

TECHNICAL DATA SHEET

1136-TDS-ENG-2025

INDOMETACINA (EUR. PH.)		
DESCRIPTION DCI: indometacin		DESCRIPTION DOE: INDOMETACINA
CAS Nº: 53-86-1	EC Nº: 200-186-5	AEMPS CODE: 167A
MOL. WEIGHT: 357,79	MOL. FORMULA: C ₁₉ H ₁₆ ClNO ₄	ARTICLE CODE: 1136

ATTRIBUTES	SHOULD BE
Appearance	White or yellow, crystalline powder
Solubility	Practically insoluble in water, sparingly soluble in ethanol (96 %)
Identification A	Complies
Identification B	Complies
Melting point	158 - 162 °C
Related substances	
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.3 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	98.0 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 11.4

STORAGE

Keep the container tightly closed, in a cool, dry place. Protected from air and light.

REMARKS

Indometacin is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.