

<b>INDOMETACINA (EUR. PH.)</b>			
PRODUCT CODE: 1136		CAS Nº: 53-86-1	ANALYSIS Nº: 344/25
MANUFACTURER BATCH:	E250601	CERTIFICATE ID:	48.995
SUPPLIER BATCH:	----	MANUFACTURING DATE:	14/05/2025
METAPH BATCH:	0341025	EXPIRY DATE:	13/05/2029

ATTRIBUTES	SHOULD BE	IS
Appearance	White or yellow, crystalline powder	Almost white crystalline powder
Solubility	Practically insoluble in water, sparingly soluble in ethanol (96 %)	Complies (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Melting point	158 - 162 °C	160.7 °C
Related substances		
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.3 %	< 0.05 %
Loss on drying	=< 0.5 %	0.06 %
Sulfated ash	=< 0.1 %	0.08 %
Assay	98.0 - 102.0 %	100.1 %

#### COMPLIES WITH

European Pharmacopoeia 11.4

#### REMARKS

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

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".

All data controlled by Metapharmaceutical Industrial SL.

(\*) Data adapted from the manufacturer's certificate of analysis.

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.

#### STORAGE

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

Release date: 01/12/2025  
Signature: Albert Sánchez López (QP)  
Conclusion: Complies



Manufacturer: 40001585  
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Original certificate available upon request

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