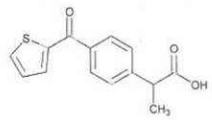
Suprofen



$C_{14}H_{12}O_3S$ 260.31
Benzeneacetic acid, α-methyl-4-(2-thienylcarbonyl)-; *p*-2-Thenoylhydratropic acid [40828-46-4].

DEFINITION
Suprofen contains NLT 98.0% and NMT 102.0% of suprofen ($C_{14}H_{12}O_3S$), calculated on the dried basis.

IDENTIFICATION
- **A. Infrared Absorption ⟨197K⟩**
- **B. Ultraviolet Absorption ⟨197U⟩**
  Analytical wavelengths: 267 and 297 nm
  Sample solution: 10 µg/mL
  Medium: 0.1 N hydrochloric acid in isopropyl alcohol (10 in 100)
  Acceptance criteria: The absorptivities, calculated on the dried basis, do not differ by more than 3.0%. The ratio of A_{267}/A_{297} is 0.97–1.03.

ASSAY
- **Procedure**
  Solution A: Dissolve 7.1 g of anhydrous dibasic sodium phosphate in 800 mL of water, and adjust with phosphoric acid to a pH of 6.0 ± 0.1. Dilute with water to 1 L.
  Mobile phase: Methanol and *Solution A* (40:60)
  Standard stock solution: 1 mg/mL of USP Suprofen RS in methanol
  Standard solution: 0.016 mg/mL of USP Suprofen RS from *Standard stock solution* in *Solution A*
  Sample stock solution: 1 mg/mL of Suprofen in methanol
  Sample solution: 0.016 mg/mL of Suprofen from *Sample stock solution* in *Solution A*
  Chromatographic system
  (See *Chromatography* ⟨621⟩, *System Suitability*.)
  Mode: LC
  Detector: UV 254 nm
  Column: 4.6-mm × 25-cm; packing L1
  Flow rate: 2 mL/min
  Injection volume: 20 µL
  System suitability
  Sample: *Standard solution*
  Suitability requirements
  Column efficiency: NLT 500 theoretical plates
  Tailing factor: NMT 2.0
  Relative standard deviation: NMT 2.0%
  Analysis
  Samples: *Standard solution* and *Sample solution*
  Calculate the percentage of suprofen ($C_{14}H_{12}O_3S$) in the portion taken:

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

r_U = peak area from the *Sample solution*
r_S = peak area from the *Standard solution*
C_S = concentration of USP Suprofen RS in the *Standard solution* (mg/mL)
C_U = concentration of Suprofen in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES
- **Residue on Ignition ⟨281⟩**
  Sample: 500 mg
  Analysis: Add 1 mL of sulfuric acid to the *Sample* in a crucible, heat gently to char the substance, and ignite.
  Acceptance criteria: NMT 0.2%

Delete the following:

- **Heavy Metals, *Method II* ⟨231⟩:** NMT 20 ppm (Official 1-Jan-2018)
- **Ordinary Impurities ⟨466⟩**
  Standard solution: Chloroform
  Sample solution: Chloroform
  Eluant: Chloroform, methyl ethyl ketone, and methanol (40:30:30)
  Visualization: 1
  Acceptance criteria: Meets the requirements

SPECIFIC TESTS
- **Melting Range or Temperature ⟨741⟩:** 118°–125°, within a range of less than 4°
- **Loss on Drying ⟨731⟩**
  Analysis: Dry a sample under vacuum at 70° for 4 h.
  Acceptance criteria: NMT 0.5%
- **Clarity of Solution**
  Sample: 50 mg
  Analysis: Dissolve the *Sample* in 10 mL of 0.1 N sodium hydroxide.
  Acceptance criteria: The solution is clear and free of undissolved solid.

ADDITIONAL REQUIREMENTS
- **Packaging and Storage:** Preserve in well-closed containers.
- **USP Reference Standards ⟨11⟩**
  USP Suprofen RS

Suprofen Ophthalmic Solution

DEFINITION
Suprofen Ophthalmic Solution is a sterile, buffered, aqueous solution of Suprofen adjusted to a suitable tonicity. It contains a suitable antimicrobial preservative. It contains NLT 90.0% and NMT 115.0% of the labeled quantity of suprofen ($C_{14}H_{12}O_3S$).

IDENTIFICATION
A. 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**
  Solution A: Dissolve 7.1 g of anhydrous dibasic sodium phosphate in 800 mL of water. Adjust with phosphoric acid to a pH of 6.0 ± 0.1, and dilute with water to 1 L.
  Mobile phase: Methanol and *Solution A* (40:60)
  Standard stock solution: 1 mg/mL of USP Suprofen RS in methanol
  Standard solution: 0.016 mg/mL of USP Suprofen RS from *Standard stock solution* in *Solution A*
  Sample stock solution: 0.2 mg/mL of suprofen from a volume of Ophthalmic Solution in *Solution A*
  Sample solution: 0.016 mg/mL of suprofen from *Sample stock solution* in *Solution A*