



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 217177**

|                    |                                                |
|--------------------|------------------------------------------------|
| Product:           | TESTOSTERONE                                   |
| Lot:               | 217177                                         |
| Expiry date:       | 01/10/2025                                     |
| Reference:         | Cumple PhEur10.7                               |
| Synonyms:          | 17-Hydroxyandrost-4-en-3-one                   |
| Formule:           | C <sub>19</sub> H <sub>28</sub> O <sub>2</sub> |
| Poids moléculaire: | 288,4 g/mol                                    |

| Assay                      | Result     | Specification      |   |
|----------------------------|------------|--------------------|---|
| Assay (HPLC)               | 99,0 %     | 98,0 - 102,0 % sps |   |
| Impurity I                 | <=0,05 %   | <= 0,2 %           |   |
| Impurity C                 | <=0,05 %   | <= 0,3 %           |   |
| Total impurities           | <=0,05 %   | <= 0,6 %           |   |
| Any other impurity         | <=0,05 %   | <= 0,10 %          |   |
| Impurity K                 | <=0,05 %   | <= 0,15 %          |   |
| Methanol (GC)              | <=3000 ppm | <= 3000 ppm        | # |
| Dichloromethane            | <=600 ppm  | <= 600 ppm         | # |
| Triethylamine              | <=320 ppm  | <= 320 ppm         | # |
| Elemental impurities       | Conform    |                    | # |
| Ethanol                    | <=5000 ppm | <= 5000 ppm        | # |
| Acetone                    | <=5000 ppm | <= 5000 ppm        | # |
| Organoleptic properties    | Conform    | PhEur              |   |
| Identification             | Conform    | Test PhEur         |   |
| Loss on drying (2h, 105°C) | 0,95 %     | <= 1,0 %           |   |
| Related substances (HPLC)  | Conform    | Complies           |   |
| Specific rotation          | +108       | (+106) - (+114)    |   |

Organoleptic characteristics: White or almost white crystalline powder, or colourless or yellowish-white crystals. Practically insoluble in water, freely soluble in ethanol 96%l and in methylene chloride, practically insoluble in fatty oils.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 29/04/2022

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00330 SYMBIOTEC PHARMALAB LIMITED

Manufacturer batch: ZTSTCY20004

| Produit | Nom                          | Capacité | Lot        |
|---------|------------------------------|----------|------------|
| 1184512 | TESTOSTERONA BASE (INACTIVO) | 1 g      | 217177-D-1 |
| 1184513 | TESTOSTERONA BASE (INACTIVO) | 5 g      | 217177-E-1 |
| 1184514 | TESTOSTERONA BASE (INACTIVO) | 10 g     | 217177-F-1 |
| 1184515 | TESTOSTERONA BASE            | 25 g     | 217177-G-1 |
| 1184516 | TESTOSTERONA BASE (INACTIVO) | 100 g    | 217177-J-1 |
| 1184517 | TESTOSTERONA BASE            | 1 kg     | 217177-P-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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