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Ascorbic Acid Injection

DEFINITION

Ascorbic Acid Injection is a sterile solution, in Water for Injection, of Ascorbic Acid prepared with the aid of Sodium Hydroxide, Sodium Carbonate, or Sodium Bicarbonate. It contains NLT 90.0% and NMT 110.0% of the labeled amount of ascorbic acid ($C_6H_8O_6$).

IDENTIFICATION

• **A.**

Analysis: To a volume of Injection, equivalent to 40 mg of ascorbic acid, add 4 mL of 0.1 N hydrochloric acid, then add 4 drops of methylene blue TS, and warm to 40°.

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

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, obtained as directed in the *Assay*.

• **C.** The Injection imparts an intense yellow color to a nonluminous flame.

ASSAY

Change to read:

• **Procedure**

Mobile phase: Dissolve 15.6 g of dibasic sodium phosphate and 12.2 g of monobasic potassium phosphate in 2000 mL of water, and adjust with phosphoric acid to a pH of 2.5 ± 0.05.

Standard solution: 0.5 mg/mL of USP Ascorbic Acid RS in *Mobile phase*. [Note—Refrigerate and store protected from light until use. The solution is stable for at least 24 h. Inject within 3 h after removal from the refrigerator.]

Sample solution: Dilute the Injection, if necessary, with *Mobile phase* to obtain a solution with a concentration of about 0.5 mg/mL. [Note—Refrigerate and store protected from light until use. The solution is stable for at least 24 h. Inject within 3 h after removal from the refrigerator.]

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 245 nm

Column: ▲15-cm▲ (ERR 1-Jul-2022) × 6-mm; packing L39

Flow rate: 0.6 mL/min

Injection volume: 4 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 3500 theoretical plates

Tailing factor: NMT 1.6

Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ascorbic acid ($C_6H_8O_6$) in the portion of Injection taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response 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%–110.0%

IMPURITIES

• **Limit of Oxalate**

Analysis: Dilute a volume of Injection, equivalent to 50 mg of ascorbic acid, with water to 5 mL. Add 0.2 mL of acetic acid and 0.5 mL of calcium chloride TS.

Acceptance criteria: No turbidity is produced in 1 min.

SPECIFIC TESTS

• **pH ⟨791⟩:** 5.5–7.0

• **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products ⟨1⟩*.

• **Bacterial Endotoxins Test ⟨85⟩:** It contains NMT 1.2 USP Endotoxin Units/mg of ascorbic acid.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in light-resistant, single-dose containers, preferably of Type I or Type II glass.

• **Labeling:** In addition to meeting the requirements in *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*, fused-seal containers of the Injection in concentrations of 250 mg/mL and greater are labeled to indicate that since pressure may develop on long storage, precautions should be taken to wrap the container in a protective covering while it is being opened.

• **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 INJECTION	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

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