



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 241582

| | |
|--------------------|------------------|
| Product: | CYCLOSPORINE A |
| Lot: | 241582 |
| Expiry date: | 30/05/2028 |
| Reference: | Cumple PhEur11.5 |
| Synonyms: | |
| Formule: | C62H111N11O12 |
| Poids moléculaire: | 1202,63 g/mol |

| Assay | Result | Specification | |
|---------------------------------|---------------|------------------|---|
| Identification | Conform (A,B) | Test PhEur (A,B) | |
| Organoleptic properties | Conform | PhEur | |
| Appearance of solution | Conform | Test PhEur | |
| Related substances (HPLC) | Conform | Test PhEur | |
| Specific rotation | -187 | (-185) - (-193) | |
| Elemental impurities | Conform | Test PhEur | # |
| Loss on drying | 0,39 % | <= 2,0 % | |
| Assay (HPLC) | 98,9 % | 97,0 - 102,0 % | |
| Sum of impurities B and E | 0,27 % | <= 0,5 % | |
| Impurity G | 0,11 % | <= 0,4 % | |
| Any impurity | 0,14 % | <= 0,3 % | |
| Total impurities | 0,82 % | <= 1,5 % | |
| Residual solvent: Ethyl acetate | < 2000 ppm | <= 2000 ppm | # |
| Residual solvent: acetone | < 4500 ppm | <= 4500 ppm | # |

Organoleptic characteristics: White or almost white powder. Practically insoluble in water, freely soluble in anhydrous ethanol and in methylene chloride

Conservation: In tightly closed containers. Protect from light and moisture.

Date of analysis: 29/08/2024

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00010 CONCORD BIOTECH LTD.

Manufacturer batch: 1213A424110

| Produit | Nom | Capacité | Lot |
|---------|------------------------|----------|------------|
| 1119023 | CICLOSPORINA A Ph.Eur. | 5 g | 241582-E-2 |
| 1119025 | CICLOSPORINA A Ph.Eur. | 25 g | 241582-G-1 |
| 1119027 | CICLOSPORINA A Ph.Eur. | 100 g | 241582-J-1 |

1119029

CICLOSPORINA A Ph.Eur.

1 kg

241582-P-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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