SHAKTI LIFESCIENCE

CERTIFICATE OF ANALYSIS

Name of the Product	:	**Estradiol Benzoate BP/EP**	**Product Code**	:	EB
Batch No.	:	EB/22003	**Batch size**	:	1.93 Kg
(A) PRODUCT IDENTIFICATION: -					
Manufacturing Date	:	February - 2022	**Sampling date**	:	13/02/2022
Retest / Expiry Date	:	January - 2026	**Release date**	:	15/02/2022
Spec. Reference No.	:	SP/FP/029	**A. R. No.**	:	HM/FP/22/008
Product Category	:	Hormones (Estrogen)	**CAS No.**	:	50-50-0
Molecular Formula	:	$C_{25}H_{28}O_3$	**Molecular Wt.**	:	376.49
Manufactured at	:	Shakti Lifescience Private Limited, Plot No.: K-2, MIDC, Tarapur, Boisar- 401506, Tal. & Dist.: Palghar, State: Maharashtra - INDIA.			
Packaging	:	**Primary packing: -** Packed in a food grade, transparent LDPE bag followed by black coloured LDPE bag. **Secondary packing: -** This bag is packed in a triple laminated aluminum sandwiched bag. **Tertiary packing: -** Above aluminium bag is packed in an HDPE drum sealed with drum seal and label.			
Storage Condition		Preseve in a tightly closed, light-resistant container, at ambient temperature.			

(B) PHYSICAL ANALYTICAL DATA: -

S. N.	TESTS	OBSERVATIONS	SPECIFICATIONS & LIMITS
1.0	Description	White, crystalline powder.	Almost white, crystalline powder or colourless crystals
2.0	Solubility	Complies.	Practically insoluble in water. Freely soluble in Methylene chloride, sparingly soluble in acetone, slightly soluble in methanol.
3.0	Loss on drying (LOD)	0.24%.	Not more than 0.5% (at 105°C for 3 hrs).

(C) CHEMICAL ANALYTICAL DATA: -

S. N.	TESTS	OBSERVATIONS	SPECIFICATIONS & LIMITS
4.0	**Identification-** By IR Spectrophotometer	Complies.	The Infrared spectrum of Sample preparation should concordant with Standard preparation of Estradiol Benzozte CRS / WS.
5.0	Specific Optical Rotation	+ 57.17°.	Between + 55.0° and + 59.0° (on dried basis).

SHAKTI LIFESCIENCE PRIVATE LIMITED
Head Office : 1004, Unique Tower, Gaiwadi Ind. Estate, Nr Kamat Club, Off S.V. Road, Goregaon (W), Mumbai-400 104. 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@shaktilifescience.com
• Web : www.shaktilifescience.com • CIN No. : U24290MH2021PTC373066

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Batch No.	:	EB/22003	**Batch size**	:	1.93 Kg

(C) CHEMICAL ANALYTICAL DATA: -

S. N.	TESTS	OBSERVATIONS	SPECIFICATIONS & LIMITS
6.0	Related Substances By HPLC	Not Detected.	Impurity A; Not more than 0.2%.
		Not Detected.	Impurity B; Not more than 0.3%.
		0.07%.	Impurity C; Not more than 0.5%.
		0.08%.	Impurity E; Not more than 0.3%.
		Not Detected.	Impurity G; Not more than 0.3%.
		0.01%.	Unspecified impurity; Not more than 0.10%.
		0.17%.	Total of all impurities; Not more than 1.0%.
7.0	Assay of $C_{25}H_{28}O_3$ by UV	100.10%.	Between 97.0 and 103.0% (on dried basis).

(D) ADDITIONAL IN-HOUSE TEST DATA: -

8.0	Organic Volatile Impurities (OVI) / Residual Solvents (by GC)	394 ppm.	Methanol; Not more than 3000 ppm
		16 ppm.	Acetone; Not more than 5000 ppm
		Not Detected.	Ethyl Acetate; Not more than 5000 ppm
		Not Detected.	Dimethyl Formamide; Not more than 880 ppm.
		Not Detected.	Methylene Chloride; Not more than 600 ppm.

Remark:

1. 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.
2. The above particulars do not release the customer from the obligation to carry out an inspection and analysis of goods received.

10/11/22	10/11/22	10/11/22
Prepared By: (S. V. Padwal – Asst. Manager QA)	**Checked By:** (Ankush Sawant – Asst. Manager QC)	**Approved By:** (Dhiraj M. Kini – Quality Head)

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