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Cholecalciferol Chewable Gels

DEFINITION

Cholecalciferol Chewable Gels contain NLT 90.0% and NMT 140.0% 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 test for *Strength*.

STRENGTH

Change to read:

PROCEDURE

[NOTE—Use amber, low-actinic glassware. Use cryogenic gloves when handling liquid nitrogen.]

Mobile phase: 1.2% [isopropyl alcohol](#) in [hexane](#)

[NOTE—Wash the column periodically with 5% [isopropyl alcohol](#) in [hexane](#) to eliminate retained substances and avoid carryover interferences.]

Standard stock solution: 0.3 mg/mL of [USP Cholecalciferol RS](#) in [2,2,4-trimethylpentane](#). Shake on a mechanical shaker for 15 min.

Standard solution: 1 µg/mL of [USP Cholecalciferol RS](#) in [2,2,4-trimethylpentane](#) from the *Standard stock solution*, prepared accurately

Sample solution: Immerse 25–30 Chewable Gels in liquid nitrogen in a cryogenic vessel for 10 min. Cool a blender jar by swirling liquid nitrogen for about 1 min and discard the contents. Add frozen Chewable Gels to the cooled blender jar and grind to a fine powder. Transfer a portion of the powder, nominally equivalent to 10 µg of cholecalciferol, into a 50-mL centrifuge tube. [NOTE—Proceed to this step immediately or keep the powdered Chewable Gels frozen until use.] Add 300 mg of [pancreatin](#) and 5 mL of water and shake on a shaker water bath at 55° until complete dissolution (about 20 min). Mix the solution on a vortex mixer to suspend any undissolved solids, add 20 mL of [dimethyl sulfoxide](#), and mix again on a vortex mixer until well mixed. Pipet 10 mL of [2,2,4-trimethylpentane](#), mix on a vortex mixer until the phases are well mixed, then shake the tube on a horizontal shaker for 20 min, and centrifuge the sample at 2500 rpm for 10 min. Pass a portion of the 2,2,4-trimethylpentane layer through a 0.45-µm glass microfiber filter, discarding the first 2 mL of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 265 nm

Column: 4.6-mm × 25-cm; 5-µm packing [L3](#)

Flow rate: 1.3 mL/min

Injection volume: 80 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 3.0%

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 Chewable Gels 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 ▲[USP Cholecalciferol RS](#)▲ (USP 1-Dec-2019) in the *Standard solution* (µg/mL)

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

Acceptance criteria: 90.0%–140.0%

PERFORMANCE TESTS**Change to read:**

- [DISINTEGRATION AND DISSOLUTION \(2040\), Dissolution](#)

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

Medium: 0.1% (w/v) octoxynol-9 in 0.05 M phosphate buffer pH 6.8; 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 the *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 polyvinylidene fluoride (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 [USP Cholecalciferol RS](#) (USP 1-Dec-2019) in the *Standard solution* (μg/mL)

V = volume of *Medium*, 500 mL

L = label claim of cholecalciferol (μg/Chewable Gel)

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

Change to read:

- [WEIGHT VARIATION \(2091\)](#)  (USP 1-Dec-2019): Meet the requirements

SPECIFIC TESTS

- [pH \(791\)](#)

Sample solution: Cut the Chewable Gels into small pieces. Transfer about 15 g of the cut Chewable Gels into a 50-mL centrifuge tube, add 15 g of hot [water](#) (80°–90°), close the cap, place the centrifuge tube into a shaker water bath at 55°, and shake for 50–60 min or until all of the Chewable Gels are dissolved. Cool down to 30° and measure the pH.

Acceptance criteria: NMT 4.5

- **WATER ACTIVITY**

Sample: Slice the Chewable Gels into pieces about 2 mm thick.

Procedure: Measure the water activity using the AOAC's *Official Methods of Analysis*, Official Method #978.18.

Acceptance criteria: NMT 0.75

CONTAMINANTS

- [MICROBIAL ENUMERATION TESTS \(2021\)](#): The total aerobic microbial count is NMT 10^3 cfu/g, and the total combined yeasts and molds count is NMT 10^2 cfu/g.
- [ABSENCE OF SPECIFIED MICROORGANISMS \(2022\), Test Procedures, Test for Absence of Salmonella Species](#) and [Test for Absence of Escherichia coli](#): Meet the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers; protect from heat.