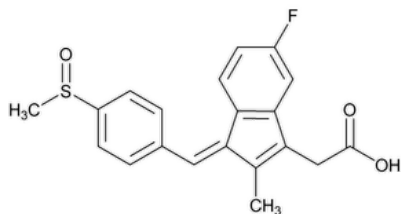


Sulindac



$C_{20}H_{17}FO_3S$ 356.41
1*H*-Indene-3-acetic acid, 5-fluoro-2-methyl-1-[[4-(methylsulfinyl) phenyl]methylene]-, (Z)-;
cis-5-Fluoro-2-methyl-1-[(*p*-methylsulfinyl)benzylidene]indene-3-acetic acid CAS RN®: 38194-50-2; UNII: 184SNS8VUH.

DEFINITION
Sulindac contains NLT 98.0% and NMT 102.0% of sulindac ($C_{20}H_{17}FO_3S$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197M▲](#) (CN 1-MAY-2020)

Change to read:

- **B.** [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Ultraviolet-Visible Spectroscopy: 197U▲](#) (CN 1-MAY-2020)

- Analytical wavelength:** 284 nm
Medium: Hydrochloric acid in methanol (1 in 120)
Sample solution: 15 µg/mL in *Medium*
Acceptance criteria: Absorptivities, calculated on the dried basis, do not differ by more than 3.0%.
- **C.** 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: 0.1% Formic acid in water
Solution B: 0.1% Formic acid in acetonitrile
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0.0	70	30
8.0	70	30
15.0	10	90
18.0	10	90
18.1	70	30

Time (min)	Solution A (%)	Solution B (%)
20.0	70	30

Diluent: Acetonitrile and water (50:50)

System suitability solution: 0.003 mg/mL each of [USP Sulindac RS](#), [USP Sulindac Related Compound A RS](#), [USP Sulindac Related Compound B RS](#), and [USP Sulindac Related Compound C RS](#) in *Diluent*

Standard solution: 0.2 mg/mL of [USP Sulindac RS](#) in *Diluent*

Sample solution: 0.2 mg/mL of Sulindac in *Diluent*

Chromatographic system

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

Mode: LC

Detector: 330 nm

Column: 2.1-mm × 15-cm; 1.7-μm packing L1

Column temperature: 45°

Flow rate: 0.3 mL/min

Injection volume: 2 μL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for sulindac related compound A, sulindac related compound B, and sulindac related compound C are 1.25, 1.34, and 1.67, respectively.]

Suitability requirements

Resolution: NLT 4.0 between sulindac and sulindac related compound A and between sulindac related compound A and sulindac related compound B, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of sulindac ($C_{20}H_{17}FO_3S$) in the portion of Sulindac taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of [USP Sulindac RS](#) in the *Standard solution* (mg/mL)

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

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

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• [RESIDUAL SOLVENTS \(467\)](#)

Solvent: Dimethylsulfoxide

Acceptance criteria: Meets the requirements except that chloroform is NMT 500 ppm

• ORGANIC IMPURITIES

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

Standard solution: 0.6 μg/mL of [USP Sulindac RS](#) and 3 μg/mL each of [USP Sulindac Related Compound A RS](#), [USP Sulindac Related Compound B RS](#), and [USP Sulindac Related Compound C RS](#) in *Diluent*. Sonicate for 2–5 min.

Sample solution: 600 μg/mL of Sulindac in *Diluent*. Sonicate for 2–5 min.

System suitability

Sample: *Standard solution*

Suitability requirements