



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 250645

| | |
|--------------------|--------------------|
| Product: | ESTRADIOL VALERATE |
| Lot: | 250645 |
| Expiry date: | 25/09/2028 |
| Reference: | Cumple PhEur11.7 |
| Synonyms: | |
| Formule: | C23H32O3 |
| Poids moléculaire: | 356.5 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 | = |
| Loss on drying | 0,10 % | <= 1,0 % | |
| Specific rotation | 44 | (+41) – (+47) | = |
| Elemental impurities | Conform | Test PhEur | # |
| Assay | 100,2 % | 97,5 - 102,0 % | |
| Impurity A | < 0,05 % | <= 0,2 % | = |
| Impurity C | 0,11 % | <= 0,2 % | = |
| Impurity D | < 0,05 % | <= 0,4 % | = |
| Impurity E | < 0,05 % | <= 0,15 % | = |
| Unspecified Impurities | ND | <= 0,10 % | = |
| Total impurities | 0,11 % | <= 0,5 % | = |
| Residual solvent: Ethyl acetate | < 5000 ppm | <= 5000 ppm | # |
| Residual solvent: Methanol | < 5000 ppm | <= 5000 ppm | # |

Organoleptic characteristics: White or almost white, crystalline powder or colourless crystals. Practically insoluble in water, freely soluble in methylene chloride, soluble in ethanol (96 per cent).

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 03/04/2025

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00381 STEROID S.P.A.

Manufacturer batch: 082223

| | | | |
|---------|----------------------------------|----------|------------|
| Produit | Nom | Capacité | Lot |
| 1130364 | ESTRADIOL VALERATO (BIOIDENTICA) | 1 g | 250645-D-1 |

| | | | |
|---------|----------------------------------|------|------------|
| 1130366 | ESTRADIOL VALERATO (BIOIDENTICA) | 5 g | 250645-E-1 |
| 1130367 | ESTRADIOL VALERATO (BIOIDENTICA) | 10 g | 250645-F-1 |
| 1130368 | ESTRADIOL VALERATO (BIOIDENTICA) | 25 g | 250645-G-1 |
| 1130368 | ESTRADIOL VALERATO (BIOIDENTICA) | 25 g | 250645-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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