

Certificate of Analysis**Product Name:** Testosterone Propionate
(European Pharmacopoeia - current edition)**CAS Number:** 57-85-2 **Molecular Formula:** $C_{22}H_{32}O_3$
Molecular Weight: 344.5 g/mole **Net weight:** 5.0 kg**Batch Number:** FP003f17
Retest Date: 28/02/2022**Manufacturing Date:** 03/03/2017

Test	Unit	Specification Limits	Results
Appearance		White or almost white crystalline powder or colourless crystals	Conform
Solubility		Practically insoluble in Water, freely soluble in Ethanol, Acetone; soluble in Vegetable Oils.	Conform
Identification (IR)		Conform	Conform
Loss on Drying	%w/w	≤0.50	0.46
Specific Optical Rotation (C=1%w/v, Ethanol, RT)	°	+84.0÷+90.0	+87.7
Related Substances (HPLC)	%	Total amount: ≤ 0.7 Testosterone: ≤ 0.2 Testosterone acetate: ≤ 0.5 Any other impurity: ≤ 0.1	Total amount = 0.06 Testosterone: b.d.l. Testosterone acetate : b.d.l. Other impurity = 0.06
Assay (HPLC)	%w/w	97.5 ÷ 102.0	101.6
Residual Solvents (GC)	ppm	Not more than 5000 as sum See ICH Guideline limits for each solvent Acetone: ≤ 5000 Pyridine: ≤ 200 Methanol: ≤ 3000	Acetone: b.d.l. Pyridine: b.d.l. Methanol: 690

Residual Solvents (GC): "b.d.l." means below detection limit.

Limit of detection: Acetone: 0.0540%

Methanol: 0,0260%

Pyridine: 0,0017%

R. Bellunghi
QP Signature**05/04/2017**
Date of Release**R. Viotti**
QC Signature**05/04/2017**
Date of Approval

Data of issue: 27/07/2017

