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Ascorbic Acid Compounded Oral Solution

DEFINITION
Ascorbic Acid Compounded Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of ascorbic acid ($C_6H_8O_6$).

Prepare Ascorbic Acid Compounded Oral Solution, 100 mg/mL, as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Ascorbic Acid	10 g
Purified Water	50 mL
Ora-Sweet,[a] a sufficient quantity to make	100 mL

[a] Perrigo Laboratories, Allegan, MI.

Place the *Ascorbic Acid* into a suitable container. Dissolve the powder in the *Purified Water*. Transfer the contents to a calibrated container. Add sufficient *Ora-Sweet* to bring to final volume. Shake to mix well.

ASSAY

• **Procedure**

Mobile phase: 50 mM monobasic sodium phosphate; adjusted with phosphoric acid to a pH of 2.5

Standard solution: 0.2 mg/mL of USP Ascorbic Acid RS in *Mobile phase*

Sample solution: Transfer 0.2 mL of Oral Solution into a 100-mL volumetric flask and dilute with *Mobile phase* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 25-cm; 5-µm packing L96

Temperatures

Autosampler: 5°

Column: 10°

Flow rate: 1.0 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for ascorbic acid is about 4.4 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

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 Oral Solution taken:

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

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

r_S = peak response 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%–110.0%

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SPECIFIC TESTS

• **pH** ⟨791⟩**:** 1.8–2.8

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant plastic containers. Store in a refrigerator or at controlled room temperature.

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored in a refrigerator; or NMT 60 days after the date on which it was compounded when stored at controlled room temperature

• **Labeling:** Label it to state the *Beyond-Use Date*.

• **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 COMPOUNDED ORAL SOLUTION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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