

**TECHNICAL DATA SHEET**

1699-TDS-ENG-2025

<b>TESTOSTERONA BASE (EUR. PH.)</b>		
DESCRIPTION DCI: testosterone		DESCRIPTION DOE: TESTOSTERONA
CAS Nº: 58-22-0	EC Nº: 200-370-5	AEMPS CODE: 890A
MOL. WEIGHT: 288,42	MOL. FORMULA: C19H28O2	ARTICLE CODE: 1699

ATTRIBUTES	SHOULD BE
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 11.0

**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.