

Ipca Laboratories Limited			
QUALITY CONTROL DEPARTMENT			
FINISH PRODUCT CERTIFICATE OF ANALYSIS			
Product	: TESTOSTERONE Ph.Eur	QC AR No.	: QCD/FP/17/0107
Batch No.	: 17008TS1JN	Release Date	: 19/07/2017
Mfg. Date	: May-2017	Batch size	: 14.75 Kg
Expiry Date	: Apr-2021	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 alcohol and in methylene chloride, practically insoluble in fatty oils.	Practically insoluble in water, freely soluble in alcohol 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	+112°	+106° to +114° (dried substances)
06.	Impurities D and F (By TLC)		
	Impurity D	Less than 0.2 %	Not more than 0.2 %
	Impurity F	Less than 0.1 %	Not more than 0.1 %
07.	Related substances by HPLC		
	Impurity G (Androstadienedione)	Not detected	Not more than 0.10 %
	Impurity H (Boldenone)	Not detected	Not more than 0.10 %
	Impurity A (Androstenedione)	Less than 0.05 %	Not more than 0.10 %
	Impurity I (Delta-6-Testosterone)	Less than 0.05 %	Not more than 0.20 %
	Impurity C (Epitestosterone)	Less than 0.05 %	Not more than 0.50 %
	Impurity E (Testosterone Acetate)	Not detected	Not more than 0.10 %

Prepared by
Date : 22/07/2017

Manager QC
Date : 22/07/2017

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Product : TESTOSTERONE Ph.Eur		QC AR No. : QCD/FP/17/0107	
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	Impurity J (Androstenedione methylenolether)	Not detected	Not more than 0.10 %
	Impurity B (Androstenedione ethylenolether)	Not detected	Not more than 0.10 %
	Any Unspecified impurity	0.05 %	Not more than 0.10 %
	Total impurities	0.05 %	Not more than 0.60 %
08.	Loss on drying (at 105 °C for 2 hrs)	0.22 %	Not more than 1.0 % w/w
09.	Assay (By HPLC)	99.3 %	97.0% to 103.0% of C ₁₉ H ₂₈ O ₂ on dried basis.
Additional Test:			
01.	Particle size distribution	8.03 µm 19.9 µm	Dn (90): For information only Dn (99): For information only
Remarks: The above sample conforms as per EP 9.0 .			

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