



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 240981**

|                   |   |
|-------------------|---|
| Product:          | TRIAMCINOLONE ACETONIDE                         |
| Lot:              | 240981  |
| Expiry date:      | 16/02/2029                                      |
| Reference:        | Cumple PhEur11.4                                |
| Synonyms:         |   |
| Formula:          | C <sub>24</sub> H <sub>31</sub> FO <sub>6</sub> |
| Molecular weight: | 434,5 g/mol                                     |

| Assay                                | Result        | Specification   |   |
|--------------------------------------|---------------|-----------------|---|
| Identification                       | Conform (A,C) |                 |   |
| Organoleptic properties              | Conform       |                 |   |
| Related substances (HPLC)            | Conform       |                 | = |
| Specific rotation                    | +112          | (+110) - (+117) | = |
| Moisture - K.F.                      | 1,5 %         | <=2,0 %         |   |
| Assay (HPLC)                         | 99,3 %        | 97,5-102,0%     |   |
| Impurity B                           | < 0,05 %      | <= 0,2 %        | = |
| Impurity C                           | 0,05 %        | <= 0,15 %       | = |
| Unspecified Impurities               | < 0,05 %      | <= 0,10 %       | = |
| Total impurities                     | 0,1 %         | <= 0,5 %        | = |
| Residual solvent: Methanol           | < 3000 ppm    | <= 3000 ppm     | # |
| Residual solvent: acetone            | < 5000 ppm    | <= 5000 ppm     | # |
| Residual solvent: methylene chloride | < 600 ppm     | <= 600 ppm      | # |
| Elemental impurities                 | Conform       | Test PhEur      | # |

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 06/06/2024

Judgement:  
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F01002 FARMABIOS SpA

Manufacturer batch: 2196NM4 0042421

| Product | Name                    | Capacity | Batch      |
|---------|-------------------------|----------|------------|
| 1186923 | TRIAMCINOLONA ACETONIDO | 1 g      | 240981-D-1 |
| 1186923 | TRIAMCINOLONA ACETONIDO | 1 g      | 240981-D-2 |
| 1186924 | TRIAMCINOLONA ACETONIDO | 5 g      | 240981-E-1 |
| 1186924 | TRIAMCINOLONA ACETONIDO | 5 g      | 240981-E-2 |

|         |                         |       |            |
|---------|-------------------------|-------|------------|
| 1186925 | TRIAMCINOLONA ACETONIDO | 10 g  | 240981-F-1 |
| 1186925 | TRIAMCINOLONA ACETONIDO | 10 g  | 240981-F-2 |
| 1186926 | TRIAMCINOLONA ACETONIDO | 25 g  | 240981-G-1 |
| 1186926 | TRIAMCINOLONA ACETONIDO | 25 g  | 240981-G-2 |
| 1186928 | TRIAMCINOLONA ACETONIDO | 250 g | 240981-N-1 |
| 1186928 | TRIAMCINOLONA ACETONIDO | 250 g | 240981-N-2 |
| 1200233 | TRIAMCINOLONA ACETONIDO | 50 g  | 240981-I-1 |

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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