

Lot: 0090419

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.	ZEON19001-M	Mfg. Date	January 2019
A. R. No.	P2FP19001	Retest Date	June 2021
Date of sampling	14/02/2019		

S. No.	Test	Result	Specification
1.0	Description	Small, crystalline powder. Is odorless, and is stable in air. Melt at 258.1°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)	+160.05°	Between +158° and +165°, calculated on the dried basis.
6.0	Loss on drying (At 105° for 3 hours)	0.33 % 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)	100.16 % 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 227 ppm Not Detected	NMT 320 ppm NMT 3000 ppm NMT 5000 ppm NMT 5000 ppm
2.0	Particle size Malvern (By Dry Method)	6.50 µm 17.8 µm	90.0 % < 10 µm 99.5 % < 20 µm

Opinion: The above material complies with the prescribed USP 41 specifications.

Date of Release: 23/02/2019

Prepared by
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