



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 241813**

|                    |  |
|--------------------|--|
| Product:           | CLOBETASOL 17-PROPIONATE                       |
| Lot:               | 241813   |
| Expiry date:       | 30/03/2029                                     |
| Reference:         | Cumple PhEur11.5                               |
| Synonyms:          |  |
| Formule:           | C <sub>25</sub> H <sub>32</sub> O <sub>5</sub> |
| Poids moléculaire: | 467,0 g/mol                                    |

| Assay                                | Result      | Specification     |   |
|--------------------------------------|-------------|-------------------|---|
| Identification                       | Conform     | Test PhEur        |   |
| Organoleptic properties              | Conform     | PhEur             |   |
| Related substances (HPLC)            | Conform     | Test PhEur        |   |
| Specific rotation                    | +116,6      | (+112,0)-(+118,0) |   |
| Loss on drying                       | 0,03 %      | <= 0,5 %          |   |
| Sulphated ashes                      | 0,01 %      | <= 0,1%           |   |
| Assay (HPLC)                         | 99,5 %      | 97,0-102,0%       |   |
| Impurity A                           | < 0,05 %    | <= 0,2 %          |   |
| Impurity B                           | 0,05 %      | <= 0,3 %          |   |
| Impurity D                           | < 0,05 %    | <= 0,2 %          |   |
| Impurity E                           | < 0,05 %    | <= 0,3 %          |   |
| Unspecified Impurities               | < 0,05 %    | <= 0,10 %         |   |
| Total impurities                     | 0,05 %      | <= 1,0 %          |   |
| Residual solvent: Methanol           | <= 3000 ppm | <= 3000 ppm       | # |
| Residual solvent: methylene chloride | <= 600 ppm  | <= 600 ppm        | # |
| Residual solvent: acetone            | <= 5000 ppm | <= 5000 ppm       | # |
| Residual solvent: Ethyl acetate      | <= 5000 ppm | <= 5000 ppm       | # |
| Residual solvent: Dimethylformamide  | <= 880 ppm  | <= 880 ppm        | # |
| Residual solvent: Pyridine           | <= 200 ppm  | <= 200 ppm        | # |

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

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 30/09/2024

Judgement:  
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00056 SYMBIOTICA SPECIALITY INGREDIENTS SDN BHD

Manufacturer batch: CLO105-0424

| Produit | Nom                      | Capacité | Lot        |
|---------|--------------------------|----------|------------|
| 1119582 | CLOBETASOL 17-PROPIONATO | 1 g      | 241813-D-1 |
| 1119582 | CLOBETASOL 17-PROPIONATO | 1 g      | 241813-D-2 |
| 1119583 | CLOBETASOL 17-PROPIONATO | 5 g      | 241813-E-1 |
| 1119583 | CLOBETASOL 17-PROPIONATO | 5 g      | 241813-E-2 |
| 1119585 | CLOBETASOL 17-PROPIONATO | 100 g    | 241813-J-1 |
| 1119585 | CLOBETASOL 17-PROPIONATO | 100 g    | 241813-J-2 |
| 1119586 | CLOBETASOL 17-PROPIONATO | 25 g     | 241813-G-1 |
| 1119586 | CLOBETASOL 17-PROPIONATO | 25 g     | 241813-G-2 |

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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