

### CERTIFICATE OF ANALYSIS

Name of the Product	: Estradiol Hemihydrate BP/EP	Product Code	: ET
Batch No.	: ET/21005	Batch size	: 8.60 Kg
<b>(A) PRODUCT IDENTIFICATION: -</b>			
Manufacturing Date	: November - 2021	Sampling date	: 08/11/2021
Retest Date	: October - 2025	Release date	: 12/11/2021
Spec. Reference No.	: SP/FP/017	A. R. No.	: HM/FP/21/073
Product Category	: Hormones (Estrogen)	CAS No.	: 35380-71-3
Molecular Formula	: $C_{18}H_{24}O_2, \frac{1}{2} H_2O$	Molecular Wt.	: 281.4
Manufactured at	Shakti Lifescience Private Limited, Plot No.: K-2, MIDC, Tarapur, Boisar - 401 506, Dist: Palghar, State: Maharashtra - INDIA.		
Packaging	<b>Primary packing:</b> - Packed in a food grade, transparent LDPE bag followed by black coloured LDPE bag. <b>Secondary packing:</b> - Above bag is packed in an Aluminium bag. <b>Tertiary packing:</b> - Aluminium bag is packed in a HDPE drum.		
Storage Condition	Preseve in a tightly closed, light-resistant container, store at ambient temperature.		

<b>(B) PHYSICAL ANALYTICAL DATA: -</b>			
S. N.	TESTS	OBSERVATIONS	SPECIFICATIONS & LIMITS
1.0	Description	White, crystalline powder.	White or almost white, crystalline powder or colourless crystals.
2.0	Solubility	Complies.	Soluble in acetone; Sparingly soluble in Ethanol (96%); Slightly soluble in Methylene chloride; Practically insoluble in water.
3.0	Water Content	3.15%.	Between 2.9% and 3.5%.

<b>(C) CHEMICAL ANALYTICAL DATA: -</b>			
4.0	Identification A : By MP	176.2°C - 177.0°C.	Melts between 175°C and 180°C.
	Identification B : By IR Spectrophotometer	Complies.	The Infrared spectrum of Sample preparation should concordant with Standard preparation of Estradiol Hemihydrate CRS / WS.
	Identification C : By TLC	Complies.	The principal spot in the chromatogram obtained with the test soln. is similar in position, clour in daylight, fluorescence in UV light at 365 nm and size to that with reference solution (a).

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**(C) CHEMICAL ANALYTICAL DATA: -**

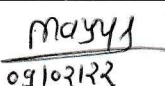
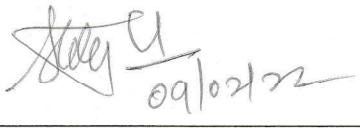
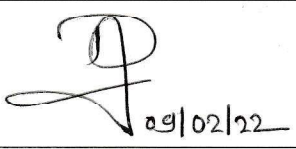
S. N.	TESTS	OBSERVATIONS	SPECIFICATIONS & LIMITS
4.0	Identification D : Colour Test (fluorescence)	Complies.	The resultant soln. should be becomes pink with showing yellowish fluorescence
	Identification E : by Water %	3.15%.	Should be between 2.9% and 3.5%,
5.0	Specific Optical Rotation	+ 80.95°.	Between + 76° and + 83° (OAB).
6.0	Related Substances (by HPLC)	0.03%.	Impurity-A; Not more than 0.3%.
		0.13%.	Impurity-B; Not more than 0.3%.
		Not Detected.	Impurity-C; Not more than 0.3%.
		0.10%.	Impurity-D; Not more than 0.3%.
		0.02%.	Unspecified Impurity; NMT 0.10%.
		0.28%.	Total of all Impurities; NMT 0.5%.
7.0	Assay of $C_{18}H_{24}O_2, \frac{1}{2} H_2O$ by UV	99.31%.	Between 97.0% and 103.0% (OAB).

**(D) ADDITIONAL IN-HOUSE TEST DATA: -**

8.0	Organic Volatile Impurities / Residual Solvents by GC	138 ppm.	Methanol; Not more than 3000 ppm.
		1553 ppm.	Acetone; Not more than 5000 ppm.
		Not Detected.	Methylene Dichloride; Not more than 600 ppm.

**Remark:**

- In the opinion of undersigned, the sample submitted complies with respect to the prescribed standards as specified in respective **BP/EP** monograph & **IN-HOUSE** specification.
- The above particulars do not release the customer from the obligation to carry out an inspection and analysis of goods received.

 09/02/22	 09/02/22	 09/02/22
Prepared by: (Mayur Patel - Officer QC)	Checked by: (S. V. Padwal - Asst. Manger QA)	Approved by: (Dhiraj M. Kini - Quality Head)