

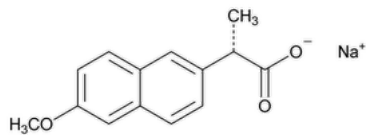
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Naproxen Sodium

Change to read:

▲



▲ (USP 1-Aug-2024)

C₁₄H₁₃NaO₃ 252.24

2-Naphthaleneacetic acid, 6-methoxy- α -methyl-, sodium salt, (S)-;

(-)-Sodium (S)-6-methoxy- α -methyl-2-naphthaleneacetate;

▲Sodium (S)-2-(6-Methoxynaphthalen-2-yl)propanoate▲ (USP 1-Aug-2024) CAS RN[®]: 26159-34-2; UNII: 9TN87S3A3C.

DEFINITION

Naproxen Sodium contains NLT 98.0% and NMT 102.0% of naproxen sodium (C₁₄H₁₃NaO₃), calculated on the dried basis.

IDENTIFICATION

Change to read:

- A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197K ▲ or 197A ▲ (USP 1-Aug-2024)

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- B. ▲The retention time of the major peak of the *Sample solution* corresponds to that of the naproxen peak in the *System suitability solution*, as obtained in the [Enantiomeric Purity Test](#).▲ (USP 1-Aug-2024)

ASSAY

Change to read:

PROCEDURE

▲**Solution A:** 0.1% [glacial acetic acid](#) in [water](#)

Solution B: 0.01% [glacial acetic acid](#) in [methanol](#)

Mobile phase: See [Table 1](#). The recommended equilibration time after the gradient is 5–10 min.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	45	55
20	45	55
27	20	80
32	20	80
32.1	45	55
35	45	55

Diluent: [Methanol](#) and [water](#) (50:50)

Standard solution: 110 µg/mL of [USP Naproxen Sodium RS](#) in *Diluent*

Sample solution: 110 µg/mL of Naproxen Sodium in *Diluent*

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC**Detector:** UV 272 nm**Column:** 4.6-mm × 15-cm; 3.5-μm packing [L1](#)**Column temperature:** 35°**Flow rate:** 1 mL/min**Injection volume:** 20 μL**System suitability****Sample:** *Standard solution***Suitability requirements****Tailing factor:** NMT 2.0**Relative standard deviation:** NMT 0.73%**Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of naproxen sodium ($C_{14}H_{13}NaO_3$) in the portion of Naproxen Sodium taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

 r_U = peak response of naproxen from the *Sample solution* r_S = peak response of naproxen from the *Standard solution* C_S = concentration of [USP Naproxen Sodium RS](#) in the *Standard solution* (μg/mL) C_U = concentration of Naproxen Sodium in the *Sample solution* (μg/mL) ▲ (USP 1-Aug-2024)**Acceptance criteria:** 98.0%–102.0% on the dried basis**IMPURITIES****Change to read:**• **ORGANIC IMPURITIES**▲ **Solution A, Solution B, Mobile phase, and Diluent:** Prepare as directed in the Assay.**System suitability solution:** 110 μg/mL of [USP Naproxen Sodium RS](#) and 0.5 μg/mL each of [USP Naproxen Related Compound K RS](#), [USP Naproxen Related Compound A RS](#), and [USP Naproxen Related Compound L RS](#) in *Diluent***Standard solution:** 0.1 μg/mL each of [USP Naproxen Sodium RS](#), [USP Naproxen Related Compound E RS](#), [USP Naproxen Related Compound A RS](#), and [USP Naproxen Related Compound L RS](#) in *Diluent***Sensitivity solution:** 0.05 μg/mL each of [USP Naproxen Sodium RS](#), [USP Naproxen Related Compound A RS](#), [USP Naproxen Related Compound L RS](#), and [USP Naproxen Related Compound E RS](#) in *Diluent* from *Standard solution***Sample solution:** 110 μg/mL of Naproxen Sodium in *Diluent***Chromatographic system**(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** LC**Detector:** UV 240 nm**Column:** 4.6-mm × 15-cm; 3.5-μm packing [L1](#)**Column temperature:** 35°**Flow rate:** 1 mL/min**Injection volume:** 20 μL**System suitability****Samples:** *System suitability solution*, *Standard solution*, and *Sensitivity solution*[NOTE—See [Table 2](#) for the relative retention times.]**Suitability requirements****Resolution:** NLT 1.5 between naproxen related compound K and naproxen related compound A; NLT 2.0 between naproxen related compound L and naproxen, *System suitability solution***Relative standard deviation:** NMT 5.0% for each peak, *Standard solution***Signal-to-noise ratio:** NLT 10 for each peak, *Sensitivity solution***Analysis****Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of naproxen related compound E, naproxen related compound A, and naproxen related compound L in the portion of Naproxen Sodium taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

 r_U = peak response of naproxen related compound E, naproxen related compound A, or naproxen related compound L from the *Sample solution*