



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 224414

| | |
|-------------------|--|
| Product: | ESTRADIOL VALERATE |
| Lot: | 224414 |
| Expiry date: | 30/05/2027 |
| Reference: | Cumple PhEur 10.8 |
| Synonyms: | |
| Formula: | C ₂₃ H ₃₂ O ₃ |
| Molecular weight: | 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 | 0,02 % | <= 1,0 % | |
| Specific rotation | +45 | (+41) – (+47) | = |
| Elemental impurities | Conform | Test PhEur | # |
| Assay | 99,0 % | 97,5 - 102,0 % | |
| Impurity A | < 0,2 % | <= 0,2 % | = |
| Impurity C | < 0,2 % | <= 0,2 % | = |
| Impurity D | < 0,4 % | <= 0,4 % | = |
| Impurity E | < 0,15 % | <= 0,15 % | = |
| Unspecified Impurities | < 0,10 % | <= 0,10 % | = |
| Total impurities | < 0,5 % | <= 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: 22/09/2022

Judgement:
APPROVED

Responsible: C. Codina

Technical director: Montserrat Enrique

Manufacturer: F00381 STEROID S.P.A.

Manufacturer batch: 048422

| Product | Name | Capacity | Batch |
|---------|----------------------------------|----------|------------|
| 1130364 | ESTRADIOL VALERATO (BIOIDENTICA) | 1 g | 224414-D-1 |

| | | | |
|---------|----------------------------------|------|------------|
| 1130366 | ESTRADIOL VALERATO (BIOIDENTICA) | 5 g | 224414-E-1 |
| 1130367 | ESTRADIOL VALERATO (BIOIDENTICA) | 10 g | 224414-F-1 |
| 1130368 | ESTRADIOL VALERATO (BIOIDENTICA) | 25 g | 224414-G-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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