


SYMBIOTEC**CERTIFICATE OF ANALYSIS****PHARMALAB PVT. LIMITED**

Formerly Known as Symbiotec Pharnalab Ltd.

Product Name	ESTRADIOL HEMIHYDRATE EP (MICRONISED) (CAS No. 35380-71-3)		
Batch No.	ZESDy20002	Mfg. Date	July 2020
A. R. No.	P2FP20373	Retest Date	June 2025
Date of Sampling	09/08/2020		

S. No.	Test	Results	Specification
1.0	Description	White, crystalline powder.	White or almost white, crystalline powder or colourless crystals.
2.0	Solubility	Practically insoluble in water, soluble in acetone, sparingly soluble in ethanol (96 per cent), slightly soluble in methylene chloride.	Practically insoluble in water, soluble in acetone, sparingly soluble in ethanol (96 per cent), slightly soluble in methylene chloride.
3.0	Identification		
	A. Melting point	177.7°C	175°C to 180°C
	B. IR	Concordant	The IR Spectrum of sample should be concordant with the IR spectrum obtained from Estradiol Hemihydrate working standard.
	C. TLC	Complies	The principal spot in the chromatogram obtained with the test solution should be similar in position, colour in daylight, fluorescence in ultraviolet light at 365 nm and size to the principal spot in the chromatogram obtained with reference solution (a).
	D. Chemical Test	Complies	A blue colour should be develops which in ultraviolet light at 365 nm has an intense green fluorescence. Add 1.0 ml of sulfuric acid and 9.0 ml of water. The colour should becomes pink with a yellowish fluorescence.
	E. Water	3.25 %	2.9 % to 3.5 %
4.0	Specific optical rotation (C = 1 %, ethanol, at 20°C)	+80.86°	Between +76.0° to +83.0° (anhydrous substance)
5.0	Related substances (by HPLC)		
	Impurity A	BRL	NMT 0.3 %
	Impurity B	0.07 %	NMT 0.3 %
	Impurity C	Not Detected	NMT 0.3 %
	Impurity D	0.03 %	NMT 0.3 %
	Unspecified impurity	0.03 %	NMT 0.10 %
	Total impurities	0.14 %	NMT 0.5 %
6.0	Water (by KF)	3.25 %	2.9 % to 3.5 %
7.0	Assay (by UV)	99.85 %	Between 97.0 % to 103.0 % (anhydrous substance).
1.0	Additional Test		
	Residual Solvents (by GC)		
	Methanol	24 ppm	NMT 3000 ppm
	Acetone	221 ppm	NMT 5000 ppm
2.0	Particle Size		
	Malvern	3.69 µm	90.0 % < 10 µm
	(By wet method)	5.93 µm	99.5 % < 20 µm

Opinion: The above material complies with the prescribed EP 10.0 specifications.

BRL = Below reporting limit

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Addendum No. ESD/00/Euro OTC/R0

Manufacturing Site: Plot No. 5, 6, 7 & 8 SEZ Phase - II, Pharma Zone

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