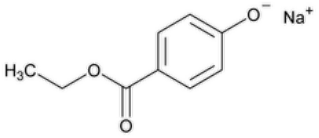
Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2016
Document Type: NF Monographs
DocId: GUID-960D9D74-91CD-4603-B42B-E0412FC59EEE_1_en-US
DOI: https://doi.org/10.31003/USPNF_M8966_01_01
DOI Ref: t9p1c

Ethylparaben Sodium



$C_9H_9NaO_3$ 188.2

Benzoic acid, 4-hydroxy-, methyl ester, sodium salt;

Ethyl *p*-hydroxybenzoate, sodium salt;

Sodium 4-ethoxycarbonylphenolate CAS RN®: 35285-68-8.

DEFINITION

Ethylparaben Sodium contains NLT 95.0% and NMT 102.0% of ethylparaben sodium ($C_9H_9NaO_3$), calculated on the anhydrous basis.

IDENTIFICATION

• **A.**

Standard: 0.5 g of USP Ethylparaben RS

Sample: 0.5 g of Ethylparaben Sodium

Analysis: Dissolve the *Sample* in 5 mL of water, acidify with hydrochloric acid, and filter the resulting precipitate. Wash the precipitate with water, and dry under vacuum at 80° for 2 h.

Acceptance criteria: The IR absorption spectrum of a mineral oil dispersion of the *Sample* exhibits maxima only at the same wavelengths as those of a similar preparation of the *Standard*.

• **B.**

Sample solution: Ignite 0.3 g of Ethylparaben Sodium, cool, and dissolve the residue in about 3 mL of 3 N hydrochloric acid.

Acceptance criteria: A platinum wire dipped in the *Sample solution* imparts an intense, persistent yellow color to a nonluminous flame.

ASSAY

• **Procedure**

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

System suitability solution: 5.0 µg/mL each of *p*-hydroxybenzoic acid, USP Methylparaben RS, and USP Ethylparaben RS in *Mobile phase*

Standard solution: 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.

Sample solution: Dissolve 50.0 mg of Ethylparaben Sodium 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.

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 volume: 10 µL

Run time: About 4 times the retention time of the ethylparaben peak

System suitability

Samples: *System suitability solution* and *Standard solution*

[Note—The retention time of ethylparaben is about 2.9 min; the relative retention times for *p*-hydroxybenzoic acid, methylparaben, and ethylparaben are about 0.5, 0.8, and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between methylparaben and ethylparaben peaks, *System suitability solution*

Relative standard deviation: NMT 0.85% for six injections, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ethylparaben sodium in the portion of Ethylparaben Sodium taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times P$$

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

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

C_S = concentration of USP Ethylparaben RS in the *Standard solution*

C_U = concentration of Ethylparaben Sodium in the *Sample solution*

M_{r1} = molecular weight of ethylparaben sodium, 188.2

M_{r2} = molecular weight of ethylparaben, 166.17

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

Acceptance criteria: 95.0%–102.0% on the anhydrous basis

IMPURITIES

• **Related Compounds**

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

Standard solution: 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.

System suitability

Sample: *System suitability solution*

[Note—The retention time of ethylparaben is about 2.9 min; the relative retention times for *p*-hydroxybenzoic acid, methylparaben, and ethylparaben are about 0.5, 0.8, and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between methylparaben and ethylparaben peaks

Analysis

Samples: *Standard solution* and *Sample solution*

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 6 times the area of the principal peak in the *Standard solution*; NMT 3.0%.

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

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

• **Chloride and Sulfate,** *Chloride* ⟨221⟩

Sample: 0.2 g

Control solution: 0.10 mL of 0.020 N hydrochloric acid

Acceptance criteria: 0.035%; the *Sample* shows no more chloride than the *Control solution*.

• **Chloride and Sulfate,** *Sulfate* ⟨221⟩

Sample: 1.0 g

Control solution: 0.31 mL of 0.020 N sulfuric acid

Acceptance criteria: 0.030%; the *Sample* shows no more sulfate than the *Control solution*.

SPECIFIC TESTS

• **pH** ⟨791⟩

Sample solution: 1 mg/mL

Acceptance criteria: 9.5–10.5

• **Water Determination, *Method I*⟨921⟩:** NMT 5.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight 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 SODIUM	Documentary Standards Support	SE2020 Simple Excipients

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 41(1)

Current DocID: GUID-960D9D74-91CD-4603-B42B-E0412FC59EEE_1_en-US
DOI: https://doi.org/10.31003/USPNF_M8966_01_01
DOI ref: t9p1c