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Indomethacin Oral Suspension

DEFINITION
Indomethacin Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of indomethacin ($C_{19}H_{16}ClNO_4$).

IDENTIFICATION
• **A.** The UV absorption spectrum of the indomethacin peak of the *Sample solution* exhibits maxima and minima at the same wavelengths as those of the *Standard solution*, as obtained in the *Assay*.
• **B.** The retention time of the indomethacin peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY
• **Procedure**

Solution A: 0.2% (v/v) phosphoric acid in water

Solution B: Dehydrated alcohol and butyl alcohol (80:50)

Mobile phase: *Solution B* and *Solution A* (39:61). Pass through a suitable filter of 0.5-µm or finer pore size.

Standard solution: 0.8 mg/mL of USP Indomethacin RS and 0.16 mg/mL of sorbic acid prepared as follows. Transfer appropriate amounts of USP Indomethacin RS and sorbic acid to a suitable volumetric flask. Add 20% of the total volume of *Solution A* and 30% of the total volume of *Solution B*, and sonicate for 5 min. Dilute with *Solution A* to the total volume.

Sample solution: Nominally 0.8 mg/mL of indomethacin prepared as follows. Transfer an appropriate volume of Oral Suspension, freshly mixed and free from air bubbles, to a suitable volumetric flask. Add 30% of *Solution B*, and sonicate for 10 min. Dilute with *Solution A* to volume, and pass through a suitable filter of 0.5-µm or finer pore size.

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

Mode: LC

Detector: UV 240 nm. For *Identification A*, use a diode array detector in the range of 200–400 nm.

Column: 8-mm × 10-cm; packing L1

Flow rate: 3 mL/min

Injection volume: 15 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 4.0 between sorbic acid and indomethacin

Tailing factor: NMT 2.0 for indomethacin

Relative standard deviation: NMT 2.0% for indomethacin

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of indomethacin ($C_{19}H_{16}ClNO_4$) in the portion of Oral Suspension taken:

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

r_U = peak response of indomethacin from the *Sample solution*

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

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

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

Acceptance criteria: 90.0%–110.0%

OTHER COMPONENTS

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Buffer solution: 0.01 M pH 7.2 phosphate buffer prepared by dissolving 1.36 g of monobasic potassium phosphate in 1 L of water and adjusting with 0.1 N sodium hydroxide to a pH of 7.2 ± 0.1

Medium: *Buffer solution*; 900 mL

Apparatus 2: 50 rpm

Time: 20 min

Standard solution: USP Indomethacin RS at a known concentration in *Medium*. [Note—A quantity of methanol not to exceed 1.0% of the volume of the *Standard solution* may be used to bring the USP Reference Standard into solution before dilution with *Medium*, and the solution may be sonicated to effect complete dissolution of the USP Reference Standard.]

Sample solution: Transfer to the surface of the *Medium* in the dissolution vessel a volume of Oral Suspension, freshly mixed and free from air bubbles, nominally equivalent to 25 mg of indomethacin. Filter portions of the solution under test, and suitably dilute with *Medium* if necessary.

Instrumental conditions

Mode: UV

Analytical wavelength: 320 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Tolerances: NLT 80% (*Q*) of the labeled amount of indomethacin ($C_{19}H_{16}ClNO_4$) is dissolved.

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

For single-unit containers

Acceptance criteria: Meets the requirements

• **Deliverable Volume ⟨698⟩**

For multiple-unit containers

Acceptance criteria: Meets the requirements

IMPURITIES

• **Content of Indomethacin Related Compound B**

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

Standard stock solution: 0.09 mg/mL of USP Indomethacin Related Compound B RS in *Solution B*

Standard solution: 0.0018 mg/mL of USP Indomethacin Related Compound B RS prepared as follows. Transfer an adequate amount of *Standard stock solution* to a suitable volumetric flask containing 30% of the total volume of *Solution B*, and dilute with *Solution A* to the total volume.

System suitability

Sample: *Standard solution*

Suitability requirements

Capacity factor, *k'*: NLT 1.0

Relative standard deviation: NMT 2.5%

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of indomethacin related compound B in the portion of Oral Suspension taken:

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

r_U = peak response of indomethacin related compound B from the *Sample solution*

r_S = peak response of indomethacin related compound B from the *Standard solution*

C_S = concentration of USP Indomethacin Related Compound B RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: NMT 0.44%

SPECIFIC TESTS

• **pH ⟨791⟩:** 2.5–5.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Store below 30° and avoid temperatures above 50°. Preserve in tight, light-resistant containers and protect from freezing.

• **USP Reference Standards** ⟨11⟩

USP Indomethacin RS

USP Indomethacin Related Compound B RS

4-Chlorobenzoic acid.

$C_7H_5ClO_2$ 156.57

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

Topic/Question	Contact	Expert Committee
INDOMETHACIN ORAL SUSPENSION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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