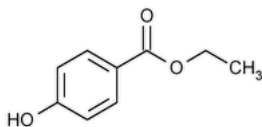


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Ethylparaben



$C_9H_{10}O_3$ 166.17
Benzoic acid, 4-hydroxy-, ethyl ester;
Ethyl *p*-hydroxybenzoate CAS RN®: 120-47-8.

DEFINITION

Ethylparaben contains NLT 98.0% and NMT 102.0% of $C_9H_{10}O_3$.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197M ▲](#) (CN 1-MAY-2020)
- **B.** [MELTING RANGE OR TEMPERATURE \(741\)](#): 115°–118°

ASSAY

• PROCEDURE

Mobile phase, Sample solution, Standard solution B, and Chromatographic system: Proceed as described in the procedure for *Related Substances*.

System suitability

Sample: *Standard solution B*

Suitability requirements

Relative standard deviation: NMT 0.85% for 6 injections

Analysis

Samples: *Sample solution* and *Standard solution B*

Calculate the percentage of Ethylparaben in the *Sample solution*:

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

P = labeled purity of [USP Ethylparaben RS](#) expressed as a percentage

r_U = peak area of ethylparaben from the *Sample solution*

C_S = concentration of ethylparaben in *Standard solution B*

r_S = peak area of ethylparaben from *Standard solution B*

C_U = concentration of Ethylparaben in the *Sample solution*

Acceptance criteria: 98.0%–102.0%

IMPURITIES

Inorganic Impurities

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%, determined on 1.0 g

Organic Impurities

• PROCEDURE: RELATED SUBSTANCES

Mobile phase: Methanol and a 6.8-g/L solution of potassium dihydrogen phosphate (65:35 v/v)

Sample solution: Dissolve 50.0 mg of Ethylparaben in 2.5 mL of methanol, and dilute with *Mobile phase* to 50.0 mL. Dilute 10.0 mL of this solution with *Mobile phase* to 100.0 mL.

Standard solution A: 5.0 µg/mL each of *p*-hydroxy benzoic acid, [USP Methylparaben RS](#), and [USP Ethylparaben RS](#) in *Mobile phase*

Standard solution B: Dissolve 50.0 mg of [USP Ethylparaben RS](#) in 2.5 mL of methanol, and dilute with *Mobile phase* to 50.0 mL. Dilute 10.0 mL of this solution with *Mobile phase* to 100.0 mL.

Standard solution C: Dilute 1.0 mL of the *Sample solution* with *Mobile phase* to 20.0 mL. Dilute 1.0 mL of this solution with *Mobile phase* to 10.0 mL.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 272 nm

Column: 4.6-mm × 15-cm; 5-μm packing L1

Flow rate: 1.3 mL/min

Injection size: 10 μL

Run time: About 4 times the retention time of ethylparaben

System suitability

Sample: *Standard solution A*

[NOTE—The retention time of ethylparaben is about 3.0 min; the relative retention times for *p*-hydroxybenzoic acid, ethylparaben, and methylparaben are about 0.5, 1.0, and 0.8, respectively.]

Suitability requirements

Resolution: NLT 2.0 between the methylparaben and ethylparaben peaks

Analysis

Samples: *Sample solution* and *Standard solution C*

[NOTE—Disregard any limit that is 0.2 times the area of the principal peak in the chromatogram obtained with *Standard solution C* (0.1%).]

Acceptance criteria

***p*-Hydroxybenzoic acid:** The peak area in the *Sample solution*, multiplied by 1.4 to correct for the calculation of content, is NMT the area of the principal peak in *Standard solution C* (0.5%).

Unspecified impurities: The peak area of each impurity in the *Sample solution* is NMT the area of the principal peak in *Standard solution C* (0.5%).

Total impurities: The total peak area for all impurities in the *Sample solution* is NMT twice the area of the principal peak in *Standard solution C* (1.0%).

SPECIFIC TESTS

• COLOR OF SOLUTION

Sample solution: 100 mg/mL in alcohol

Comparison solution: Mix 2.4 mL of ferric chloride CS, 1.0 mL of cobaltous chloride CS, and 0.4 mL of cupric sulfate CS with 0.3 N hydrochloric acid to make 10 mL. Dilute 5 mL of this solution with 0.3 N hydrochloric acid to make 100 mL. [NOTE—Prepare and use this solution immediately.]

Analysis

Samples: Alcohol, *Sample solution*, and *Comparison solution*

Make the comparison by viewing the solutions downward in matched color-comparison tubes against a white surface (see [Color and Achromicity \(631\)](#)).

Acceptance criteria: The *Sample solution* is clear and not more intensely colored than alcohol or the *Comparison solution*.

• ACIDITY

Sample solution: To 2 mL of *Sample solution* prepared in the test for *Color of Solution*, add 3 mL of alcohol, 5 mL of carbon dioxide-free water, and 0.1 mL of bromocresol green TS.

Analysis: Titrate with 0.10 N sodium hydroxide.

Acceptance criteria: NMT 0.1 mL is required to produce a blue color.

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in well-closed containers.

• **USP REFERENCE STANDARDS (11).**

[USP Ethylparaben RS](#)

[USP Methylparaben RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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