

Ipca Laboratories Limited

QUALITY CONTROL DEPARTMENT

FINISH PRODUCT CERTIFICATE OF ANALYSIS

Annexure-XI

Format No.: QCD/115/F/11/01

Product	: TESTOSTERONE Ph.Eur.	QC AR No.	: QCD/FP/20/0137
Batch No.	: 20002TS1AJN	Date of Analysis	: 23/11/2020
Mfg. Date	: Oct-2020	Batch size	: 47.03 Kg
Exp. Date	: Sep-2025	Specification No.	: TS/BPC/TS1/PS/EP

Sr No.	TEST	RESULTS	SPECIFICATIONS
01.	Appearance	White crystalline powder.	White or almost white crystalline powder, or colourless or yellowish-white crystals.
02.	Solubility	Practically insoluble in water, freely soluble in ethanol (96%) and in methylene chloride, practically insoluble in fatty oils.	Practically insoluble in water, freely soluble in ethanol (96%) and in methylene chloride, practically insoluble in fatty oils.
03.	Melting Point	155°C	About 155°C
04.	Identification	Infrared absorption spectra of sample and standard are concordant.	Infrared absorption spectra of sample and standard are concordant.
05.	Specific Optical Rotation	+113	+106 to +114 (dried substances)
06.	Related Substances (By HPLC)		
	Impurity C	<0.05%	NMT 0.30 %
	Impurity I	<0.05%	NMT 0.20 %
	Impurity K	<0.05%	NMT 0.15 %
	Any Unspecified Impurity	0.06%	NMT 0.10 %
	Total Impurities	0.06%	NMT 0.60 %
07.	Loss on Drying (at 105 °C for 2 hrs)	0.4 %	NMT 1.0 % w/w
08.	Assay (By HPLC)	100.3 %	98.0% to 102.0% (dried substance)
01.	Additional Test		
	Particle size distribution		
	Dn(99):	21.3 µm	For Information.

Prepared by (QCD)

Date: 28/11/2020

Approved by (QCD)

Date: 28/11/2020

Released by (QAD)

Date: 30/11/2020

Reviewed By QA

Sign / Date

Plot No. 23-24, G. I. D. C. Estate, Dist. Vadodara, Nandesari 391 340 (Gujarat), India | T: +91 265 2840868, 2841486
Regd. Office: 48, Kandivli Industrial Estate, Kandivli (West), Mumbai 400 067 (Maharashtra), India | T: +91 22 6647 4444
E: ipca@ipca.com CIN: L24239MH1949PLC007837

Ipca Laboratories Ltd.

www.ipca.com