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Ascorbic Acid Tablets

DEFINITION

Ascorbic Acid Tablets 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 110.0% of the labeled amount of ascorbic acid ($C_6H_8O_6$).

IDENTIFICATION

- **A.**

  Sample solution: Triturate a quantity of finely powdered Tablets with diluted alcohol to make a solution of ascorbic acid with a concentration of 20 mg/mL, and filter.

  Analysis: Add alkaline cupric tartrate TS to a portion of the *Sample solution*.

  Acceptance criteria: The *Sample solution* reduces alkaline cupric tartrate TS slowly at room temperature but more readily upon heating.

- **B.**

  Sample solution: Use the *Sample solution* from *Identification* test *A*.

  Analysis: To 2 mL of the *Sample solution* add 4 drops of methylene blue TS, and warm to 40°.

  Acceptance criteria: The deep blue color of methylene blue becomes appreciably lighter or is completely discharged within 3 min.

- **C.**

  Sample solution: Use the *Sample solution* from *Identification* test *A*.

  Analysis: To 1 mL of the *Sample solution* add 15 mL of trichloroacetic acid solution (1 in 20) and 200 mg of activated charcoal, shake the mixture vigorously for 1 min, and pass through a small fluted filter, returning the filtrate if necessary, until clear. To 5 mL of the filtrate add 1 drop of pyrrole, agitate gently until dissolved, and then heat in a bath at 50°.

  Acceptance criteria: A blue color develops.

ASSAY

[Note—Where more than one assay procedure is given in the monograph, the requirements may be met by following any one of the specified procedures, the procedure used being stated in the labeling only if *Procedure 1* is not used.]

- **Procedure 1**

  Sample stock solution: Transfer NLT 20 Tablets to a 1000-mL volumetric flask containing 250 mL of metaphosphoric–acetic acids TS. Insert the stopper in the flask, and shake by mechanical means for 30 min or until the Tablets have disintegrated completely. Dilute with water to volume.

  Sample solution: Transfer a portion of the *Sample stock solution* to a centrifuge tube, and centrifuge until a clear supernatant is obtained. Quantitatively dilute the clear supernatant with water, if necessary, to obtain a solution containing 0.5 mg/mL of ascorbic acid.

  Blank: A mixture of 5.5 mL of metaphosphoric–acetic acids TS and 15 mL of water

  Titrimetric system

  (See *Titrimetry* ⟨541⟩.)

  Mode: Direct titration

  Titrant: Standard dichlorophenol–indophenol VS

  Endpoint detection: Visual, a rose-pink color that persists for at least 5 s

  Analysis: Transfer a volume of the *Sample solution*, equivalent to 2 mg of ascorbic acid, to a 50-mL conical flask. Add 5 mL of metaphosphoric–acetic acids TS, and titrate with *Titrant*. Correct for the volume of the *Titrant* consumed by the *Blank*. Calculate the percentage of the labeled amount of ascorbic acid ($C_6H_8O_6$) in the portion of Tablets taken:

$$\text{Result} = [(V_S - V_B) \times F/W] \times 100$$

  V_S = *Titrant* volume consumed by the *Sample solution* (mL)

  V_B = *Titrant* volume consumed by the *Blank* (mL)

  F = concentration of the *Titrant* in terms of the equivalent of ascorbic acid (mg/mL)

  W = nominal weight of ascorbic acid taken for *Analysis* (mg)

  Acceptance criteria: 90.0%–110.0%

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• **Procedure 2**

(See *Vitamin C Assay ⟨580⟩, Method II—Chromatographic Method*.)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Time: 45 min

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

Analysis: Proceed as directed in the *Assay, Procedure 1* or *Procedure 2*, conducting the procedure without delay and making any necessary modifications.

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

For *Procedure 1*

$$\text{Result} = [(V_S - V_B) \times F \times (V_M/a)/L] \times 100$$

V_S = *Titrant* volume consumed by the *Sample solution* (mL)

V_B = *Titrant* volume consumed by the *Blank* (mL)

F = concentration of the *Titrant* in terms of the equivalent of ascorbic acid (mg/mL)

V_M = volume of *Medium*, 900 mL

a = volume of the aliquot taken for *Analysis*

L = label claim of ascorbic acid (mg/Tablet)

For *Procedure 2*

$$\text{Result} = (r_U/r_S) \times C_S \times V \times (1/L) \times 100$$

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 (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of ascorbic acid ($C_6H_8O_6$) is dissolved.

• **Disintegration ⟨701⟩**

[Note—Meet this additional test if the label recommends to disintegrate the Tablets in the mouth before swallowing.]

Medium: Water

Time: NMT 5 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.

• **Labeling:** The label states the quantity of ascorbic acid in mg/Tablet, and the chemical form of ascorbic acid present in the Tablets. The labeling states with which assay procedure the product complies only if *Procedure 1* is not used. Tablets that are intended to be disintegrated in the mouth before swallowing are so labeled.

• **USP Reference Standards ⟨11⟩**

USP Ascorbic Acid RS

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Auxiliary Information - Please check for your question in the FAQs before contacting USP.

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

Chromatographic Database Information: Chromatographic Database

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