

Indometacin EP10.4

Batch no

20250206

Mf date

Feb 04 2025

Exp date

Feb 03 2028

Molecular Structure

Molecular Formula

C₁₉H₁₆C I NO₄

Molecular Weight

357.8

CAS Registry Number

53-86-1

Mar 10 2025

<u>Tests</u>	<u>Specifications</u>	Results
Appearance Solubility	White or yellow crystalline powder Practically insoluble in water, sparingly soluble in ethanol(96%)	White crystalline powder Conforms
Identification Melting point Related substances	IR 158 ~ 162°C Unspecified impurities ≤ 0.1% Reporting threshold ≤ 0.05%	Positive 160 ~ 161°C 0.05% Conforms
Loss on drying Sulfated ash Microbial limits	Total impurities ≤ 0.3% ≤ 0.5% ≤ 0.1% Aerobic bacteria ≤ 1000 cfu/gr Yeast & molds ≤ 100 cfu/gr	0. 18% 0. 06% 0. 07% < 10 cfu/gr < 10 cfu/gr
Particle size Assay (odb)	Escherichia coli Negative 100 mesh 98.0 $^{\sim}$ 102.0% of $C_{28}H_{28}O_3$	ND Conforms 100.0%

Packaging and storage	Protected from light
Conclusion	Material complies with EP10.4

