SYMBIOTEC
PHARMALAB PVT. LIMITED
Formerly Known as Symbiotec Pharmalab Ltd.

CERTIFICATE OF ANALYSIS

Product Name	TESTOSTERONE USP / EP (MICRONISED) (CAS No. 58-22-0)		
Batch No.	ZTSTγ18007	Mfg. Date	July 2018
A. R. No.	P2FP18297	Retest Date	June 2023
Date of Sampling	29/07/2018		

S. No.	Test	Result	Specification
10.0	Related substances (By HPLC) (EP) Impurity C	BRL	NMT 0.5 %
	Impurity I	0.02 %	NMT 0.2 %
	Impurity A	0.04 %	NMT 0.1 %
	Impurity B	BLD	NMT 0.1 %
	Impurity E	Not Detected	NMT 0.1 %
	Impurity G	BLD	NMT 0.1 %
	Impurity H	BLD	NMT 0.1 %
	Impurity J	Not Detected	NMT 0.1 %
	Any other impurity	0.04 %	NMT 0.10 %
	Total Impurities	0.18 %	NMT 0.6 %
11.0	Assay (by UV) (USP)	98.84 %	Between 97.0 % to 103.0 % (Calculated on the dried basis)
12.0	Assay (by UV) (EP)	99.11 %	Between 97.0 % to 103.0 % (dried substance)
1.0	**Additional Test** Residual Solvents (by GC)		
	Triethylamine	BLD	NMT 320 ppm
	Methylene Dichloride	BLD	NMT 600 ppm
	Methanol	BLD	NMT 3000 ppm
	Acetone	43 ppm	NMT 5000 ppm
	Ethanol	BLD	NMT 5000 ppm
2.0	Particle Size (by Microscopic Method)	< 6.64 µm < 9.96 µm	90.0 % < 10 µm 99.0 % < 20 µm

Opinion: The above material complies with the prescribed USP 41 / EP 9.0 specifications.
BRL = Below reporting limit, BLD = Below limit of detection, BLQ = Below limit of Quantitation
Date of Release : 31/07/2018
Reprint on : 11/04/2019

11/04/19
Prepared by
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(Chemist – QC)

11/04/19
Checked by
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(Sr. Executive – QC)

11/04/19
Approved by
Ashok Sharma
(Head – QC)

Manufacturing Site: Plot No. 5, 6, 7 & 8 SEZ Phase – II, Pharma Zone
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S. No.	Test	Result	Specification
1.0	Description (USP / EP)	Almost white crystalline powder. Is odorless and is stable in air.	White or almost white crystalline powder. Is odorless and is stable in air.
2.0	Solubility (USP / EP)	Practically insoluble in water, fatty oils; freely soluble in dehydrated alcohol, in chloroform, in methylene chloride; soluble in dioxane and in vegetable oils; slightly soluble in ether.	Practically insoluble in water, fatty oils; freely soluble in dehydrated alcohol, in chloroform, in methylene chloride; soluble in dioxane and in vegetable oils; slightly soluble in ether.
3.0	Identification A. IR (USP / EP)	Concordant	The IR Spectrum of sample should be concordant with the IR spectrum obtained from Testosterone Reference standard.
	B. UV (USP)	Complies	The UV absorption spectra of the test solution and the standard solution should exhibit maxima and minima at the same wavelengths.
4.0	Melting range (USP / EP)	153.2°C – 154.2°C	Between 153°C and 157°C
5.0	Specific rotation (C = 1 %, dioxane, at 25°C)	+102.15°	Between +101° and +105°
6.0	Specific optical rotation (C = 1 %, ethanol, at 20°C)	+111.92°	Between +106° to 114° (dried substance)
7.0	Loss on drying (Vacuum over phosphorus pentoxide for 4 hours) (USP)	0.12 % w/w	NMT 1.0 % w/w
8.0	Loss on drying (at 105°C for 2 hours) (EP)	0.47 % w/w	NMT 1.0 % w/w
9.0	Impurity D	Complies	Any spot due to impurity D is not more intense than the spot in the chromatogram obtained with reference solution (c) (0.2 %)
	Impurity F (By TLC) (EP)	Complies	Any spot due to impurity F is not more intense than the spot in the chromatogram obtained with reference solution (d) (0.1 %).

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