



TECHNICAL DATA SHEET

1701-TDS-ENG-2023

| TESTOSTERONA PROPIONATO (PH.EUR) | | |
|--|------------------------|--|
| DESCRIPTION DCI: TESTOSTERONE PROPIONATE | | DESCRIPTION DOE: TESTOSTERONA PROPIONATO |
| CAS N°: 57-85-2 | EC N°: 200-351-1 | AEMPS CODE: 890PR |
| MOL. WEIGHT: 344.5 | MOL. FORMULA: C22H32O3 | ARTICLE CODE: 1701 |

| ATTRIBUTES | SHOULD BE |
|---------------------------|--|
| Appearance | White or almost white crystalline powder or colourless crystals |
| Solubility | Practically insoluble in water, freely soluble in acetone and in ethanol (96 %), soluble in fatty oils |
| Identification | Complies |
| Specific optical rotation | +84 / +90 |
| Related substances | |
| Impurity A | =< 0.5 % |
| Impurity C | =< 0.2 % |
| Unspecified impurities | =< 0.10 % |
| Total impurities | =< 0.7 % |
| Loss on drying | =< 0.5 % |
| Assay | 97.5 - 102.0 % |
| Residual solvents | |
| Acetone | =< 5000 ppm |
| Methanol | =< 3000 ppm |
| Pyridine | =< 200 ppm |

COMPLIES WITH

European Pharmacopoeia 10.0

STORAGE

Store in a cool place. Keep the container tightly closed in a dry and well-ventilated place.

REMARKS

Testosterone Propionate 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.