Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-Aug-2023
Document Type: USP Monographs
DocId: GUID-5088E927-9EE5-4642-9195-E7B42D7F4B7D_3_en-US
DOI: https://doi.org/10.31003/USPNF_M55772_03_01
DOI Ref: 1j8wq

Naproxen Delayed-Release Tablets

DEFINITION
Naproxen Delayed-Release Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of naproxen ($C_{14}H_{14}O_3$).

IDENTIFICATION

• **A. Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*: 197U**

Standard solution and **Sample solution:** Prepare as directed in the *Buffer stage* of the *Dissolution* test.

Acceptance criteria: Meet the requirements

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and 1% acetic acid solution (900:1100). Filter and degas.

Diluent A: Acetonitrile and water (9:1)

Diluent B: Acetonitrile and water (1:1)

Standard stock solution: 0.5 mg/mL of USP Naproxen RS in *Diluent A*

Standard solution: 0.1 mg/mL of USP Naproxen RS in *Mobile phase* from the *Standard stock solution*

Sample solution: Transfer an amount nominally equivalent to 250 mg of naproxen from 20 powdered Tablets into a 100-mL volumetric flask, and add about 70 mL of *Diluent B*. Shake by mechanical means for 15 min, sonicate for 15 min, dilute with *Diluent B* to volume, and mix. Pass this solution through a suitable filter of 0.45-µm pore size. Transfer 2.0 mL of the filtrate into a 50-mL volumetric flask, and dilute with *Mobile phase* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1.0 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 2.0%

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 Tablets 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 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%

Change to read:

PERFORMANCE TESTS

• **Dissolution, *Delayed-Release Dosage Forms, Method B* ⟨711⟩**

Acid stage

Medium: 0.1 N hydrochloric acid; 1000 mL

Apparatus 2: 50 rpm

Time: 2 h

Standard solution: A known concentration of USP Naproxen RS in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Medium* if necessary.

Analysis: Determine the amount of naproxen ($C_{14}H_{14}O_3$) dissolved by UV absorption at the wavelength of maximum absorbance at about 332 nm with the *Sample solution* in comparison with the *Standard solution*.

Tolerances: NMT 10% (*Q*) of the labeled amount of naproxen ($C_{14}H_{14}O_3$) is dissolved.

Buffer stage

Buffer: 0.2 M phosphate buffer, pH 6.8

Medium: *Buffer*; 1000 mL

Apparatus 2: 50 rpm

Time: 45 min

Standard solution: A known concentration of USP Naproxen RS in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Medium* if necessary.

Analysis: Determine the amount of naproxen ($C_{14}H_{14}O_3$) dissolved by UV absorption at the wavelength of maximum absorbance at about 332 nm with the *Sample solution* in comparison with the *Standard solution*.

Tolerances: NLT 80% (*Q*) of the labeled amount of naproxen ($C_{14}H_{14}O_3$) is dissolved.

Change to read:

• **Uniformity of Dosage Units ⟨905⟩:**

▲Meet the requirements▲ (CN 1-Aug-2023)

Procedure for content uniformity

Mobile phase, Diluent A, Diluent B, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Standard stock solution: 0.25 mg/mL of USP Naproxen RS in *Diluent A*

Standard solution: 0.1 mg/mL of USP Naproxen RS in *Diluent B* from *Standard stock solution*

Sample solution: Transfer 1 Tablet to a 200-mL volumetric flask, and add 140 mL of *Diluent B*. Shake by mechanical means for 15 min, sonicate for 15 min, and dilute with *Diluent B* to volume. Pass a portion of this solution through a suitable filter of 0.45-µm pore size, pipet 2.0 mL of the filtrate for a 500-mg tablet and 2.5 mL for a 375-mg tablet into a 50-mL volumetric flask, and dilute with *Mobile phase* to volume.

▲▲ (CN 1-Aug-2023)

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers, and store at controlled 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 DELAYED-RELEASE TABLETS	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 42(4)

Current DocID: GUID-5088E927-9EE5-4642-9195-E7B42D7F4B7D_3_en-US

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