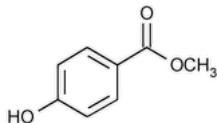


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## Methylparaben



$C_8H_8O_3$  152.15  
Benzoic acid, 4-hydroxy-, methyl ester;  
Methyl *p*-hydroxybenzoate CAS RN®: 99-76-3.

### DEFINITION

Methylparaben contains NLT 98.0% and NMT 102.0% of  $C_8H_8O_3$ .

### IDENTIFICATION

*Change to read:*

- A. [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197M](#) ▲ (CN 1-MAY-2020)
- B. [MELTING RANGE OR TEMPERATURE \(741\)](#): 125°–128°

### 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 Methylparaben in the *Sample solution*:

$$\text{Result} = P \times (r_u \times C_s) / (r_s \times C_u)$$

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

$r_u$  = peak area of methylparaben from the *Sample solution*

$C_s$  = concentration of methylparaben in *Standard solution B*

$r_s$  = peak area of methylparaben from *Standard solution B*

$C_u$  = concentration of Methylparaben 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 Methylparaben 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  $\mu$ g/mL each of *p*-hydroxy benzoic acid and [USP Methylparaben RS](#) in *Mobile phase*

**Standard solution B:** Dissolve 50.0 mg of [USP Methylparaben 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 5 times the retention time of methylparaben

#### System suitability

**Sample:** *Standard solution A*

[*NOTE*—The retention time of methylparaben is about 2.3 min; the relative retention time for *p*-hydroxy benzoic acid is about 0.6.]

#### Suitability requirements

**Resolution:** NLT 2.0 between the *p*-hydroxybenzoic acid and methylparaben 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 the *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 Methylparaben RS](#)

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

Topic/Question	Contact	Expert Committee
METHYLPARABEN	<a href="#">Documentary Standards Support</a>	SE2020 Simple Excipients

**Chromatographic Database Information:** [Chromatographic Database](#)

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