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# Ascorbic Acid Oral Solution

## DEFINITION

Ascorbic Acid Oral Solution is a solution of Ascorbic Acid in a hydroxylic organic solvent or an aqueous mixture thereof. It contains NLT 90.0% and NMT 110.0% of the labeled amount of ascorbic acid ($C_6H_8O_6$).

## IDENTIFICATION

- **A.**

**Sample solution:** A volume of Oral Solution equivalent to 40 mg of ascorbic acid

**Analysis:** To the *Sample solution* add 4 mL of 0.1 N hydrochloric acid, then 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.**

**Sample solution:** A volume of Oral Solution equivalent to 20 mg of ascorbic acid

**Analysis:** To the *Sample solution* add 15 mL of trichloroacetic acid solution (1 in 20). Add 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, then heat in a bath at 50°.

**Acceptance criteria:** A blue color develops.

## ASSAY

- **Procedure**

**Sample solution:** Transfer a volume of Oral Solution equivalent to 50 mg of ascorbic acid, previously diluted with water if necessary, to a 100-mL volumetric flask. Add 20 mL of metaphosphoric–acetic acid TS, dilute with water to volume, and mix.

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

**Titrimetric system**

(See *Titrimetry* ⟨541⟩.)

**Mode:** Direct titration

**Titrant:** Standard dichlorophenol–indophenol VS

**Analysis:** Transfer a volume of the *Sample solution*, equivalent to 2 mg of ascorbic acid, into a 50-mL conical flask. Add 5 mL of metaphosphoric–acetic acid TS, and titrate with *Titrant* until a rose-pink color persists for at least 5 s. Correct for the volume of the *Titrant* consumed by the *Blank*.

Calculate the percentage of ascorbic acid ($C_6H_8O_6$) in the portion of Oral Solution 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 *Titrant* in terms of its equivalent of ascorbic acid (mg/mL)

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

**Acceptance criteria:** 90.0%–110.0%

## OTHER COMPONENTS

- **Alcohol Determination,** *Method I* ⟨611⟩ (if present)**:** 90.0%–110.0% of the labeled content of alcohol ($C_2H_5OH$)

## ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight, light-resistant containers.
- **Labeling:** Label Oral Solution that contains alcohol to state the alcohol content.

| Topic/Question | Contact | Expert Committee |
|---|---|---|
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