



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 224794

Product:	INDOMETHACIN
Lot:	224794
Expiry date:	15/05/2025
Reference:	Cumple PhEur10.8
Synonyms:	
Formula:	C ₁₉ H ₁₆ ClNO ₄
Molecular weight:	357,79 g/mol

Assay	Result	Specification	
Unspecified Impurities	< 0,10 %	<= 0,10 %	
Total impurities	< 0,3 %	<= 0,3 %	
Residual solvents	Conform	Test PhEur	#
Identification	Conform (A,C)	Test PhEur (A,B)	
Organoleptic properties	Conform	PhEur	
Elemental impurities	Conform	Test PhEur	#
Related substances (HPLC)	Conform	Test PhEur	
Loss on drying	0,11 %	<= 0,5 %	
Sulphated ashes	0,07 %	<= 0,1%	
Assay (HPLC)	100,5 %	98,0 - 102,0 %	

Organoleptic characteristics: White or yellow, crystalline powder. Practically insoluble in water, quite soluble in ethanol 96%.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 14/09/2022

Judgement:
APPROVED

Responsible: C. Codina

Technical director: Montserrat Enrique

Manufacturer: F00356 CSPC OUYI PHARMACEUTICAL CO. LTD.

Manufacturer batch: 174210514

Product	Name	Capacity	Batch
1153302	INDOMETACINA	50 g	224794-I-1
1153302	INDOMETACINA	50 g	224794-I-2
1153302	INDOMETACINA	50 g	224794-I-3
1153302	INDOMETACINA	50 g	224794-I-4
1153302	INDOMETACINA	50 g	224794-I-5
1153302	INDOMETACINA	50 g	224794-I-6
1153302	INDOMETACINA	50 g	224794-I-7

1153304	INDOMETACINA	250 g	224794-N-10
1153304	INDOMETACINA	250 g	224794-N-2
1153304	INDOMETACINA	250 g	224794-N-4
1153304	INDOMETACINA	250 g	224794-N-5
1153304	INDOMETACINA	250 g	224794-N-6
1153304	INDOMETACINA	250 g	224794-N-7
1153304	INDOMETACINA	250 g	224794-N-8
1153304	INDOMETACINA	250 g	224794-N-9
1200261	INDOMETACINA	10 g	224794-F-10
1200261	INDOMETACINA	10 g	224794-F-11
1200261	INDOMETACINA	10 g	224794-F-2
1200261	INDOMETACINA	10 g	224794-F-3
1200261	INDOMETACINA	10 g	224794-F-4
1200261	INDOMETACINA	10 g	224794-F-5
1200261	INDOMETACINA	10 g	224794-F-8
1200261	INDOMETACINA	10 g	224794-F-9
1370198	INDOMETACINA (FLB)	250 g	224794-N-1
1370203	INDOMETACINA (FLB)	10 g	224794-F-1
1370203	INDOMETACINA (FLB)	10 g	224794-F-7

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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