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Naproxen Oral Suspension

DEFINITION
Naproxen Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of naproxen ($C_{14}H_{14}O_3$).

IDENTIFICATION

• **A.**

Sample solution: *Standard solution* and *Sample solution* (1:1), prepared as directed in the *Assay*

Analysis: Chromatograph as directed in the *Assay*.

Acceptance criteria: The chromatogram of the *Sample solution* exhibits two main peaks corresponding to naproxen and the internal standard.

ASSAY

• **Procedure**

Mobile phase: Prepare a mixture of 500 mL of methanol, 500 mL of water, and 2.46 g of anhydrous sodium acetate, and mix until dissolved. Adjust with glacial acetic acid to a pH of 5.8.

Internal standard solution: 1.1 mg/mL of ethylparaben in methanol

Standard stock solution: Transfer about 62.5 mg of USP Naproxen RS, accurately weighed, to a 50-mL volumetric flask, add about 30 mL of methanol, and sonicate to dissolve. Add 5.0 mL of *Internal standard solution*, dilute with methanol to volume, and mix.

Standard solution: 0.05 mg/mL of USP Naproxen RS and 0.0044 mg/mL of ethylparaben in *Mobile phase* from *Standard stock solution*

Sample stock solution: Transfer an accurately measured volume of Oral Suspension, previously well-mixed and free from air bubbles, nominally equivalent to about 125 mg of naproxen, to a 100-mL volumetric flask, using a “to contain” pipet. Rinse the pipet several times with methanol, and add the rinsings to the volumetric flask. Add 10.0 mL of *Internal standard solution*, dilute with methanol to volume, and mix.

Sample solution: Nominally equivalent to 0.05 mg/mL of naproxen and 0.0044 mg/mL of ethylparaben in *Mobile phase* from *Sample stock solution*. Filter if necessary to obtain a clear solution.

Chromatographic system

(See *Chromatography (621), System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 2 mL/min

Injection volume: 35 µL

System suitability

Sample: *Standard solution*

[Note—The relative retention times for ethylparaben and naproxen are 0.6 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 3.0 between ethylparaben and naproxen

Tailing factor: NMT 2.0 for the naproxen peak

Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of naproxen ($C_{14}H_{14}O_3$) in the portion of Oral Suspension taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of naproxen to ethylparaben from the *Sample solution*

R_S = peak response ratio of naproxen to ethylparaben from the *Standard solution*

C_S = concentration of USP Naproxen RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of naproxen in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Deliverable Volume ⟨698⟩:** Meets the requirements for oral suspension packaged in multiple-unit containers

• **Uniformity of Dosage Units ⟨905⟩:** Meets the requirements for oral suspension packaged in single-unit containers

SPECIFIC TESTS

• **pH ⟨791⟩:** 2.2–3.7

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers. Store at room temperature.

• **USP Reference Standards ⟨11⟩**
USP Naproxen RS

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

Topic/Question	Contact	Expert Committee
NAPROXEN ORAL SUSPENSION	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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