


SYMBIOTEC**PHARMALAB PVT. LIMITED**

Formerly Known as Symbiotec Pharmed Lab Ltd.

CERTIFICATE OF ANALYSIS

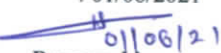


Product Name	ESTRONE USP (MICRONISED) (CAS No. 53-16-7)		
Batch No.	ZEON19002-M	Mfg. Date	March 2019
A. R. No.	P2FP19296	Retest Date	February 2022
Date of sampling	18/07/2019		

S. No.	Test	Result	Specification
1.0	Description	White, crystalline powder. Is odorless, and is stable in air. Melt at 257.6°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	Soluble in alcohol, in acetone, in dioxane, and in vegetable oils; slightly soluble in solutions of fixed alkali hydroxides; practically insoluble in water.	Soluble in alcohol, in acetone, in dioxane, and in vegetable oils; slightly soluble in solutions of fixed alkali hydroxides; practically insoluble in water.
3.0	Clarity of solution	Complies	The solution should be clear.
4.0	Identification A. IR B. UV	Concordant Complies	The IR Spectrum of sample should be concordant with the IR spectrum obtained from Estrone working standard. 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)	+163.88°	Between +158° and +165°, calculated on the dried basis.
6.0	Loss on drying (At 105° for 3 hours)	0.11 % w/w	NMT 0.5 % w/w
7.0	Residue on ignition	0.05 % 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)	102.51 % w/w	Between 97.0 % and 103.0 % w/w, calculated on the dried basis.
1.0	Additional Test Residual Solvents (by GC) Triethylamine Methanol Acetone 1, 2 Dimethoxyethane	Not Detected Not Detected 229 ppm Not Detected	NMT 320 ppm NMT 3000 ppm NMT 5000 ppm NMT 5000 ppm
2.0	Particle size Malvern (By Dry Method)	9.00 µm 15.1 µm	90.0 % < 10 µm 99.5 % < 20 µm

Opinion: The above material complies with the prescribed USP 42 specifications.

Date of Release : 24/07/2019

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