

Ipca Laboratories Limited			
QUALITY CONTROL DEPARTMENT			
CERTIFICATE OF ANALYSIS			
Product : TESTOSTERONE USP		QG A.R. No. : QCD/FP/16/0033	
Batch No. : 6011TS1JN		Release Date : 13/04/2016	
Mfg. Date : Apr-2016		Batch size : 48.84 Kg	
Expiry Date : Mar-2020		Specification : TS/BPC/TS1/PS/USP	
Sr No.	TEST	RESULTS	SPECIFICATIONS
01.	Description	Slightly Creamy white crystalline powder. Is odorless and is stable in air.	White or slightly creamy white crystals or crystalline powder. Is odorless and is stable in air.
02.	Solubility	Freely soluble in dehydrated alcohol and in chloroform; soluble in dioxane; slightly soluble in ether; practically insoluble in water.	Freely soluble in dehydrated alcohol and in chloroform; soluble in dioxane; slightly soluble in ether; practically insoluble in water.
03.	Identification A. By IR  B. By UV	Infrared absorption spectra of sample is concordant to that obtained with the standard. The UV absorption spectra of 10 µg/ml solution of Test and Standard in Methanol, exhibit maxima and minima at the same wavelengths.	Infrared absorption spectra of sample is concordant to that obtained with the standard. The UV absorption spectra of 10 µg/ml solution of Test and Standard in Methanol, exhibit maxima and minima at the same wavelengths.
04.	Melting Range	154.8°C to 156.0°C	Between 153 °C and 157°C
05.	Specific Rotation at 25°C	+103.5°	Between +101.0° and +105.0°
06.	Loss on drying (under vacuum for 4 hrs)	0.35 % w/w	Not more than 1.0 % w/w
07.	Assay (By UV)	99.7 %	97.0% to 103.0% of C <sub>19</sub> H <sub>28</sub> O <sub>2</sub> on dried basis
08.	Residual Solvents Methanol Acetone Pyridine Triethylamine Additional test:	Below Disregard Limit Below Disregard Limit Not detected Not detected	Not more than 3000 ppm Not more than 5000 ppm Not more than 200 ppm Not more than 320 ppm
01.	Particle size distribution (By wet method)	17.9 µm	Dn (99%): For information only
Remarks: The above sample conforms as per above specifications.			

Prepared by

Date 13/04/2016

Himanshu Dave - Analyst

Manager QC

Date 13/04/2016

Ipca Laboratories Ltd.

www.ipca.com

Plot No. 23-24, G. I. D. C. Estate, Nandesar 391 340 (Dist. Vadodra), India | T: +91 265 2840795, 2841486 F: +91 265 2840868

Regd. Office: 48, Kandivli Industrial Estate, Kandivli (West), Mumbai 400 067, India | T: +91 22 6647 4444 F: +91 22 2868 6613

E: ipca@ipca.com CIN: L24239MH1949PLC007837

FAGRON IBÉRICA, S.A.U

Corresponde al lote de Fagron:

416110137

Director Técnico