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Add the following:

Ubidecarenone Chewable Gels

DEFINITION

Ubidecarenone Chewable Gels contain NLT 90.0% and NMT 140.0% of the labeled amount of ubidecarenone ($C_{59}H_{90}O_4$).

IDENTIFICATION

• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Procedure for Strength*.

STRENGTH

PROCEDURE

[NOTE—Conduct this test promptly with minimum exposure to actinic light.]

Solvent: [n-Hexane](#) and [dehydrated alcohol](#) (5:2)

Mobile phase: [Acetonitrile](#), [tetrahydrofuran](#), and [water](#) (55:40:5)

System suitability stock solution: 1.0 mg/mL of [USP Ubidecarenone Related Compound A RS](#) in *Solvent*. Dilute a portion of this solution with [dehydrated alcohol](#) to obtain a concentration of 40 µg/mL.

Standard stock solution: 1.0 mg/mL of [USP Ubidecarenone RS](#) in *Solvent*

Standard solution: 40 µg/mL of [USP Ubidecarenone RS](#) in [dehydrated alcohol](#), from the *Standard stock solution*

System suitability solution: *System suitability stock solution* and *Standard solution* (1:1)

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 100 mg of ubidecarenone, into a 50-mL centrifuge tube. [NOTE—Proceed to this step immediately or keep the powdered Chewable Gels frozen until use.] Add 15 mL of [water](#) and shake on water bath shaker at 60° until complete dissolution (about 10 min). Add 20 mL of *Solvent* and shake by mechanical means for 3 min. Centrifuge for 10 min and then transfer the upper organic phase into a 100-mL volumetric flask. Repeat the extraction twice, combine the organic phases, and dilute with *Solvent* to volume. Mix well. Transfer 1.0 mL of the solution to a 25-mL volumetric flask, add 2.5 mL of a 0.1% solution of anhydrous ferric chloride in [dehydrated alcohol](#), and dilute with [dehydrated alcohol](#) to volume. Mix well.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 8-mm × 10-cm; 5-µm packing [L1](#)

Column temperature: 35°

Flow rate: 2.5 mL/min

Injection volume: 15 µL

System suitability

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

[NOTE—The relative retention times for ubidecarenone related compound A and ubidecarenone are 0.8 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.5 between ubidecarenone and ubidecarenone related compound A, *System suitability solution*

Tailing factor: NMT 1.5, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ubidecarenone ($C_{59}H_{90}O_4$) 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 ubidecarenone from the *Sample solution*

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

C_S = concentration of [USP Ubidecarenone RS](#) in the *Standard solution* (µg/mL)

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

Acceptance criteria: 90.0%–140.0%

PERFORMANCE TESTS

• **DISINTEGRATION AND DISSOLUTION (2040):** Proceed as directed in the test for [Disintegration](#), except where the product is labeled to contain a water-soluble form of ubidecarenone. For Chewable Gels labeled to contain a water-soluble or enhanced absorption form of ubidecarenone, proceed as directed in the test for [Dissolution](#).

Test for Disintegration

Medium: [Water](#)

Time: 30 min, using disk

Tolerances: Meet the requirements

Test for Dissolution

Medium: [Water](#); 500 mL

Apparatus 2: 100 rpm

Time: 60 min

Standard solution: Dissolve 25 mg of [USP Ubidecarenone RS](#) in 1 mL of ethyl ether, and dilute with alcohol to obtain a concentration of 2.5 µg/mL. [NOTE—Use a freshly prepared solution only.]

Sample solution: Withdraw a portion of the solution under test and pass through a suitable filter of 0.45-µm pore size. Combine equal aliquots of filtered solutions under test from each of the 6 dissolution vessels and mix. Dilute with [alcohol](#) a volume of the pooled sample to obtain a concentration of 2.5 µg/mL of ubidecarenone.

Mobile phase and Chromatographic system: Proceed as directed in the *Procedure for Strength*, except for *Injection volume*.

Injection volume: 100 µL

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ubidecarenone ($C_{59}H_{90}O_4$) dissolved:

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

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

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

C_S = concentration of [USP Ubidecarenone RS](#) in the *Standard solution* (mg/mL)

V = volume of *Medium*, 500 mL

D = dilution factor for the *Sample solution*

L = label claim (mg/Chewable Gel)

Tolerances: NLT 75% of the labeled amount of ubidecarenone ($C_{59}H_{90}O_4$) is dissolved

• **WEIGHT VARIATION (2091):** 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 to 30° and measure the pH.

Acceptance criteria: NMT 4.5

• **WATER ACTIVITY (922).**