Analysis
Sample: *Sample solution*
From the *Standard curve*, determine the lead concentration in the *Sample solution*. Calculate the lead content, in ppm, in the portion of Erythorbic Acid taken:

$$\text{Result} = V \times C_S/W$$

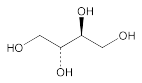
V = volume of the *Sample solution* (mL)
C_S = concentration of lead in the *Sample solution* (µg/mL)
W = weight of Erythorbic Acid in the *Sample solution* (g)

Acceptance criteria: NMT 10 ppm

SPECIFIC TESTS
- **OPTICAL ROTATION,** *Specific Rotation* ⟨**781S**⟩**:** –16.5° to –18.0°
  Sample solution: 100 mg/mL in water
- **LOSS ON DRYING** ⟨**731**⟩**:** Dry a sample in a vacuum over silica gel for 3 h: it loses NMT 0.4% of its weight.

ADDITIONAL REQUIREMENTS
- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.
- **USP REFERENCE STANDARDS** ⟨**11**⟩
  USP Erythorbic Acid RS

Erythritol



$C_4H_{10}O_4$ 122.12
1,2,3,4-Butanetetrol;
Butane 1,2,3,4-tetrol (*meso*-erythritol) [149-32-6].

DEFINITION
Erythritol is obtained by fermentation of starch enzyme hydrolysate (from starches such as wheat and corn). It is obtained from the fermentation broth of suitable osmophilic yeasts such as *Moniliella pollinis* or *Trichosporonoides megachiliensis*. It contains NLT 96.0% and NMT 102.0% of erythritol ($C_4H_{10}O_4$), calculated on the anhydrous basis.

IDENTIFICATION
- **A. INFRARED ABSORPTION** ⟨**197K**⟩
- **B. MELTING RANGE OR TEMPERATURE** ⟨**741**⟩**:** 119°–123°

ASSAY
- **PROCEDURE**
  Mobile phase: 0.01% sulfuric acid
  System suitability solution: 0.05 mg/mL each of USP Erythritol RS and glycerol
  Standard solution: 50 mg/mL of USP Erythritol RS
  Sample solution: 50 mg/mL of Erythritol
  Chromatographic system
  (See *Chromatography* ⟨621⟩*, System Suitability*.)
  Mode: LC
  Detector: Refractive index
  Column: 7.8-mm × 30-cm; packing L17
  Column temperature: 70°
  Flow rate: 0.8 mL/min
  Injection size: 10 µL
  System suitability
  Samples: *System suitability solution* and *Standard solution*
  [NOTE—The relative retention times for erythritol and glycerol are about 1.0 and 1.1, respectively.]
  Suitability requirements
  Resolution: NLT 2.0 between erythritol and glycerol, *System suitability solution*
  Relative standard deviation: NMT 2.0%, *Standard solution*
  Analysis
  Samples: *Standard solution* and *Sample solution*
  [NOTE—Record chromatograms for over a period of three times the retention time of erythritol.]
  Calculate in percentage of erythritol ($C_4H_{10}O_4$) in the portion of Erythritol 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 Erythritol RS in the *Standard solution* (mg/mL)
C_U = concentration of Erythritol in the *Sample solution* (mg/mL)

  Acceptance criteria: 96.0%–102.0% on the anhydrous basis

IMPURITIES
- **RESIDUE ON IGNITION** ⟨**281**⟩**:** NMT 0.1%
- **LIMIT OF LEAD**
  Standard lead solution: Prepare as directed under *Heavy Metals* ⟨231⟩*, Special Reagents*.
  Sample solution: Dissolve 20.0 g of Erythritol in diluted acetic acid, and dilute with the same medium to 100 mL. Add 2.0 mL of a saturated ammonium pyrrolidinedithiocarbamate solution (10 mg/mL of ammonium pyrrolidinedithiocarbamate) and 10.0 mL of methyl isobutyl ketone, and shake for 30 s. Protect from bright light. Allow the two layers to separate, and use the methyl isobutyl ketone layer.
  Standard solutions: Prepare as directed for the *Sample solution*, except prepare three solutions by adding 0.5, 1.0, and 1.5 mL of *Standard lead solution* in addition to the 20.0 g of Erythritol.
  Blank solution: Prepare as directed for the *Sample solution*, omitting Erythritol.
  Instrumental conditions
  (See *Spectrophotometry and Light-Scattering* ⟨851⟩.)
  Mode: Atomic absorption spectrophotometry, using methyl isobutyl ketone previously treated as described under *Sample solution*, but without the sample added
  Analytical wavelength: 283.3 nm
  Lamp: Lead hollow-cathode
  Flame: Air–acetylene
  Analysis
  Samples: *Sample solution* and *Standard solutions*
  Introduce the *Sample solution* and each of the three *Standard solutions* into the instrument. Record the steady absorbance reading. Plot the absorbance readings against the known concentrations of added lead (in µg), and draw a straight line. Extrapolate the line until it meets the concentration axis, which is equal to the concentration, in ppm, of lead in the sample.
  Acceptance criteria: NMT 0.5 ppm
- **RELATED COMPOUNDS**
  Mobile phase, System suitability solution, Standard solution, and **Sample solution:** Proceed as directed in the *Assay*.
  Standard solution: Transfer 2.0 mL of the *Standard solution* from the *Assay* to a 100-mL volumetric flask, and dilute with water (1 mg/mL of erythritol).
  Chromatographic system: Proceed as directed in the *Assay*, except use an *Injection size* of 20 µL.
  Analysis
  Samples: *Sample solution* and *Standard solution*
  Calculate the percentage of each impurity found:

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

r_U = peak response from the *Sample solution*
r_S = peak response of erythritol from the *Standard solution*

