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# Ergocalciferol Tablets

## DEFINITION

Ergocalciferol Tablets contain NLT 100.0% and NMT 120.0% of the labeled amount of ergocalciferol (C<sub>28</sub>H<sub>44</sub>O).

## IDENTIFICATION

### Change to read:

• **A. ULTRAVIOLET ABSORPTION:** ▲The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (USP 1-Aug-2024)

### Delete the following:

▲ **B. COLOR REACTION**▲ (USP 1-Aug-2024)

### Add the following:

▲ **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (USP 1-Aug-2024)

## ASSAY

### Change to read:

#### • PROCEDURE

▲[NOTE—Use low-actinic glassware.]

**Diluent:** [Water](#), [dimethylformamide](#), and [isopropyl alcohol](#) (5:10:35)

**Mobile phase:** [Acetonitrile](#) and [water](#) (70:30)

**Standard stock solution:** 0.5 mg/mL of [USP Ergocalciferol RS](#) in [isopropyl alcohol](#)

**Cholecalciferol stock solution:** 0.5 mg/mL of [USP Cholecalciferol RS](#) in [isopropyl alcohol](#)

**System suitability solution:** Combine equal volumes of the *Standard stock solution* and *Cholecalciferol stock solution* and dilute with *Diluent* to obtain a concentration of about 1 µg/mL each of cholecalciferol and ergocalciferol.

**Standard solution:** 1 µg/mL of [USP Ergocalciferol RS](#) from the *Standard stock solution* in *Diluent*. Dilute stepwise, if necessary.

**Sample solution:** Finely powder NLT 20 Tablets. Transfer a portion of the powder, nominally equivalent to 50 µg of ergocalciferol, into a 50-mL volumetric flask, add 5 mL of [water](#), and sonicate for 10 min with intermittent shaking. Add 10 mL of [dimethylformamide](#), sonicate for 15 min with intermittent shaking, cool to room temperature, and dilute with [isopropyl alcohol](#) to volume. Mix well and pass through a membrane filter of 0.45-µm or finer pore size.

### Chromatographic system

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

**Mode:** LC

**Detector:** UV 265 nm

**Column:** 4.6-mm × 15-cm; 2.7-µm packing [L96](#)

**Column temperature:** 40°

**Flow rate:** 1 mL/min

**Injection volume:** 20 µL

### System suitability

**Samples:** *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for cholecalciferol and ergocalciferol are 0.9 and 1.0, respectively.]

### Suitability requirements

**Resolution:** NLT 1.5 between the cholecalciferol and ergocalciferol peaks, *System suitability solution*

**Relative standard deviation:** NMT 2.0%, *Standard solution*

### Analysis

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ergocalciferol (C<sub>28</sub>H<sub>44</sub>O) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

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

$r_s$  = peak area of ergocalciferol from the *Standard solution*

$C_s$  = concentration of ergocalciferol in the *Standard solution* (µg/mL)

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

▲ (USP 1-Aug-2024)

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

PERFORMANCE TESTS

- [DISINTEGRATION \(701\)](#).  
**Time:** 30 min  
**Acceptance criteria:** Meet the requirements
- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.
- Change to read:**
- **LABELING:** Label the Tablets to indicate the content of ergocalciferol, in ▲micrograms. Expression of the amount of ergocalciferol in terms of units may be added in parentheses after the mass units. <sup>1</sup>▲ (USP 1-Aug-2024)

**Change to read:**

- [USP REFERENCE STANDARDS \(11\)](#).

▲ [USP Cholecalciferol RS](#)▲ (USP 1-Aug-2024)  
[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 TABLETS	<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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