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METAPHARMACEUTICAL

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28/04/2022
ipca
A dose of life

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)

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

Prepared by (QCD)
Date: 20/08/2021

Approved by (QCD)
Date: 20/08/2021

Released by (QAD)
Date: 20/08/2021

Reviewed By QA

Sign / Date

20/08/2021

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E: ipca@ipca.com CIN: L24239MH1949PLC007837

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Sr. No.	TEST	RESULTS	SPECIFICATIONS
01.	Additional Test: Residual Solvents		
	Methanol	Below detection limit	NMT 3000 ppm
	Acetone	Below detection limit	NMT 5000 ppm
	Pyridine	Not detected	NMT 200 ppm
02.	Particle size distribution Dn(99):	16.0 µm	For Information.
Remarks: The above sample conforms / does not conform as per above specifications.			

Prepared by (QCD)
Date: 20/08/2021

Approved by (QCD)
Date: 21/08/2021

Released by (QAD)
Date: 20/08/2021

Reviewed By QA

Sign / Date

20/08/2021

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