



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 250555**

|                    |   |
|--------------------|---|
| Product:           | INDOMETHACIN                                      |
| Lot:               | 250555  |
| Expiry date:       | 12/05/2028  |
| Reference:         | Cumple PhEur11.6                                  |
| Synonyms:          |   |
| Formule:           | C <sub>19</sub> H <sub>16</sub> ClNO <sub>4</sub> |
| Poids moléculaire: | 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

| Produit | Nom          | Capacité | Lot        |
|---------|--------------|----------|------------|
| 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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