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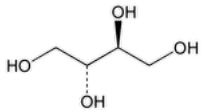
Erythritol



$C_4H_{10}O_4$ 122.12

1,2,3,4-Butanetetrol;

Butane 1,2,3,4-tetrol (*meso*-erythritol) CAS RN®: 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

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)

• **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 volume: 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 3 times the retention time of erythritol.]

Calculate the 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**

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 TS in addition to the 20.0 g of Erythritol.

Blank solution: Prepare as directed for the *Sample solution*, omitting Erythritol.

Instrumental conditions

(See *Atomic Absorption Spectroscopy ⟨852⟩*.)

Mode: Atomic absorption spectrophotometry, using methyl isobutyl ketone previously treated as described in the *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 µg/g

Change to read:

• **Related Compounds**

Mobile phase, System suitability solution, Standard solution, and **Sample solution:** Proceed as directed in the *Assay*.

Standard solution A: 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 volume* of 20 µL.

Analysis

Samples: ▲*Standard solution A*▲ (ERR 1-Jun-2018) and *Sample 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 A*▲ (ERR 1-Jun-2018)

C_S = concentration of USP Erythritol RS in the ▲*Standard solution A* (mg/mL)▲ (ERR 1-Jun-2018)

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-Count Methods* is NMT 10^3 cfu/g, and the total combined molds and yeasts count is NMT 10^2 cfu/g. It meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*.

• **Loss on Drying ⟨731⟩**

Sample: 8 g

Analysis: Dry the *Sample* at 105° for 4 h.

Acceptance criteria: NMT 0.2%

• **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

meso-Erythritol, 1,2,3,4-butanetetrol.

$C_4H_{10}O_4$ 122.12

[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.

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

Topic/Question	Contact	Expert Committee
ERYTHRITOL	Documentary Standards Support	SE2020 Simple Excipients

Chromatographic Database Information: Chromatographic Database

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