

IPCA LABORATORIES LIMITED

QUALITY CONTROL DEPARTMENT

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

ANNEXURE - XI

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

Product	: TESTOSTERONE Ph.Eur.	QC AR No.	: QCD/FP/21/0081
Batch No.	: 21003TS1AJN	Date of Analysis	: 11/08/2021
Mfg. Date	: Jul-2021	Batch size	: 70.93 Kg
Retest/ Exp. Date	: Jun-2026	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 percent) and in methylene chloride, practically insoluble in fatty oils.	Practically insoluble in water, freely soluble in ethanol (96 percent) and in methylene chloride, practically insoluble in fatty oils.
03.	Melting Point	156°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 substance)
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	<0.05%	NMT 0.10 %
	Total Impurities	0.05%	NMT 0.60 %
07.	Loss on drying (at 105 °C for 2 hrs)	0.3 %	NMT 1.0 % w/w.
08.	Assay (By HPLC)	100.4 %	98.0% to 102.0% (dried substance)
01.	Additional Test: Particle size distribution	Dn(99): 16.0 µm	Less than 20.0 µm

Remarks: The above sample **conforms / does not conform** as per above specifications.

Prepared by (QCD)

Date: 09/10/2021

Approved by (QCD)

Date: 09/10/2021

Released by (QAD)

Date: 09/10/2021

Reviewed By QA

Sign / Date: 09/10/2021

Ipca Laboratories Ltd.

www.ipca.com

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