

Certificate of Analysis

Product Name: Testosterone Propionate
Ph. Eur. 7.4
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: FP030f15 Manufacturing Date: 30-October-2015
Retest Date: September-2016 Expiry Date: September-2018

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	0.16
Specific Optical Rotation (C=1%w/v, Ethanol, RT)		+84.0÷+90.0	+87.3
Related Substances (HPLC)	%	Total amount: ≤ 0.7 Testosterone: ≤ 0.2 Testosterone acetate: ≤ 0.5 Any other impurity: ≤ 0.1	b.d.l.
Assay (HPLC)	%w/w	97.0 ÷ 102.0	99.8
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 = 1210

R.Bellunghi
QP Signature

03/11/2015
Date of Release

R.Viotti
QC Signature

02/11/2015
Date of Approval

Issue date

