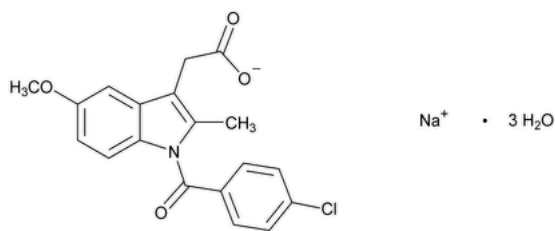


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Indomethacin Sodium



$C_{19}H_{15}ClINNaO_4 \cdot 3H_2O$ 433.82
1*H*-Indole-3-acetic acid, 1-(4-chlorobenzoyl)-5-methoxy-2-methyl-, sodium salt, trihydrate;
Sodium 1-(*p*-chlorobenzoyl)-5-methoxy-2-methylindole-3-acetate, trihydrate CAS RN®: 74252-25-8; UNII: 0IMX38M2GG.
Anhydrous 379.78

DEFINITION
Indomethacin Sodium contains NLT 98.0% and NMT 102.0% of indomethacin sodium ($C_{19}H_{15}ClINNaO_4$), calculated on the dried basis.

- IDENTIFICATION**
- A.**
Sample: A small quantity
Analysis: Ignite the *Sample* on a platinum wire in a nonluminous flame.
Acceptance criteria: An intense yellow flame is produced.
 - B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
 - C.** 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: 0.025% formic acid in acetonitrile
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	70	30
2	70	30
20	15	85
25	15	85
26	70	30
30	70	30

Diluent: *Solution B* and *Solution A* (45:55) adjusted with 0.2 M sodium hydroxide to a pH of 8.0
System suitability solution: 0.82 mg/mL of [USP Indomethacin RS](#), 0.002 mg/mL of [USP Indomethacin Related Compound A RS](#), and 0.002 mg/mL of [USP Indomethacin Related Compound B RS](#) in *Diluent*. Sonicate to dissolve.
Standard solution: 0.82 mg/mL of [USP Indomethacin RS](#) dissolved in a minimum quantity of acetonitrile. Dilute with *Diluent* to volume. Sonicate to dissolve.
Sample solution: 1.0 mg/mL of Indomethacin Sodium trihydrate in *Diluent*. Sonicate to dissolve.

Chromatographic system(See [Chromatography \(621\), System Suitability.](#))**Mode:** LC**Detector:** 240 nm. For *Identification C*, use a diode array detector in the range of 190–400 nm.**Column:** 4.6-mm × 25-cm; 5-μm packing L1**Column temperature:** 40°**Flow rate:** 1 mL/min**Injection volume:** 10 μL**System suitability****Samples:** *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for indomethacin related compound A and indomethacin related compound B are 0.50 and 0.67, respectively.]

Suitability requirements**Resolution:** NLT 10 between indomethacin related compound A and indomethacin related compound B, *System suitability solution***Tailing factor:** NMT 2.0 for indomethacin, *Standard solution***Relative standard deviation:** NMT 0.73%, *Standard solution***Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of indomethacin sodium ($C_{19}H_{15}ClNNaO_4$) in the portion of Indomethacin Sodium taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

 r_U = peak response from the *Sample solution* r_S = peak response from the *Standard solution* C_S = concentration of [USP Indomethacin RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Indomethacin Sodium in the *Sample solution* (mg/mL) M_{r1} = molecular weight of anhydrous indomethacin sodium, 379.78 M_{r2} = molecular weight of indomethacin, 357.79**Acceptance criteria:** 98.0%–102.0% on the dried basis**IMPURITIES**• **LIMIT OF ACETONE****Standard solution:** Transfer 1.0 mL of acetone to a 100-mL volumetric flask, and dilute with water to volume. Transfer 1.0 mL of this solution to a 200-mL volumetric flask, dilute with water to volume, insert a stopper, and cool in an ice bath.**Sample solution:** Transfer 100 mg of Indomethacin Sodium to a 15-mL centrifuge tube, and dissolve in 1.0 mL of cool water. While vortexing this solution, add 1.0 mL of 0.24 N hydrochloric acid, centrifuge promptly, and filter the supernatant. Collect the filtrate in a suitable tube, cap, and cool in an ice bath.**Chromatographic system**(See [Chromatography \(621\), System Suitability.](#))**Mode:** GC**Detector:** Flame ionization**Column:** 3-mm × 1.8-m; support S3**Column temperature:** 165°**Carrier gas:** Nitrogen**Injection volume:** 3 μL**System suitability****Sample:** *Standard solution***Suitability requirements****Capacity factor, k' :** 4–7 for acetone**Relative standard deviation:** NMT 2.0%**Analysis****Samples:** *Standard solution* and *Sample solution*

[NOTE—Use the solvent flush technique, with water as the flushing agent, and record the chromatograms for 6 min.]

Calculate the percentage of acetone in the portion of Indomethacin Sodium taken:

$$\text{Result} = S_G(10/W_U)(r_U/r_S)$$

 S_G = specific gravity of acetone, 0.79