



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 252242

| | |
|-------------------|---|
| Product: | TRIAMCINOLONE ACETONIDE |
| Lot: | 252242 |
| Expiry date: | 28/02/2029 |
| Reference: | Cumple PhEur12.1 |
| Synonyms: | |
| Formula: | C ₂₄ H ₃₁ FO ₆ |
| Molecular weight: | 434,5 g/mol |

| Assay | Result | Specification | |
|--------------------------------------|---------------|-----------------|---|
| Identification | Conform (A,C) | | |
| Organoleptic properties | Conform | | |
| Related substances (HPLC) | Conform | | |
| Specific rotation | +113 | (+110) - (+117) | |
| Moisture - K.F. | 1,5 % | <= 2,0 % | |
| Assay (HPLC) | 98,4 % | 97,5-102,0% | |
| Impurity B | 0,10 % | <= 0,2 % | |
| Impurity C | < 0,05 % | <= 0,15 % | |
| Unspecified Impurities | < 0,05 % | <= 0,10 % | |
| Total impurities | 0,10 % | <= 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 | # |
| Nitrosamine impurities | Conform | | # |

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 15/01/2026

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00340 SWATI SPENLOSE PRIVATE LIMITED (UNIT-I)

Manufacturer batch: TCA-125004

| Product | Name | Capacity | Batch |
|---------|-------------------------|----------|------------|
| 1186923 | TRIAMCINOLONA ACETONIDO | 1 g | 252242-D-1 |
| 1186924 | TRIAMCINOLONA ACETONIDO | 5 g | 252242-E-1 |
| 1186925 | TRIAMCINOLONA ACETONIDO | 10 g | 252242-F-1 |

| | | | |
|---------|-------------------------|-------|------------|
| 1186926 | TRIAMCINOLONA ACETONIDO | 25 g | 252242-G-1 |
| 1186928 | TRIAMCINOLONA ACETONIDO | 250 g | 252242-N-1 |
| 1200233 | TRIAMCINOLONA ACETONIDO | 50 g | 252242-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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