METAPHARMACEUTICAL

N DE LOTE: 0390523

30/08/2023

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.	ZEONγ22001-M1	Mfg. Date	February 2022
A. R. No.	P2FP22456	Retest Date	January 2025
Date of sampling	13/11/2022		

S. No.	Test	Result	Specification
1.0	Description	White, crystalline powder. Is odorless, and is stable in air. Melt at 258.0°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)	+162.0°	Between +158° and +165°, calculated on the dried basis.
6.0	Loss on drying (At 105° for 3 hours)	0.14 % w/w	NMT 0.5 % w/w
7.0	Residue on ignition	0.09 % 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)	100.23 % 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 Not Detected 0.02 % 0.02 %	 NMT 0.15 % NMT 0.10 % NMT 0.10 % NMT 0.30 % NMT 1.0 %
2.0	Residual Solvents (by GC) Triethylamine Methanol Acetone 1, 2 Dimethoxyethane Hexane	 Not Detected 80 ppm 417 ppm Not Detected 01 ppm	 NMT 320 ppm NMT 3000 ppm NMT 5000 ppm NMT 100 ppm NMT 290 ppm

14/11/22
Prepared by
Gopal Bairagi
(Sr. Officer – QC)

14/11/22
Checked by
Manish Singh
(Manager – QC)

14/11/22
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
3.0	Particle size Malvern (By Wet Method)	 4.06 µm 7.10 µm	 90.0 % < 10 µm 99.5 % < 20 µm

Opinion: The above material complies with the prescribed USP 43 specifications.
Date of Release: 14/11/2022

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