C_S = concentration of USP Erythritol RS in the *Standard solution* (mg/mL)
C_U = concentration of Erythritol in the *Sample solution* (mg/mL)

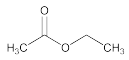
Acceptance criteria
Individual impurities: NMT 2.0%
Total impurities: NMT 2.0%

SPECIFIC TESTS
- **MICROBIAL ENUMERATION TESTS ⟨61⟩** and **TESTS FOR SPECIFIED MICROORGANISMS ⟨62⟩:** The total aerobic microbial count using the *Plate Method* is NMT 1000 cfu/g, and the total combined molds and yeasts count is NMT 100 cfu/g. It meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli.*
- **LOSS ON DRYING ⟨731⟩:** Dry an 8-g sample at 105° for 4 h: it loses NMT 0.2% of its weight.
- **WATER DETERMINATION,** *Method I* **⟨921⟩:** NMT 0.5%
- **CONDUCTIVITY**
  Sample solution: 200 mg/mL in water
  Analysis: Using an appropriate conductivity meter, choose a conductivity cell that is appropriate for the properties and conductivity of the solution to be examined. Use a certified reference material,[1] for example, a solution of potassium chloride, that is appropriate for the measurement. The conductivity value of the certified reference material should be near the expected conductivity value of the solution to be examined. After calibrating the apparatus with a certified reference material solution, rinse the conductivity cell several times with water and at least twice with the aqueous solution to be examined. Measure the conductivity of the solution at a temperature of 20° while stirring gently with a magnetic stirrer.

  Acceptance criteria: NMT 20 µS/cm

ADDITIONAL REQUIREMENTS
- **PACKAGING AND STORAGE:** Preserve in well-closed containers. Store at room temperature.
- **USP REFERENCE STANDARDS ⟨11⟩**
  USP Erythritol RS

Ethyl Acetate



$C_4H_8O_2$ 88.11
Acetic acid, ethyl ester;
Ethyl acetate [141-78-6].

DEFINITION
Ethyl Acetate contains NLT 99.0% and NMT 100.5% of ethyl acetate ($C_4H_8O_2$).

IDENTIFICATION
- **A.** It is readily volatilized, even at low temperatures, and is flammable. When burned, a yellow flame and acetous odor are produced.

ASSAY
- **PROCEDURE**
  Sample: Weigh 1.5 g of Ethyl Acetate in a stoppered weighing bottle.

  Titrimetric system
  (See *Titrimetry* ⟨541⟩.)
  Mode: Residual titration
  Titrant: 0.5 N sodium hydroxide VS
  Back-titrant: 0.5 N hydrochloric acid VS
  Blank: 50 mL of 0.5 N sodium hydroxide VS, accurately measured
  Endpoint detection: Visual
  Analysis: Transfer the *Sample* to a suitable flask. Add 50.0 mL of 0.5 N sodium hydroxide VS, and heat on a steam bath under a reflux condenser for 1 h. Allow to cool, and add phenolphthalein TS. Titrate the excess sodium hydroxide with 0.5 N hydrochloric acid VS. Perform a blank determination.
  Calculate the percentage of ethyl acetate ($C_4H_8O_2$) in the *Sample* taken:

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

V_B = *Back-titrant* volume consumed by the *Blank* (mL)
V_S = *Back-titrant* volume consumed by the *Sample* (mL)
N = actual normality of the *Back-titrant* (mEq/mL)
F = equivalency factor for ethyl acetate, 88.1 mg/mEq
W = *Sample* weight (mg)

  Acceptance criteria: 99.0%–100.5%

IMPURITIES
- **LIMIT OF NONVOLATILE RESIDUE**
  Sample: Ethyl Acetate
  Analysis: Evaporate the *Sample* in a tared porcelain dish on a steam bath, and dry at 105° for 1 h.
  Acceptance criteria: NMT 0.02%
- **LIMIT OF METHYL COMPOUNDS**
  Sample: 20 mL of Ethyl Acetate
  Analysis: Place the *Sample* in a 500-mL separator. Add a solution of 20 g of sodium hydroxide in 50 mL of water, and insert the stopper in the separator. Wrap it securely in a towel for protection against the heat of the reaction. Shake the mixture vigorously for about 5 min, cautiously opening the stopcock from time to time to permit the escape of air. Continue shaking vigorously until a homogeneous liquid results, then distill, and collect about 25 mL of the distillate. To 0.05 mL of the distillate add 1 drop of dilute phosphoric acid (1 in 20) and 1 drop of potassium permanganate solution (1 in 20). Mix, allow to stand for 1 min, and add sodium bisulfite solution (1 in 20), dropwise, until the permanganate color is discharged. If a brown color remains, add 1 drop of the dilute phosphoric acid. To the colorless solution add 5 mL of freshly prepared chromotropic acid TS, and heat on a steam bath at 60° for 10 min.
  Acceptance criteria: No violet color appears.
- **CHROMATOGRAPHIC PURITY**
  System suitability solution: Chloroform, ethyl acetate, isobutyl acetate, and *n*-butyl acetate (3:1:1:1)
  Chromatographic system
  (See *Chromatography* ⟨621⟩, *System Suitability*.)
  Mode: GC
  Detector: Flame ionization
  Column: 1.8-m × 4-mm; support S11
  Column temperature: See *Table 1*.

Table 1

Initial Temperature (°)	Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
115	—	115	6
115	16	200	15

[1] Commercially available conductivity calibration solutions for conductivity meter standardization, standardized by methods traceable to the National Institute of Standards and Technology (NIST), may be used. Solutions prepared according to instructions given in the American Society for Testing and Materials (ASTM) Standard D1125 may be used, provided that the conductivity of the resultant solution is the same as that of the solution prepared from the NIST-certified material.