SHAKTI INDUSTRIES

CERTIFICATE OF ANALYSIS

Name of the Product	:	Estradiol Hemihydrate USP	Product Code	:	ET
Batch No.	:	ET/21004	Batch size	:	9.05 Kg
(A) PRODUCT IDENTIFICATION: -					
Manufacturing Date	:	July – 2021	Sampling date	:	11/07/2021
Retest Date	:	June - 2024	Release date	:	14/07/2021
Spec. Reference No.	:	SP/FP/017	A. R. No.	:	HM/FP/21/044
Product Category	:	Hormones (Estrogen)	CAS No.	:	35380-71-3
Molecular Formula	:	$C_{18}H_{24}O_2$, ½ H_2O	Molecular Wt.	:	281.39
Manufactured at	:	Shakti Industries, Plot No.: K-2, MIDC, Tarapur, Boisar - 401 506, Dist: Palghar, State: Maharastra - INDIA.			
Packaging	:	**Primary packing: -** Packed in a food grade, transparent LDPE bag followed by black coloured LDPE bag. **Secondary packing: -** Above bag is packed in an Aluminium bag. **Tertiary packing: -** Aluminium bag is packed in a HDPE drum.			
Storage Condition	:	Preseve in a tightly closed, light-resistant container, store at ambient temperature.			

(B) PHYSICAL ANALYTICAL DATA: -

S. N.	TESTS	OBSERVATIONS	SPECIFICATIONS & LIMITS
1.0	Description	White, odourless, crystalline powder. Is stable in air.	White or creamy white, crystalline powder or small crystals. Is odourless, is stable in air. Is hygroscopic.
2.0	Solubility	Complies.	Soluble in alcohol, in acetone, in dioxane and in alkali hydroxide soln.; Slightly soluble in chlroform; Sparingly soluble in veg. oils; Insoluble in water.
3.0	Water Content	3.20%.	Not more than 3.5% (by KF).

(C) CHEMICAL ANALYTICAL DATA: -

4.0	Identification: By IR Spectrophotometer	Complies.	The Infrared spectrum of Sample preparation should concordant with Standard preparation of Estradiol Hemihydrate CRS / WS.
	Identification: By UV Spectrophotometer	1.65%.	Absorptivities at 280 nm, calculated OAB, should not be differ by more than 3.0%.

Head Office : 1004, Unique Tower, Off. S.V. Road, Behind Patel Auto, Goregaon (W), Mumbai-400062. India. • T : +91 22- 28780912 • F : +91 22 -28780892
Factory Add. : Plot No. K-2, M.I.D.C. Tarapur, Dist. Palghar, Boisar - 401 506, India. • T : +91 2525 661144 • Email : info@shaktiindustries.co.in • Web : www.shaktiindustries.co.in

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(C) CHEMICAL ANALYTICAL DATA: -

S. N.	TESTS	OBSERVATIONS	SPECIFICATIONS & LIMITS
5.0	Melting Point	176.1°C – 177.0°C.	Melts between 173°C and 179°C.
6.0	Specific Optical Rotation	+ 78.31°.	Between + 76° and + 83° (OAB).
7.0	Chromatographic Purity (by HPLC)	0.21%.	Any Individual Impurity; NMT 0.5%.
		0.35%.	Total of all Impurities; NMT 1.0%.
8.0	Assay of $C_{18}H_{24}O_2$, ½ H_2O	98.43%.	NLT 97.0% and NMT 103.0% (OAB, by HPLC).

(D) ADDITIONAL IN-HOUSE TEST DATA: -

9.0	Organic Volatile Impurities / Residual Solvents by GC	153 ppm.	Methanol; Not more than 3000 ppm.
		1282 ppm.	Acetone; Not more than 5000 ppm.
		53 ppm.	Methylene Dichloride; Not more than 600 ppm.
10.0	Elemental Impurities	Complies.	Meets the requirement as per USP <232>.
11.0	Particle Size by Malvern	3.32 µm.	D (90) should not be more than 9.99 µm.

Remark: In the opinion of undersigned, the sample submitted complies with respect to the prescribed standards as specified in respective USP monograph & **IN-HOUSE** specification.

26/08/21	26/08/21	26/8/21
Prepared by: (Sagar Hon - Officer QA)	Checked by: (Vaibhav Kanawade - Executive QA)	Approved by: (Dhiraj M. Kini – Quality Head)

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