

La Chandra
Pharmalab Pvt Ltd

METAPHARMACEUTICALS CIN : U24230GJ2013PTC078033

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0290725



CERTIFICATE OF ANALYSIS

Name of Product: Estradiol Hemihydrate EP/BP (Micronised)		Page No. : 1 of 2
Batch No. : ESDγ-25003M2	A.R No. : AR/FP/ESDγ/25/0195	Effective date : 01/08/2024
Mfg. Date : Jun.-2025	Sampling Date. : 17/06/2025	Retest. Date : May.-2030
Ref. Specification : LC/QC/FP/ESDγ/001-03	Release Date : 26/06/2025	

Sr. No.	Test	Result	Specification
1.0	Description	White crystalline micronised powder	White or almost white, crystalline powder or colourless crystals.
2.0	Solubility	Complies	Practically insoluble in water, soluble in acetone, sparingly soluble in ethanol (96 per cent) and slightly Soluble in methylene chloride.
3.0	Identification		
	A) Melting Point	177.4°C to 178.2°C	175°C to 180°C
	B) IR	Complies	The IR Spectrum of sample should be concordant with the IR spectrum obtained from Estradiol Hemihydrate WS/CRS.
	C) TLC	Complies	The principal spot in the chromatogram obtained with the test solution is similar in position, color in daylight, fluorescence in ultraviolet light at 365 nm and size to the principal spot in the chromatogram obtained with the reference solution (a).
	D) Chemical Test	Complies	Pink color develops with yellowish fluorescence
	E) Water	Complies	If complies with test for water content.
4.0	Specific optical rotation	+ 81.5°	+ 76.0° to + 83.0° (anhydrous substance).
5.0	Water content	3.29% w/w	Between 2.9 to 3.5 % w/w
6.0	Related Substances (By HPLC)		
	Impurity-A	Not Detected	NMT 0.3%
	Impurity-B	0.03% (BDL)	NMT 0.3%
	Impurity-C	Not Detected	NMT 0.3%
	Impurity-D	0.01%(BDL)	NMT 0.3%
	Unspecified Impurity	Below disregard limit	NMT 0.10%
	Total Impurities	0.04%	NMT 0.5%

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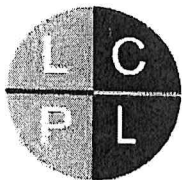
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Reg Add : 714, Maple Trade Centre, Near Surdhara Circle, Sal Hospital Road, Thaltej, Ahmedabad - 380 054 Gujarat, India
Phone : +91 79 4004 7439

Mfg Site : Survey No.: 64/2/2, Village - Vaghrol, Ta - Dantiwada, Dist. Banaskantha - 385 510, Gujarat, India
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Sr. No.	Test	Result	Specification
7.0	Assay (By UV)	99.82% w/w	NLT 97.0% & NMT 103.0 % w/w (anhydrous basis)
8.0	Residual Solvent		
	Methanol	Below quantitation limit	NMT 3000 ppm
	Acetone	126 ppm	NMT 5000 ppm
9.0	Additional Test (Particle size)		
	D 15	0.82 μm	< 1 μm
	D 50	1.65 μm	< 2 μm
	D 90	3.50 μm	< 4 μm
	D 99	5.70 μm	< 7 μm
	D 100	7.62 μm	< 10 μm

Remarks: The above material complies / does not comply as per EP/BP specification.

Storage: Store in airtight container and protected from light.

Reprint: 27/06/2025

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E. S. 27/06/25

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