



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 223815

| | |
|-------------------|---|
| Product: | CLOBETASOL 17-PROPIONATE |
| Lot: | 223815 |
| Expiry date: | 30/09/2026 |
| Reference: | Cumple PhEur10.8 |
| Synonyms: | |
| Formula: | C ₂₅ H ₃₂ ClFO ₅ |
| Molecular weight: | 467,0 g/mol |

| Assay | Result | Specification | |
|--------------------------------------|------------|-------------------|---|
| Identification | Conform | Test PhEur | |
| Organoleptic properties | Conform | PhEur | |
| Related substances (HPLC) | Conform | Test PhEur | |
| Specific rotation | +114,1 | (+112,0)-(+118,0) | |
| Loss on drying | 0,09 % | <= 0,5 % | |
| Sulphated ashes | 0,01 % | <= 0,1% | |
| Assay (HPLC) | 98,8 % | 97,0-102,0% | |
| Impurity A | 0,05 % | <= 0,2 % | |
| Impurity B | 0,06 % | <= 0,3 % | |
| Impurity D | < 0,05 % | <= 0,2 % | |
| Impurity E | < 0,05 % | <= 0,3 % | |
| Unspecified Impurities | < 0,05 % | <= 0,10 % | |
| Total impurities | 0,11 % | <= 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: 27/07/2022

Judgement:
APPROVED

Responsible: C. Codina

Technical director: Montserrat Enrique

Manufacturer: F00056 SYMBIOTICA SPECIALITY INGREDIENTS SDN BHD

Manufacturer batch: CLO124-1021

| Product | Name | Capacity | Batch |
|---------|-------------------------------------|----------|------------|
| 1119581 | CLOBETASOL 17-PROPIONATO (INACTIVO) | 0.5 g | 223815-C-1 |
| 1119581 | CLOBETASOL 17-PROPIONATO (INACTIVO) | 0.5 g | 223815-C-2 |
| 1119581 | CLOBETASOL 17-PROPIONATO (INACTIVO) | 0.5 g | 223815-C-3 |
| 1119582 | CLOBETASOL 17-PROPIONATO | 1 g | 223815-D-1 |
| 1119582 | CLOBETASOL 17-PROPIONATO | 1 g | 223815-D-2 |
| 1119582 | CLOBETASOL 17-PROPIONATO | 1 g | 223815-D-3 |
| 1119583 | CLOBETASOL 17-PROPIONATO | 5 g | 223815-E-1 |
| 1119583 | CLOBETASOL 17-PROPIONATO | 5 g | 223815-E-2 |
| 1119583 | CLOBETASOL 17-PROPIONATO | 5 g | 223815-E-3 |
| 1119585 | CLOBETASOL 17-PROPIONATO | 100 g | 223815-J-1 |
| 1119585 | CLOBETASOL 17-PROPIONATO | 100 g | 223815-J-2 |
| 1119585 | CLOBETASOL 17-PROPIONATO | 100 g | 223815-J-3 |
| 1119586 | CLOBETASOL 17-PROPIONATO | 25 g | 223815-G-1 |
| 1119586 | CLOBETASOL 17-PROPIONATO | 25 g | 223815-G-2 |
| 1200129 | CLOBETASOL 17-PROPIONATO (INACTIVO) | 0,25 g | 223815-B-1 |
| 1200129 | CLOBETASOL 17-PROPIONATO (INACTIVO) | 0,25 g | 223815-B-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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