

Ipca Laboratories Limited

QUALITY CONTROL DEPARTMENT

FINISH PRODUCT CERTIFICATE OF ANALYSIS

Product : TESTOSTERONE Ph.Eur	QC AR No. : QCD/FP/19/0072
Batch No. : 19006TS1JN	Release Date : 29/06/2019
Mfg. Date : May-2019	Batch size : 77.18 Kg
Retest Date : Apr-2023	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	154°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	< 0.2 %	NMT 0.2 %
	Impurity F	< 0.1 %	NMT 0.1 %
07.	Related substances (By HPLC)		
	Impurity G (Androstadienedione)	Not detected	NMT 0.10 %
	Impurity H (Boldenone)	< 0.05 %	NMT 0.10 %
	Impurity A (Androstenedione)	< 0.05 %	NMT 0.10 %
	Impurity I (Delta-6-Testosterone)	< 0.05 %	NMT 0.20 %
	Impurity C (Epitestosterone)	< 0.05 %	NMT 0.50 %
	Impurity E (Testosterone Acetate)	Not detected	NMT 0.10 %

Fecha Entrada: 11-12-2019

10639

TESTOSTERONE GRANEL



Lot: 0090278



QC-00215346

Bultos: 1

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Prepared by (QCD)

Date: 02/07/2019

Approved by (QCD)

Date: 02/07/2019

Released by (QAD)

Date: 02/07/2019

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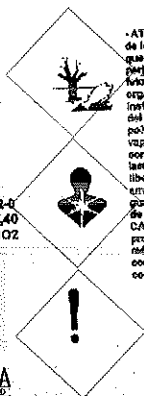
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E: ipca@ipca.com CIN: L24239MH1949PLC007837

Panel
BASE

90-22-0
286,40
C19H28O2



• ATENCIÓN: H402 No tóxico en caso de ingestión. H403 Se sospecha que provoca cáncer. P201+P202 Puede perjudicar la fertilidad o dañar al feto. H400 Muy tóxico para los organismos acuáticos. P501. Pedir instrucciones específicas antes del uso. P201 No respirar el polvo/aerosol. H400 Muy tóxico para los organismos acuáticos. P203 Evitar el contacto durante el embarazo. P273 Evitar su liberación al medio ambiente. P201+P202 Llevar guantes/ropa/ropa/ropa de protección. P201+P202 CASO DE exposición manténgala o presurizada. P201 Eliminar el contenido del recipiente en conformidad.



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Format No.: QCD/115/F/11/06

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Sr No.	TEST	RESULTS	SPECIFICATIONS
	Impurity J (Androstenedione methylenolether)	Not detected	NMT 0.10 %
	Impurity B (Androstenedione ethylenelether)	Not detected	NMT 0.10 %
	Any Unspecified impurity	0.05 %	NMT 0.10 %
	Total impurities	0.05 %	NMT 0.60 %
08.	Loss on drying (at 105 °C for 2 hrs)	0.2 %	NMT 1.0 % w/w
09.	Assay (By HPLC)	101.3 %	97.0% to 103.0% w/w on dried basis
01.	Additional Test: Particle size distribution: Dn(99):	11.4 µm	NMT 20 µm

Remarks: The above sample conforms as per above specifications.

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