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

CERTIFICATE OF ANALYSIS

Product Name	**ESTRONE USP (CAS No. 53-16-7)**		
Batch No.	**ZEON19002**	**Mfg. Date**	**March 2019**
A. R. No.	**P2FP19146**	**Retest Date**	**February 2021**
Date of sampling	**28/03/2019**		

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	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)	0.22 % w/w	NMT 0.5 % w/w
7.0	Residue on ignition	0.04 % 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)	100.80 % 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 425 ppm Not Detected	 NMT 320 ppm NMT 3000 ppm NMT 5000 ppm NMT 5000 ppm

Opinion: The above material complies with the prescribed USP 41 specifications.
Date of Release: 03/04/2019

03/04/19
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03/04/19
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