



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 µg 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.