METAPHARMACEUTICAL

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0010524

02/05/2024

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

CERTIFICATE OF ANALYSIS

Product Name	**ESTRONE USP (Micronised) (CAS No. 53-16-7)**		
Batch No.	**ZEONy23001-M1**	**Mfg. Date**	**October – 2023**
A. R. No.	**P2FP24151**	**Retest Date**	**September – 2026**
Date of sampling	**22/03/2024**		

S. No.	Test	Result	Specification
1.0	Description	White, crystalline powder. Is odorless, and is stable in air. Melt at 259.6°C	Small, white crystals or white to creamy white, crystalline powder. Is odorless, and is stable in air. Melts at about 260°.
2.0	Solubility	Freely soluble in N,N-Dimethylformamide, Soluble in Tetrahydrofuran and slightly soluble in acetone	Freely soluble in N,N-Dimethylformamide, Soluble in Tetrahydrofuran and slightly soluble in acetone.
3.0	Clarity of solution	Complies	The solution should be clear.
4.0	Identification A. IR	Concordant	The IR Spectrum of sample should be concordant with the IR spectrum obtained from Estrone working standard.
	B. UV	Complies	The UV absorption spectra of the test solution and the standard solution should exhibit maxima and minima at the same wavelengths.
5.0	Specific rotation (C = 1 %, dioxane, at 25°C)	+159.82°	Between +158° and +165°, calculated on the dried basis.
6.0	Loss on drying (At 105° for 3 hours)	0.13 % w/w	NMT 0.5 % w/w
7.0	Residue on ignition	0.02 % w/w	NMT 0.5 % w/w
8.0	Limit of equilenin and equilin	Complies	The sample should be no more red color than that produced by 20 µg of equilenin.
9.0	Ordinary impurities (By TLC)	Complies	Any spots other than the principal spot, in the chromatogram of the Test solution, and determine their relative intensities should not be more intense by comparison with the chromatograms of 2.0 % standard solutions.
10.0	Assay (By HPLC)	100.14 % w/w	Between 97.0 % and 103.0 % w/w, calculated on the dried basis.
1.0	**Additional Test** Related substances by HPLC, in area % ADD RRT about 0.76 Impurity at RRT 1.80 Impurity at RRT 2.73 Any other impurity Total impurities	 Not Detected Not Detected 0.04 % 0.04 % 0.12 %	 NMT 0.15 % NMT 0.10 % NMT 0.10 % NMT 0.30 % NMT 1.0 %

29/03/24

Prepared by
Vishal Gupta
(Manager – QC)

29/03/2024

Checked by
Sandeep K. Tiwari
(Manager – QC)

29/03/24

Approved by
Harish Nayak
(DGM – QC)

Manufacturing Site: Plot No. 5, 6, 7 & 8 SEZ Phase – II, Pharma Zone
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S. No.	Test	Result	Specification
2.0	Residual Solvents (by GC) Triethylamine Methanol Acetone 1, 2 Dimethoxyethane Hexane	 Not Detected 4 ppm 411 ppm Not Detected Not Detected	 NMT 320 ppm NMT 3000 ppm NMT 5000 ppm NMT 100 ppm NMT 290 ppm
3.0	Particle size Malvern (By Wet Method)	 4.6 µm 7.0 µm	 90.0 % < 10 µm 99.5 % < 20 µm

Opinion: The above material complies with the prescribed USP 43 specification.
Date of Release: 29/03/2024

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