Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-12875B9A-0CCF-43FA-AB8F-92B902EA87CF_3_en-US
DOI: https://doi.org/10.31003/USPNF_M40429_03_01
DOI Ref: 8u7w6

Indomethacin for Injection

DEFINITION

Indomethacin for Injection contains an amount of Indomethacin Sodium equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of indomethacin ($C_{19}H_{16}ClNO_4$).

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 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*.

ASSAY

• **Procedure**

Mobile phase: Methanol, phosphoric acid, and water (600:1:400)

Diluent: Acetonitrile, phosphoric acid, and water (300:1:700)

Standard solution: 0.1 mg/mL of USP Indomethacin RS prepared as follows. Dissolve a suitable amount of USP Indomethacin RS with 30% of the final volume of acetonitrile, and dilute with water to volume.

Sample stock solution: Nominally 0.5 mg/mL of indomethacin in *Diluent* from NLT 10 containers of Indomethacin for Injection

Sample solution: Nominally 0.1 mg/mL of indomethacin in *Diluent* from the *Sample stock solution*. Pass through a filter of 0.5-µm or finer pore size. Use the filtrate.

Chromatographic system

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

Mode: LC

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

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 2 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

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 Indomethacin for Injection taken:

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

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

r_S = peak area 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%

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩:** Meets the requirements

IMPURITIES

• **Content of Indomethacin Related Compound B**

Mobile phase, Diluent, Sample stock solution, Sample solution, and **Chromatographic system:** Proceed as directed in the *Assay.*

Standard stock solution: 0.22 mg/mL of USP Indomethacin Related Compound B RS in acetonitrile

Standard solution: 0.00044 mg/mL of USP Indomethacin Related Compound B RS prepared as follows. Transfer an adequate volume of the *Standard stock solution* to a suitable volumetric flask, and add 30% of the final volume of acetonitrile. Dilute with water to the final volume.

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 5%

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of indomethacin related compound B in the portion of Indomethacin for Injection taken:

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

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

r_S = peak area 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 2.2%

SPECIFIC TESTS

• **Constituted Solution:** At the time of use, it meets the requirements for *Injections and Implanted Drug Products ⟨1⟩, Specific Tests, Completeness and clarity of solutions*.

• **Sterility Tests ⟨71⟩:** Meets the requirements

• **Bacterial Endotoxins Test ⟨85⟩**

Sample solution: Nominally 1.0 mg/mL of indomethacin in LAL Reagent Water from Indomethacin for Injection

Acceptance criteria: NMT 20.0 USP Endotoxin Units/mg of indomethacin

• **Particulate Matter in Injections ⟨788⟩:** Meets the requirements for small-volume injections

• **pH ⟨791⟩**

Sample solution: A solution in water (1 in 2000) containing 0.3 mL of saturated potassium chloride solution per 100 mL

Acceptance criteria: 5.0–7.0

• **Other Requirements:** It meets the requirements in *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Store at controlled room temperature. Protect from light. Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging, Packaging for constitution*.

• **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 FOR INJECTION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 42(2)

Current DocID: GUID-12875B9A-0CCF-43FA-AB8F-92B902EA87CF_3_en-US
Previous DocID: GUID-12875B9A-0CCF-43FA-AB8F-92B902EA87CF_1_en-US
DOI: https://doi.org/10.31003/USPNF_M40429_03_01
DOI ref: 8u7w6