

Nº lote ACOFARMA:

217177

Firma y fecha:

23/12/21

SYMBIOTEC

CERTIFICATE OF ANALYSIS

PHARMALAB PVT. LIMITED

Formerly Known as Symbiotec Pharamlab Ltd.

Product Name	TESTOSTERONE EP (MICRONISED) (CAS No. 58-22-0)		
Batch No.	ZTSTCy20004	Mfg. Date	November 2020
A. R. No.	P2FP20626	Retest Date	October 2025
Date of Sampling	28/12/2020		

S. No.	Test	Result	Specification
1.0	Characters Appearance	White crystalline powder.	White or almost white crystalline powder, or colourless or yellowish-white crystals.
	Solubility	Practically insoluble in water, freely soluble in ethanol (96 per cent) and in methylene chloride, practically insoluble in fatty oils.	Practically insoluble in water, freely soluble in ethanol (96 per cent) and in methylene chloride, practically insoluble in fatty oils.
	Melting point	153.5°C	About 155°C.
2.0	Identification A. IR	Concordant	The IR Spectrum of sample should be concordant with the IR spectrum obtained from Testosterone Working standard.
	B. HPLC	Complies	In the Test of Assay, the principle peak in the chromatogram obtained with the test solution is similar in the Retention Time to the principle peak in chromatogram obtained with standard preparation.
3.0	Specific optical rotation (C = 1 %, ethanol, at 20°C)	+107.51°	Between +106° to 114° (dried substance)
4.0	Related substances (By HPLC)		
	Impurity C	BRL	NMT 0.3 %
	Impurity I	0.01 %	NMT 0.2 %
	Impurity K	0.05 %	NMT 0.15 %
	Unspecified impurities	0.04 %	NMT 0.10 %
	Total Impurities	0.16 %	NMT 0.6 %
5.0	Loss on drying (at 105°C for 2 hours)	0.40 % w/w	NMT 1.0 % w/w
6.0	Assay (By HPLC)	99.45 %	Between 98.0 % to 102.0 % (dried substance)
1.0	Additional Test Residual Solvents (by GC)		
	Triethylamine	< 13 ppm	NMT 320 ppm
	Methylene Dichloride	< 10 ppm	NMT 600 ppm
	Methanol	< 15 ppm	NMT 3000 ppm
	Acetone	32 ppm	NMT 5000 ppm
	Ethanol	< 15 ppm	NMT 5000 ppm
2.0	Particle Size (By microscopic method)	< 4.98 µm	90.0 % < 10 µm
		< 9.96 µm	99.0 % < 20 µm

Opinion: The above material complies with the prescribed EP 10.1 specifications.

BRL = Below reporting limit

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12/02/2021
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