



Science For Health



F&A PHARMA

F. & A. PHARMA-Handels-GmbH
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La Chandra
Pharmalab Pvt Ltd

CERTIFICATE OF ANALYSIS

Name of Product: Estradiol Hemihydrate EP/BP (Micronised)	Page No. : 1 of 2
Batch No. : ESDC-22001M2	A.R No. : AR/FP/ESDC/22/0228
Mfg. Date: Sep.-2022	Effective date : 20/07/2020
Ref. Specification : LC/QC/FP/ESDC/001-00	Retest. Date : Aug.-2027
	Release Date : 13/10/2022

Sr. No.	Test	Result	Specification
01	Description	White crystalline micronised powder	White or almost white, crystalline powder or colourless crystals.
02	Solubility	Complies	Practically insoluble in water, soluble in acetone, sparingly soluble in ethanol (96 per cent) and slightly Soluble in methylene chloride.
03	Identification		
	A) Melting Point	176.0 °C to 177.3°C	175°C to 180°C
	B) By IR	Complies	The IR Spectrum of sample should be concordant with the IR spectrum obtained from Estradiol Hemihydrate CRS.
	C) By TLC	Complies	The principal spot in the chromatogram obtained with the test solution is similar in position, colour 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
04	Specific optical rotation	+ 80.6°	+ 76.0° to + 83.0° (anhydrous substance).
05	Water content	3.01% w/w	Between 2.9 to 3.5 % w/w
06	Related Substances (By HPLC)		
	Impurity-A	Not Detected	NMT-0.3%
	Impurity-B	0.02%(BDL)	NMT-0.3%
	Impurity-C	Not Detected	NMT-0.3%
	Impurity-D	Not Detected	NMT-0.3%
	Unspecified Impurity	Below disregard limit	NMT-0.10%
	Total Impurities	0.02%(BDL)	NMT-0.5%

Prepared By

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Reg Add : C/O. Chandrabhan Hospital, 2nd Floor, Raj Plaza Complex, Sonal Char Rasta, Gurukul Road, Memnagar, Ahmedabad - 380 052, India (M) +91 90990 28738 (O) 079-4004 7439 (F) : +91 72270 3222

Manufacturing Site :- At - 64/2/2 "BANAS FARM" - Vaghrol, Ta - Dantiwada, Via Palanpur, Dist. Banaskantha - 385 510.

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Mfg. Date: Sep.-2022	Sampling Date. : 11/10/2022	Retest. Date : Aug.-2027
Ref. Specification : LC/QC/FP/ESDC/001-00		Release Date : 13/10/2022

Sr. No.	Test	Result	Specification
07	Assay (By U.V)	98.72% w/w	NLT 97.0% w/w & NMT 103.0 % w/w (on anhydrous basis)
08	Residual Solvent (By GC)		
	Methanol	Below quantification limit	NMT 3000 PPM
	Acetone	212 PPM	NMT 5000 PPM
09	Particle Size		
	D 15	0.504 µm	< 1 µm
	D 50	0.927 µm	< 2 µm
	D 90	2.139 µm	< 4 µm
	D 99	3.393 µm	< 7 µm
	D 100	4.018 µm	< 10 µm

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

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