



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 250207

| | |
|--------------------|--|
| Product: | TACROLIMUS |
| Lot: | 250207 |
| Expiry date: | 30/11/2027 |
| Reference: | Cumple PhEur11.6 |
| Synonyms: | Tacrolimus monohidrato. |
| Formule: | C ₄₄ H ₆₉ NO ₁₂ ·H ₂ O |
| Poids moléculaire: | 822,03 g/mol |

| Assay | Result | Specification | |
|-----------------------------------|------------|----------------|---|
| Identification | Conform | | |
| Organoleptic properties | Conform | PhEur | |
| Water | 2,1 % | 1,5 - 4,0 % | |
| Appearance of solution | Conform | Test PhEur | |
| Sulphated ashes | 0,01 % | <= 0,1 % | |
| Assay | 100,3 % | 97,0 - 102,0 % | |
| Related substances (HPLC) | Conform | | |
| Elemental impurities | Conform | Test PhEur | # |
| Impurity A | < 0,05 % | <= 0,5 % | |
| Unspecified Impurities | 0,07 % | <= 0,15 % | |
| Total impurities | 0,13 % | <= 1,0 % | |
| Residual solvent: acetone | < 5000 ppm | <= 5000 ppm | # |
| Residual solvent: Isopropyl ether | < 600 ppm | <= 600 ppm | # |
| Residual solvent: Ethyl acetate | < 5000 ppm | <= 5000 ppm | # |
| Residual solvent: Acetonitrile | < 410 ppm | <= 410 ppm | # |
| Residual solvent: Toluene | < 890 ppm | <= 890 ppm | # |
| Residual solvent: Hexane | < 290 ppm | <= 290 ppm | # |

Organoleptic characteristics: White or almost white, crystalline powder. Practically insoluble in water, soluble in ethanol (96 per cent), practically insoluble in heptane.

Conservation: Store in tightly closed containers. Protect from light and moisture. Store at controlled room temperature

Date of analysis: 05/02/2025

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00010 CONCORD BIOTECH LTD.

Manufacturer batch: 0403A524331

| Produit | Nom | Capacité | Lot |
|---------|------------------|----------|------------|
| 1179899 | TACROLIMUS | 0,25 g | 250207-B-1 |
| 1179900 | TACROLIMUS | 0,5 g | 250207-C-2 |
| 1179901 | TACROLIMUS | 1 g | 250207-D-2 |
| 1179902 | TACROLIMUS | 5 g | 250207-E-1 |
| 1370220 | TACROLIMUS (FLB) | 1 g | 250207-D-1 |
| 1370249 | TACROLIMUS (FLB) | 0,5 g | 250207-C-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

ACOFARMA DISTRIBUCIÓN, S.A.
C/ Llobregat, 20 - 08223 Terrassa (Barcelona)
Tel./ 93-736.00.88
www.acofarma.com

Date d'édition: 28/05/2026

