

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

## Colecalciferol Injection

### General Notices

### Action and use

Vitamin D analogue (Vitamin D<sub>3</sub>).

## DEFINITION

Colecalciferol Injection is a sterile solution containing 0.75% w/v of Colecalciferol in Ethyl Oleate.

*The injection complies with the requirements stated under Parenteral Preparations and with the following requirements.*

### Content of colecalciferol, C<sub>27</sub>H<sub>44</sub>O

0.67 to 0.83% w/v.

## CHARACTERISTICS

A pale yellow, oily liquid.

## IDENTIFICATION

To 1 mL of a 0.2% v/v solution of the injection in ethanol-free chloroform add 9 mL of antimony trichloride solution. The light absorption of the resulting solution, Appendix II B, exhibits a maximum at 500 nm.

## ASSAY

Carry out the following procedure in subdued light. Dilute 0.1 g of the injection to 50 mL with dry 1,2-dichloroethane that has been purified by passing it through a column of silica gel. To 1 mL of this solution add rapidly 9 mL of antimony trichloride in dichloroethane solution and measure the absorbance of the solution at 500 and 550 nm, Appendix II B, 90 to 120 seconds after adding the reagent. Repeat the operation using 1 mL of a 0.002% w/v solution of colecalciferol BPCRS in the dry, purified 1,2-dichloroethane, beginning at the words 'add rapidly 9 mL of ...'. Calculate the result of the assay from the difference between the absorbances at 500 and 550 nm and using the declared content of C<sub>27</sub>H<sub>44</sub>O in colecalciferol BPCRS. Calculate the percentage w/v of colecalciferol taking 0.87 g as the value of the weight per mL of the injection.

## STORAGE

Colecalciferol injection should be protected from light.

## **LABELLING**

The label states (1) that the preparation is for intramuscular use only; (2) the equivalent number of IU (units) of antirachitic activity (vitamin D) in 1 mL.

Each  $\mu$ g of Colecalciferol is equivalent to 40 IU of antirachitic activity (vitamin D).

When calciferol injection is prescribed or demanded, Colecalciferol Injection or [Ergocalciferol Injection](#) shall be dispensed or supplied.