Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Jul-2017
Document Type: USP Monographs
DocId: GUID-6CD37F35-B24B-4C74-8688-2A42697F0D62_3_en-US
DOI: https://doi.org/10.31003/USPNF_M80060_03_01
DOI Ref: 9w38w

Sulindac Tablets

DEFINITION
Sulindac Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of sulindac ($C_{20}H_{17}FO_3S$).

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*.
- **B.** The UV-Vis spectrum 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
20.0	70	30

Diluent: Acetonitrile and water (50:50)

System suitability solution: 0.018 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: Nominally 0.2 mg/mL of sulindac in *Diluent* prepared as follows. Dissolve a quantity nominally equivalent to 20 mg of sulindac from finely powdered Tablets in 70 mL of *Diluent* in a 100-mL volumetric flask. Shake by mechanical means for 60 min and dilute with *Diluent* to volume. Shake for another 5 min. Centrifuge the solution for 10 min and inject the supernatant.

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

Mode: LC

Detector: UV 330 nm. For *Identification B*, use a diode array detector in the range of 200–400 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—See *Table 2* for the relative retention times.]

Suitability requirements

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

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of sulindac ($C_{20}H_{17}FO_3S$) in the portion of Tablets 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 = nominal concentration of sulindac in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **DISSOLUTION ⟨711⟩**

Medium: 0.1 M pH 7.2 phosphate buffer prepared as directed in *Reagents, Indicators, and Solutions—Buffer Solutions*, except to use twice the stated quantities of the monobasic potassium phosphate solution and of the sodium hydroxide solution; 900 mL

Apparatus 2: 50 rpm

Time: 45 min

Standard solution: 20 µg/mL of USP Sulindac RS in *Medium*

Sample solution: Pass 20 mL of the solution under test through a suitable filter, transfer 10 mL of the filtrate to a 100-mL volumetric flask, and dilute with *Medium* to volume.

Blank: *Medium*

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum absorbance at about 326 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of sulindac ($C_{20}H_{17}FO_3S$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times D \times V \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

D = dilution volume

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of sulindac ($C_{20}H_{17}FO_3S$) is dissolved.

• **UNIFORMITY OF DOSAGE UNITS ⟨905⟩:** Meet the requirements

IMPURITIES

• **ORGANIC IMPURITIES**

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

Standard solution: 0.018 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*. Sonicate for 2–5 min and mix with inversion.

Sample solution: Nominally 0.6 mg/mL of sulindac in *Diluent* prepared as follows. Dissolve a quantity nominally equivalent to 60 mg of sulindac from finely powdered Tablets in 70 mL of *Diluent* in a 100-mL volumetric flask. Shake by mechanical means for 60 min and dilute with *Diluent* to volume. Shake for another 5 min. Centrifuge the solution for 10 min. Collect and inject the supernatant.

System suitability

Sample: *Standard solution*

[NOTE—See *Table 2* for the relative retention times.]

Suitability requirements

Resolution: NLT 4.0 between sulindac and sulindac related compound A; NLT 4.0 between sulindac related compound A and sulindac related compound B

Relative standard deviation: NMT 2.0% for sulindac, sulindac related compound B, and sulindac related compound C

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of sulindac related compound B or sulindac related compound C in the portion of Tablets taken:

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

r_U = peak response of sulindac related compound B or sulindac related compound C from the *Sample solution*

r_S = peak response of sulindac related compound B or sulindac related compound C from the *Standard solution*

C_S = concentration of the corresponding related compound in the *Standard solution* (mg/mL)

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

Calculate the percentage of any individual unspecified impurity in the portion of Tablets taken:

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

r_U = peak response of any individual unspecified impurity from the *Sample solution*

r_S = peak response of sulindac from the *Standard solution*

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

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

Acceptance criteria: See *Table 2*.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Sulindac	1.0	—
Sulindac related compound A	1.26	—[a]
Sulindac related compound B	1.36	0.5
Sulindac related compound C	1.70	0.5
Individual unspecified impurity	—	0.1
Total impurities	—	3.0

[a] Sulindac related compound A is controlled in the API. Therefore, no individual acceptance criteria is needed. Sulindac related compound B and sulindac related compound C are both degradants and process impurities.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **USP Reference Standards** ⟨11⟩

USP Sulindac RS

USP Sulindac Related Compound A RS

(*E*)-2-{5-Fluoro-2-methyl-1-[4-(methylsulfinyl)benzylidene]-1*H*-inden-3-yl}acetic acid.

$C_{20}H_{17}FO_3S$ 356.41

USP Sulindac Related Compound B RS

(*Z*)-2-{5-Fluoro-2-methyl-1-[4-(methylsulfonyl)benzylidene]-1*H*-inden-3-yl}acetic acid.

$C_{20}H_{17}FO_4S$ 372.41

USP Sulindac Related Compound C RS

(*Z*)-2-{5-Fluoro-2-methyl-1-[4-(methylthio)benzylidene]-1*H*-inden-3-yl}acetic acid.

$C_{20}H_{17}FO_2S$ 340.41

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

Topic/Question	Contact	Expert Committee
SULINDAC TABLETS	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 43(1)

Current DocID: GUID-6CD37F35-B24B-4C74-8688-2A42697F0D62_3_en-US
Previous DocID: GUID-6CD37F35-B24B-4C74-8688-2A42697F0D62_1_en-US
DOI: https://doi.org/10.31003/USPNF_M80060_03_01
DOI ref: 9w38w