

TESTOSTERONA PROPIONATO (EUR. PH.)

PRODUCT CODE: 1701	CAS Nº: 57-85-2	ANALYSIS Nº: 225/23
MANUFACTURER BATCH: TSP 102/0322	CERTIFICATE ID: 39.374	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/03/2022	
METAPH BATCH: 0080923	RETEST DATE: 28/02/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white crystalline powder or colourless crystals	White crystalline powder
Solubility	Practically insoluble in water, freely soluble in acetone and in ethanol (96 %), soluble in fatty oils	Complies (*)
Identification	Complies	Complies
Specific optical rotation	+84 / +90	+89
Related substances		
Impurity A	=< 0.5 %	0.30 %
Impurity C	=< 0.2 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.10 % (#)
Total impurities	=< 0.7 %	0.37 %
Loss on drying	=< 0.5 %	0.10 %
Assay	97.5 - 102.0 %	100.1 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

(#) Unspecified impurities detailed underneath:
RT (6.83 min) = 0.07 %

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

(*) Data adapted from the manufacturer's certificate of analysis.

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.

STORAGE

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

Analysis date: 03/10/2023
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000314
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