# ANALYSIS CERTIFICATE

## Lot/Analysis/Analysis Nº: 251241

| | |
|---|---|
| Product: | BETAMETHASONE 17,21-DIPROPIONATE |
| Lot: | 251241 |
| Expiry date: | 30/09/2029 |
| Reference: | Cumple PhEur11.8 |
| Synonyms: | |
| Formule: | C28H37FO7 |
| Poids moléculaire: | 504,59 g/mol |

| Assay | Result | Specification | |
|---|---|---|---|
| Identification | Conform (A) | | |
| Organoleptic properties | Conform | PhEur | |
| Specific rotation | 85,1 | (+84,0) - (+88,0) | |
| Related substances (HPLC) | Conform | Test PhEur | |
| Loss on drying | 0,14 % | <= 1,0 % | |
| Assay (HPLC) | 98,9 % | 97,0-102,0% | |
| Elemental impurities | Conform | Test PhEur | # |
| Impurity B | 0,10 % | <= 0,3 % | |
| Impurity C | 0,34 % | <= 0,5 % | |
| Impurity D | < 0,05 % | <= 0,2 % | |
| Impurity E | 0,07 % | <= 0,2 % | |
| Impurity G | < 0,05% | <= 0,2 % | |
| Impurity H | < 0,05% | <= 0,3 % | |
| Impurity I | < 0,05% | <= 0,15 % | |
| Unspecified Impurities | < 0,05% | <= 0,10 % | |
| Total impurities | 0,51 % | <= 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: Pyridine | <= 200 ppm | <= 200 ppm | # |
| Residual solvent: Isopropanol | <= 5000 ppm | <= 5000 ppm | # |

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

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Date of analysis: 28/07/2025

Responsible: B. Chia

Judgement:
APPROVED

Technical director: Montserrat Enrique
Manufacturer: F00056 SYMBIOTICA SPECIALITY INGREDIENTS SDN BHD
Manufacturer batch: BDP107-1024

| Produit | Nom | Capacité | Lot |
|---|---|---|---|
| 1115192 | BETAMETASONA 17,21-DIPROPIONATO | 1 g | 251241-D-1 |
| 1115192 | BETAMETASONA 17,21-DIPROPIONATO | 1 g | 251241-D-2 |
| 1115192 | BETAMETASONA 17,21-DIPROPIONATO | 1 g | 251241-D-3 |
| 1115193 | BETAMETASONA 17,21-DIPROPIONATO | 5 g | 251241-E-1 |
| 1115193 | BETAMETASONA 17,21-DIPROPIONATO | 5 g | 251241-E-2 |
| 1115193 | BETAMETASONA 17,21-DIPROPIONATO | 5 g | 251241-E-3 |
| 1115195 | BETAMETASONA 17,21-DIPROPIONATO | 25 g | 251241-G-1 |
| 1115195 | BETAMETASONA 17,21-DIPROPIONATO | 25 g | 251241-G-2 |
| 1115195 | BETAMETASONA 17,21-DIPROPIONATO | 25 g | 251241-G-3 |
| 1115197 | BETAMETASONA 17,21-DIPROPIONATO | 100 g | 251241-J-1 |
| 1115197 | BETAMETASONA 17,21-DIPROPIONATO | 100 g | 251241-J-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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