

# METAPHARMACEUTICAL

N DE LOTE:

0080322

04/03/2022

SYMBIOTEC

## CERTIFICATE OF ANALYSIS

PHARMALAB PVT. LIMITED

Formerly Known as Symbiotec Pharamlab Ltd

Product Name	ESTRONE USP (MICRONISED) (CAS No. 53-16-7)		
Batch No.	ZEONy21013-M1	Mfg. Date	July 2021
A. R. No.	P2FP21407	Retest Date	June 2024
Date of sampling	05/09/2021		
S. No.	Test	Result	Specification
1.0	Description	Small, white, crystalline powder. Is odorless, and is stable in air	Small, white crystals or white to creamy white, crystalline powder. Is odorless, and is stable in air.
2.0	Solubility	Melt at 258.4°C Freely soluble in N,N-Dimethyl formamide, Soluble in Tetrahydrofuran and slightly soluble in acetone	Melts at about 260°C. 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)	+161.65°	Between +158° and +165°, calculated on the dried basis.
6.0	Loss on drying (At 105° for 3 hours)	0.21 % 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)	101.14 % 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 Not Detected 0.02 % 0.03 %	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 86 ppm 333 ppm Not Detected 03 ppm	NMT 320 ppm NMT 3000 ppm NMT 5000 ppm NMT 100 ppm NMT 290 ppm

Prepared by  
Nitin Yadav  
(Executive - QC)

Checked by  
Mohit Shrivastava  
(Asst. Manager - QC)

Approved by  
Harish Nayak  
(Sr. Manager - QC)

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**CERTIFICATE OF ANALYSIS**


Product Name	ESTRONE USP (MICRONISED) (CAS No. 53-16-7)		
Batch No.	ZEON $\gamma$ 21013-M1	Mfg. Date	July 2021
A. R. No.	P2FP21407	Retest Date	June 2024
Date of sampling	05/09/2021		

S. No.	Test	Result	Specification
3.0	Particle size Malvern (By Wet Method)	5.17 $\mu$ m 7.73 $\mu$ m	90.0 % < 10 $\mu$ m 99.5 % < 20 $\mu$ m

Opinion: The above material complies with the prescribed USP 43/IH specifications.  
Date of Release: 15/09/2021

  
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Nitin Yadav  
(Executive - QC)

  
15/09/2021  
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Mohit Shrivastava  
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