



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 260086

| | |
|--------------------|--|
| Product: | ADAPALENE |
| Lot: | 260086 |
| Expiry date: | 30/10/2030 |
| Reference: | Cumple PhEur12.1 |
| Synonyms: | Adapalene, Adapalenum |
| Formule: | C ₂₈ H ₂₈ O ₃ |
| Poids moléculaire: | 412.5 g/mol |

| Assay | Result | Specification | |
|---------------------------------------|------------|----------------|---|
| Identification | Conform | | |
| Organoleptic properties | Conform | | |
| Appearance of solution | Conform | | |
| Related substances (HPLC) | Conform | | |
| Loss on drying | 0,09 % | <= 0,5 % | |
| Sulphated ashes | 0,05 % | <= 0,1 % | |
| Assay (HPLC) | 99,9 % | 98,0 - 102,0 % | |
| Impurity A | < 0,05 % | <= 0,3 % | |
| Impurity D | < 0,05 % | <= 0,2 % | |
| Impurity C | < 0,05 % | <= 0,15 % | |
| Unspecified Impurities | < 0,05 % | <= 0,10 % | |
| Total impurities | < 0,05 % | <= 0,5 % | |
| Elemental impurities | Conform | | # |
| Residual solvent: Methanol | < 3000 ppm | <= 3000 ppm | # |
| Nitrosamine impurities | Conform | | # |
| Residual solvent: acetone | < 5000 ppm | <= 5000 ppm | # |
| Residual solvent: methylene chloride | < 600 ppm | <= 600 ppm | # |
| Residual solvent: Methyl ethyl ketone | < 5000 ppm | <= 5000 ppm | # |
| Residual solvent: Tetrahydrofuran | < 720 ppm | <= 720 ppm | # |
| Residual solvent: Toluene | < 890 ppm | <= 890 ppm | # |
| Residual solvent: Dimethyl sulfoxide | < 5000 ppm | <= 5000 ppm | # |

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

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 21/01/2026

Responsible: B. Chia

Technical director: Montserrat Enrique

Judgement:
APPROVED

Manufacturer: F00146 BAL PHARMA LIMITED

Manufacturer batch: 1501052511003

| Produit | Nom | Capacité | Lot |
|---------|-----------|----------|------------|
| 1115230 | ADAPALENO | 1 g | 260086-D-1 |
| 1115231 | ADAPALENO | 5 g | 260086-E-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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