosorb Si60 is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1.2 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 265 nm.

(f) Inject 20 µL of each solution.

(g) If necessary, adjust the composition of the mobile phase so that the principal peak in the chromatogram obtained with solution (1) is clearly separated from the tail of the peak due to the excipient (fixed oil).

MOBILE PHASE

1 volume of *propan-1-ol*, 2 volumes of *methanol*, 40 volumes of *hexane* and 60 volumes of *ethyl acetate*.

SYSTEM SUITABILITY

The Assay is not valid unless, in the chromatogram obtained with solution (1), the peak due to calcitriol is clearly separated from the peak due to the fixed oil.

DETERMINATION OF CONTENT

Combine the peak areas of calcitriol and pre-calcitriol in solutions (1) and (2) respectively. Calculate the content of calcitriol, $C_{27}H_{44}O_3$ in the capsules, using the declared content of $C_{27}H_{44}O_3$ in *calcitriol EPCRS*.