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Cholecalciferol Tablets

DEFINITION

Cholecalciferol Tablets contain NLT 90.0% and NMT 115.0% of the labeled amount of cholecalciferol ($C_{27}H_{44}O$).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

• PROCEDURE

[NOTE—Use amber, low-actinic glassware.]

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

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

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

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

System suitability solution: Combine equal volumes of *Standard stock solution* and *Ergocalciferol 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 Cholecalciferol RS](#) in *Diluent* from the *Standard stock solution*, prepared accurately

Sample solution: Finely powder NLT 20 Tablets. Transfer a portion of the powder, nominally equivalent to 50 µg of cholecalciferol, 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 0.45-µm nylon filter.

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 1.0 and 1.1, 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 cholecalciferol ($C_{27}H_{44}O$) in the portion of Tablets taken:

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

r_U = peak area of cholecalciferol from the *Sample solution*

r_S = peak area of cholecalciferol from the *Standard solution*

C_S = concentration of cholecalciferol in the *Standard solution* (µg/mL)

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

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

[NOTE—Perform this test under light conditions that minimize photodegradation.]

Medium: 0.1% (w/v) octoxynol-9 in [water](#); 500 mL

Apparatus 2: 75 rpm

Time: 30 min

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

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

Standard solution: Dilute *Standard stock solution* with *Medium* to obtain the concentration equivalent to that expected in the *Sample solution*.

Sample solution: Withdraw a portion of the solution under test, pass through a 0.45-µm PVDF filter, and use the pooled sample as the test specimen.

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: 100 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of cholecalciferol dissolved:

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

r_U = peak area of cholecalciferol from the *Sample solution*

r_S = peak area of cholecalciferol from the *Standard solution*

C_S = concentration of cholecalciferol in the *Standard solution* (µg/mL)

V = volume of *Medium*, 500 mL

L = label claim of cholecalciferol (µg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of cholecalciferol is dissolved.

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

ADDITIONAL REQUIREMENTS

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

• **LABELING:** Label the Tablets to indicate the content of cholecalciferol in µg.

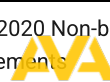
• [USP REFERENCE STANDARDS \(11\)](#)

[USP Cholecalciferol RS](#)

[USP Ergocalciferol RS](#)

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

Topic/Question	Contact	Expert Committee
CHOLECALCIFEROL TABLETS	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Tablets Supplements



Documents

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