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# Naproxen Compounded Oral Suspension

**DEFINITION**

Naproxen Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of naproxen ($C_{14}H_{14}O_3$). Prepare Naproxen Compounded Oral Suspension containing 25 mg/mL of naproxen as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

| | |
|---|---|
| Naproxen tablets,[a] equivalent to | 2500 mg of naproxen |
| Vehicle: Oral Mix[b] or Oral Mix SF,[b] a sufficient quantity to make | 100 mL |

[a] Naproxen 250-mg tablets, Apotex Inc., Weston, Ontario.

[b] Medisca Pharmaceutique Inc., Montréal, Quebec.

Place the *Naproxen tablets* in a suitable container and comminute to a fine powder. Add the *Vehicle* in small portions, and triturate to make a smooth paste. Add increasing volumes of the *Vehicle* to make a liquid that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add sufficient *Vehicle* to bring to final volume, and mix well.

**ASSAY**

***Change to read:***

• **Procedure**

**Buffer:** 5 mM solution of ammonium formate, ▲adjusted with formic acid to a pH of 4▲ (USP 1-May-2022)

**Mobile phase:** Methanol and *Buffer* (82:18)

**Internal standard solution:** 1.0 mg/mL of USP Ranitidine Hydrochloride RS in water

**Standard stock solution:** 25 mg/mL of USP Naproxen RS in methanol

**Standard solution:** Transfer 0.1 mL of *Standard stock solution* to a 100-mL volumetric flask, add 10 mL of the *Internal standard solution*, and dilute with methanol to volume to obtain a solution containing 0.025 mg/mL of naproxen and 0.1 mg/mL of ranitidine hydrochloride. Pass through a hydrophilic propylene filter of 0.45-µm pore size.

**Sample solution:** Add 0.2 mL of Oral Suspension to 1.8 mL of methanol and centrifuge at 5200 rpm for 5 min. Transfer 0.1 mL of the supernatant to a 10-mL volumetric flask, add 1 mL of the *Internal standard solution*, and dilute with methanol to volume to obtain a solution containing 0.025 mg/mL of naproxen and 0.1 mg/mL of ranitidine hydrochloride. Filter.

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 232 nm

**Columns**

**Guard:** 3.9-mm × 2-cm; packing L1

**Analytical:** 4.6-mm × 10-cm; 5-µm packing L1

**Flow rate:** See *Table 1*.

**Table 1**

| Time (min) | Flow Rate (mL/min) |
|---|---|
| 0 | 0.8 |
| 1 | 0.85 |
| 2 | 0.9 |
| 3 | 1 |

**Injection volume:** 20 µL

**System suitability**

**Sample:** *Standard solution*

[NOTE—The retention times for ranitidine hydrochloride and naproxen are about 1.4 and 2.4 min, respectively.]

**Suitability requirements**

**Relative standard deviation:** NMT 2.0% for replicate injections

**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 the internal standard from the *Sample solution*

$R_S$ = peak response ratio of naproxen to the internal standard 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%

## SPECIFIC TESTS

• **pH ⟨791⟩:** 4.0–5.0

## ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store at controlled room temperature or in a refrigerator.

• **BEYOND-USE DATE:** NMT 90 days after the date on which it was compounded when stored at controlled room temperature or in a refrigerator

• **LABELING:** Label it to state the *Beyond-Use Date*.

• **USP REFERENCE STANDARDS ⟨11⟩**

USP Naproxen RS

USP Ranitidine Hydrochloride RS

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

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| NAPROXEN COMPOUNDED ORAL SUSPENSION | Brian Serumaga<br>Science Program Manager | CMP2020 Compounding 2020 |

**Chromatographic Database Information:** Chromatographic Database

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