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Ascorbic Acid Chewable Gels

DEFINITION

Ascorbic Acid Chewable Gels contain ascorbic acid in the form of ascorbic acid ($C_6H_8O_6$), sodium ascorbate ($C_6H_7NaO_6$), calcium ascorbate dihydrate ($C_{12}H_{14}CaO_{12} \cdot 2H_2O$), or their mixture in an amount equivalent to NLT 90.0% and NMT 150.0% of the labeled amount of ascorbic acid ($C_6H_8O_6$).

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

• PROCEDURE

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

Extracting solution: Dissolve 73 g of [metaphosphoric acid](#) in 800 mL of [water](#), add 84 mL of [glacial acetic acid](#), and dilute with [water](#) to 1000 mL.

Mobile phase: 7.8 g/L of [monobasic sodium phosphate dihydrate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 2.5.

[NOTE—Wash the column periodically with [methanol](#) and [water](#) using appropriate gradients to eliminate retained substances and avoid carryover interferences.]

Standard stock solution: 1 mg/mL of [USP Ascorbic Acid RS](#) in *Extracting solution*. [NOTE—Sonicate with intermittent shaking to help dissolve, if necessary. Prepare fresh every time.]

Standard solution: Dilute *Standard stock solution* with *Extracting solution* to obtain a solution containing 0.05 mg/mL of [USP Ascorbic Acid RS](#).

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 25 mg of ascorbic acid, into a 25-mL volumetric flask. [NOTE—Proceed to this step immediately or keep the powdered Chewable Gels frozen until use.] Add 15 mL of *Extracting solution*, mix on a vortex mixer until well mixed, and sonicate for 10 min or until the sample has completely dissolved. Cool the solution to room temperature, dilute with *Extracting solution* to volume, and mix well. Quantitatively dilute a portion of the solution with *Extracting solution* to obtain a solution containing 0.05 mg/mL of ascorbic acid. Mix and pass through a 0.45- μ m glass microfiber filter, discarding the first few milliliters of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 245 nm

Column: 4.6-mm $\times$ 15-cm; 3.5- μ m packing [L7](#)

Flow rate: 0.8 mL/min

Injection volume: 10 μ L

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of vitamin C, as ascorbic acid ($C_6H_8O_6$), in the portion of sample taken:

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

r_U = peak area of ascorbic acid from the *Sample solution*

r_S = peak area of ascorbic acid from the *Standard solution*

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

C_U = nominal concentration of ascorbic acid in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–150.0%

PERFORMANCE TESTS

Change to read:

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

Medium: 0.1 N [hydrochloric acid](#); 900 mL

Apparatus 2: 75 rpm

Time: 15 min

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

Analysis: Proceed as directed in *Strength*, making any necessary modifications.

▲▲ (USP 1-Dec-2019)

Calculate the percentage of the labeled amount of ascorbic acid ($C_6H_8O_6$) dissolved:

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

r_U = peak area of ascorbic acid from the *Sample solution*

r_S = peak area of ascorbic acid from the *Standard solution*

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

V = volume of *Medium*, 900 mL

L = label claim of ascorbic acid (mg/Chewable Gel)

Tolerances: NLT 75% of the labeled amount of ascorbic acid 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 (80°–90°) [water](#), 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 tight containers; protect from heat.
- **LABELING:** The label states the quantity of ascorbic acid in mg/Chewable Gel, and the chemical form of ascorbic acid present in the Chewable Gels.
- [USP REFERENCE STANDARDS \(11\)](#)
[USP Ascorbic Acid RS](#)

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

Topic/Question	Contact	Expert Committee
ASCORBIC ACID CHEWABLE GELS	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements



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