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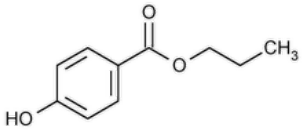
# Propylparaben



$C_{10}H_{12}O_3$ 180.20

Benzoic acid, 4-hydroxy-, propyl ester;

Propyl *p*-hydroxybenzoate CAS RN®: 94-13-3.

## DEFINITION

Propylparaben contains NLT 98.0% and NMT 102.0% of $C_{10}H_{12}O_3$.

## IDENTIFICATION

***Change to read:***

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

• **B. Melting Range or Temperature ⟨741⟩:** 96°–99°

## 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 Propylparaben in the *Sample solution*:

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

P = labeled purity of USP Propylparaben RS expressed as a percentage

$r_U$ = peak area of propylparaben from the *Sample solution*

$C_S$ = concentration of propylparaben in *Standard solution B*

$r_S$ = peak area of propylparaben from *Standard solution B*

$C_U$ = concentration of Propylparaben 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 Propylparaben 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 Ethylparaben RS, and USP Propylparaben RS in *Mobile phase*

**Standard solution B:** Dissolve 50.0 mg of USP Propylparaben 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 2.5 times the retention time of propylparaben

**System suitability**

**Sample:** *Standard solution A*

[Note—The retention time of propylparaben is about 4.5 min; the relative retention times for *p*-hydroxy benzoic acid and ethylparaben are about 0.3 and 0.7, respectively.]

**Suitability requirements**

**Resolution:** NLT 3.0 between the ethylparaben and propylparaben 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 Propylparaben RS

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

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| PROPYLPARABEN | Documentary Standards Support | SE2020 Simple Excipients |
| REFERENCE STANDARD SUPPORT | RS Technical Services<br>RSTECH@usp.org | SE2020 Simple Excipients |

**Chromatographic Database Information:** Chromatographic Database

**Most Recently Appeared In:**
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