



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 250555

Product:	INDOMETHACIN
Lot:	250555
Expiry date:	12/05/2028
Reference:	Cumple PhEur11.6
Synonyms:	
Formula:	C ₁₉ H ₁₆ ClNO ₄
Molecular weight:	357,79 g/mol

Assay	Result	Specification	
Identification	Conform (A,B)	Test PhEur (A,B)	
Organoleptic properties	Conform	PhEur	
Elemental impurities	Conform	Test PhEur	#
Related substances (UPLC)	Conform	Test PhEur	
Loss on drying	0,06 %	<= 0,5 %	
Sulphated ashes	0,01 %	<= 0,1%	
ASSAY (UPLC)	99,9 %	98,0 - 102,0 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	< 0,05 %	<= 0,3 %	
Residual solvents	Conform	Test PhEur	#
Nitrosamine impurities	Conform	Test PhEur	#

Organoleptic characteristics: Crystalline powder, white or yellow. Practically insoluble in water, fairly soluble in 96% ethanol, practically insoluble in heptane.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 07/03/2025

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00356 CSPC OUYI PHARMACEUTICAL CO. LTD.

Manufacturer batch: 174240505

Product	Name	Capacity	Batch
1153302	INDOMETACINA	50 g	250555-I-1
1153302	INDOMETACINA	50 g	250555-I-2
1153302	INDOMETACINA	50 g	250555-I-3
1153302	INDOMETACINA	50 g	250555-I-4
1153304	INDOMETACINA	250 g	250555-N-1
1153304	INDOMETACINA	250 g	250555-N-2

1153304	INDOMETACINA	250 g	250555-N-4
1200261	INDOMETACINA	10 g	250555-F-2
1200261	INDOMETACINA	10 g	250555-F-4
1200261	INDOMETACINA	10 g	250555-F-5
1200261	INDOMETACINA	10 g	250555-F-7
1200261	INDOMETACINA	10 g	250555-F-8
1370198	INDOMETACINA (FLB)	250 g	250555-N-3
1370203	INDOMETACINA (FLB)	10 g	250555-F-1
1370203	INDOMETACINA (FLB)	10 g	250555-F-3
1370203	INDOMETACINA (FLB)	10 g	250555-F-6

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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