



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 220994**

|                    |   |
|--------------------|---|
| Product:           | TRIAMCINOLONE ACETONIDE                         |
| Lot:               | 220994  |
| Expiry date:       | 01/06/2026                                      |
| Reference:         | Cumple PhEur10.6                                |
| Synonyms:          |   |
| Formule:           | C <sub>24</sub> H <sub>31</sub> FO <sub>6</sub> |
| Poids moléculaire: | 434,5 g/mol                                     |

| Assay                                | Result        | Specification    |   |
|--------------------------------------|---------------|------------------|---|
| Identification                       | Conform (A,C) |                  |   |
| Organoleptic properties              | Conform       |                  |   |
| Related substances (HPLC)            | Conform       |                  | = |
| Specific rotation (0,5% EtOH)        | +113°         | (+110°)-( +117°) | = |
| Moisture - K.F. (s/0,5g)             | 1,3 %         | <= 2,0 %         |   |
| Assay (HPLC)                         | 100,2 %       | 97,5-102,0%      |   |
| Impurity B                           | < 0,05 %      | <= 0,2 %         | = |
| Impurity C                           | 0,07 %        | <= 0,15 %        | = |
| Unspecified Impurities               | < 0,05 %      | <= 0,10 %        | = |
| Total impurities                     | 0,07 %        | <= 0,5 %         | = |
| Residual solvent: Methanol           | < 3000 ppm    | <= 3000 ppm      | # |
| Residual solvent: acetone            | < 5000 ppm    | <= 5000 ppm      | # |
| Residual solvent: methylene chloride | < 600 ppm     | <= 600 ppm       | # |

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 21/03/2022

Judgement:  
APPROVED

Responsible: C. Codina

Technical director: Montserrat Enrique

Manufacturer: F01002 FARMABIOS SpA

Manufacturer batch: 2196NM4B0342121

| Produit | Nom                                | Capacité | Lot        |
|---------|------------------------------------|----------|------------|
| 1186922 | TRIAMCINOLONA ACETONIDO (INACTIVO) | 0.5 g    | 220994-C-1 |
| 1186923 | TRIAMCINOLONA ACETONIDO            | 1 g      | 220994-D-1 |
| 1186923 | TRIAMCINOLONA ACETONIDO            | 1 g      | 220994-D-2 |
| 1186924 | TRIAMCINOLONA ACETONIDO            | 5 g      | 220994-E-1 |
| 1186925 | TRIAMCINOLONA ACETONIDO            | 10 g     | 220994-F-1 |

|         |                         |       |            |
|---------|-------------------------|-------|------------|
| 1186926 | TRIAMCINOLONA ACETONIDO | 25 g  | 220994-G-1 |
| 1186928 | TRIAMCINOLONA ACETONIDO | 250 g | 220994-N-1 |
| 1200233 | TRIAMCINOLONA ACETONIDO | 50 g  | 220994-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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