

**TECHNICAL DATA SHEET**

1699-TDS-ENG-2026

| <b>TESTOSTERONA BASE (EUR. PH.)</b> |                        |                               |
|-------------------------------------|------------------------|-------------------------------|
| DESCRIPTION DCI: testosterone       |                        | DESCRIPTION DOE: TESTOSTERONA |
| CAS N°: 58-22-0                     | EC N°: 200-370-5       | AEMPS CODE: 890A              |
| MOL. WEIGHT: 288,42                 | MOL. FORMULA: C19H28O2 | ARTICLE CODE: 1699            |

| <u>ATTRIBUTES</u>         | <u>SHOULD BE</u>   |
|---------------------------|--|
| Appearance                | White or almost white crystalline powder, or colourless or yellowish-white crystals                                      |
| Solubility                | Practically insoluble in water, freely soluble in alcohol and in methylene chloride, practically insoluble in fatty oils |
| Melting point             | about 155 °C   |
| Identification            | Complies   |
| Specific optical rotation | +106 / +114  |
| Related substances        |  |
| Impurity C                | =< 0.3 %   |
| Impurity I at 290 nm      | =< 0.2 %   |
| Impurity K                | =< 0.15 %  |
| Unspecified impurities    | =< 0.10 %  |
| Total impurities          | =< 0.6 %   |
| Loss on drying            | =< 1.0 %   |
| Assay                     | 98.0 - 102.0 %   |

**COMPLIES WITH**

European Pharmacopoeia 12.2

**STORAGE**

Keep container tightly closed. Protect from light.

**REMARKS**

**VEGETAL ORIGIN** Testosterone is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.