



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 215060**

|                    |                    |
|--------------------|--------------------|
| Product:           | ESTRADIOL VALERATE |
| Lot:               | 215060             |
| Expiry date:       | 15/01/2026         |
| Reference:         | Cumple PhEur 10.5  |
| Synonyms:          |                    |
| Formule:           | C23H32O3           |
| Poids moléculaire: | 356.5 g/mol        |

| Assay                           | Result        | Specification    |   |
|---------------------------------|---------------|------------------|---|
| Assay                           | 98,3 %        | 97,5 - 102,0 %   |   |
| Elemental impurities            | Conform       | Test PhEur       | # |
| Loss on drying                  | 0,20 %        | <= 1,0 %         |   |
| Residual solvent: Methanol      | <= 5000 ppm   | <= 5000 ppm      | # |
| Specific rotation               | +46           | (+41) – (+47)    | = |
| Appearance of solution          | Conform       | Test PhEur       | = |
| Total impurities                | <= 0,5 %      | <= 0,5 %         | = |
| Related substances (HPLC)       | Conform       | Test PhEur       | = |
| Residual solvent: Ethyl acetate | <= 5000 ppm   | <= 5000 ppm      | # |
| Identification                  | Conform (A,B) | Test PhEur (A,B) |   |
| Impurity E                      | <= 0,15 %     | <= 0,15 %        | = |
| Organoleptic properties         | Conform       | PhEur            |   |
| Unspecified Impurities          | <= 0,10 %     | <= 0,10 %        | = |
| Impurity C                      | <= 0,2 %      | <= 0,2 %         | = |
| Impurity D                      | <= 0,4 %      | <= 0,4 %         | = |
| Impurity A                      | <= 0,2 %      | <= 0,2 %         | = |

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: 29/09/2021

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00381 STEROID S.P.A.

Manufacturer batch: 003721

|         |                    |          |            |
|---------|--------------------|----------|------------|
| Produit | Nom                | Capacité | Lot        |
| 1130364 | ESTRADIOL VALERATO | 1 g      | 215060-D-1 |

|         |                    |      |            |
|---------|--------------------|------|------------|
| 1130364 | ESTRADIOL VALERATO | 1 g  | 215060-D-2 |
| 1130366 | ESTRADIOL VALERATO | 5 g  | 215060-E-1 |
| 1130366 | ESTRADIOL VALERATO | 5 g  | 215060-E-2 |
| 1130367 | ESTRADIOL VALERATO | 10 g | 215060-F-1 |
| 1130367 | ESTRADIOL VALERATO | 10 g | 215060-F-2 |
| 1130368 | ESTRADIOL VALERATO | 25 g | 215060-G-1 |
| 1130368 | ESTRADIOL VALERATO | 25 g | 215060-G-2 |
| 1130368 | ESTRADIOL VALERATO | 25 g | 215060-G-3 |

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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