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## Ergocalciferol Oral Solution

### DEFINITION

Ergocalciferol Oral Solution is a solution of Ergocalciferol in an edible vegetable oil, in Polysorbate 80, or in Propylene Glycol. It contains NLT 100.0% and NMT 120.0% of the labeled amount of vitamin D as ergocalciferol ( $C_{28}H_{44}O$ ).

### ASSAY

#### Change to read:

##### PROCEDURE

**Mobile phase:** [Chloroform](#) containing alcohol as a preservative

**Standard stock solution:** 50 µg/mL of [USP Ergocalciferol RS](#) in [chloroform](#). [NOTE—Prepare this solution fresh daily.]

**Standard solution A:** 5 µg/mL of [USP Ergocalciferol RS](#) from the *Standard stock solution* in [chloroform](#). [NOTE—Store *Standard solution A* at a temperature not above 0°.]

**Standard solution B:** Transfer 5.0 mL of the *Standard stock solution* into a round-bottom flask fitted with a reflux condenser. Displace the air with nitrogen, and reflux for 1 h in a water bath under a nitrogen atmosphere to obtain a solution containing ergocalciferol and pre-ergocalciferol. Cool and transfer, with the aid of several portions of [chloroform](#), to a 50-mL volumetric flask. Dilute with [chloroform](#) to volume, and mix.

**Sample solution:** Nominally 5 µg/mL of ergocalciferol from an accurately measured volume of Oral Solution in [chloroform](#)

#### Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

**Mode:** LC

**Detector:** UV 254 nm

**Column:** 4.6-mm × 25-cm; 5-µm packing L3

**Flow rate:** 1 mL/min

**Injection volume:** 10–20 µL

#### System suitability

**Sample:** *Standard solution B*

[NOTE—The relative retention times for pre-ergocalciferol and ergocalciferol are 0.8 and 1.0, respectively.]

#### Suitability requirements

**Resolution:** NLT 1.0 between pre-ergocalciferol and ergocalciferol

**Relative standard deviation:** NMT 2.0%

#### Analysis

**Samples:** *Standard solution A*, *Standard solution B*, and *Sample solution*

#### Ergocalciferol response factor

Calculate the *Ergocalciferol response factor*,  $F_D$ :

$$F_D = C_{SA}/r_{SA}$$

$C_{SA}$  = concentration of [USP Ergocalciferol RS](#) in *Standard solution A* (µg/mL)

$r_{SA}$  = peak  $\blacktriangle$ area $\blacktriangle$  (USP 1-Dec-2021) of ergocalciferol from *Standard solution A*

#### Pre-ergocalciferol response factor

Calculate the concentration,  $C_{SB}$  in µg/mL, of ergocalciferol in *Standard solution B*:

$$C_{SB} = F_D \times r_{SB}$$

$F_D$  = *Ergocalciferol response factor*

$r_{SB}$  = peak area of ergocalciferol from *Standard solution B*

Calculate the concentration,  $C_{pre}$  in µg/mL, of pre-ergocalciferol  $\blacktriangle$ in *Standard solution B*:  $\blacktriangle$  (USP 1-Dec-2021)

$$C_{pre} = C_{SA} - C_{SB}$$

$C_{SA}$  = concentration of [USP Ergocalciferol RS](#) in *Standard solution A* (µg/mL)

$C_{SB}$  = concentration of ergocalciferol in *Standard solution B* (µg/mL)

Calculate the *Pre-ergocalciferol response factor*,  $F_{pre}$ :

$$F_{pre} = C_{pre} / r_{SBpre}$$

$C_{pre}$  = concentration of pre-ergocalciferol ▲ in *Standard solution B* ▲ (USP 1-Dec-2021) (µg/mL)

$r_{SBpre}$  = peak ▲ area ▲ (USP 1-Dec-2021) of pre-ergocalciferol from *Standard solution B*

#### Vitamin D content

Calculate the percentage of the labeled amount of vitamin D as ergocalciferol ( $C_{28}H_{44}O$ ) in the portion of Oral Solution taken:

$$\text{Result} = \{[(F_D \times r_U) + (F_{pre} \times r_{Upre})] / C_U\} \times 100$$

$F_D$  = *Ergocalciferol response factor*

$r_U$  = peak area of ergocalciferol from the *Sample solution*

$F_{pre}$  = *Pre-ergocalciferol response factor*

$r_{Upre}$  = peak area of pre-ergocalciferol from the *Sample solution*

$C_U$  = nominal concentration of ergocalciferol in the *Sample solution* (µg/mL)

**Acceptance criteria:** 100.0%–120.0%

#### ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.

#### Change to read:

- **LABELING:** Label to indicate the concentration of ergocalciferol, ▲ in micrograms per dosage unit. Expression of the amount of ergocalciferol in terms of units may be added in parentheses after the mass units.<sup>1</sup> ▲ (USP 1-Dec-2021)
- **USP REFERENCE STANDARDS** (11).  
[USP Ergocalciferol RS](#)

<sup>1</sup> Where articles are labeled in terms of units in addition to the required labeling, the relationship of the USP Units or International Units (IU) to mass is as follows: 1 µg of cholecalciferol or ergocalciferol = 40 USP Units or IU.

**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
ERGOCALCIFEROL ORAL SOLUTION	<a href="#">Natalia Davydova</a> Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

**Chromatographic Database Information:** [Chromatographic Database](#)

#### Most Recently Appeared In:

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