



Science For Health

CERTIFICATE OF ANALYSIS

Name of Product: Progesterone EP/BP (Micronised)		Page No. : 1 of 2
Batch No. : PRG-22136	A.R No. : AR/FP/PRG/22/0220	Effective date : 28/09/2021
Mfg. Date : Sept - 2022	Sampling Date. : 30/09/2022	Retest Date : Aug - 2026
Ref. Specification : LC/QC/FP/PRG/001-04	Release Date : 03/10/2022	

Sr. No.	Test	Result	Specification
1.0	Description	Almost white crystalline micronised powder	White or almost white, crystalline powder or colorless crystals.
2.0	Solubility	Complies	Practically insoluble in water, freely soluble in anhydrous ethanol, sparingly soluble in acetone and in fatty oils.
3.0	Identification A) By IR	Complies	The transmission minima(absorption maxima) in the spectrum obtained with the substance to be examined correspond in position and relative size to those in the spectrum obtained with the Progesterone WS/CRS.
	B) TLC	Complies	The principal spot in chromatogram obtained with test solution is similar in position,color & size to the principal spot in the chromatogram obtained with the reference solution.
4.0	Specific optical rotation	+188.1°	+ 186°to + 194° (based on dried substance)
5.0	Loss on drying	0.24 % w/w	Not more than 0.5% w/w
6.0	Related Substances (By HPLC)		
	Impurity-I Sum of 2 Epimers	0.33 %	NMT 0.6%
	Impurity-C	Not detected	NMT 0.3%
	Impurity-B	Not detected	NMT 0.2%
	Sum of Impurity-D&E	Not detected	NMT 0.15%
	Impurity-G	Not detected	NMT 0.15%
	Impurity-J	0.05 % (BDL)	NMT 0.15%
	Impurity-K	Not detected	NMT 0.15%
	Impurity-L	Not detected	NMT 0.15%

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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 32322

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

Email Id : priyvatgadhvi@gmail.com, info@lachandra.in

www.lachandra.in



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F&A PHARMA
F. & A. PHARMA-Handels-GmbH
Bonhoeffering 41 • D - 46286 Dorsten • Germany
Phone: +49(0) 2369-9261947 • Fax: +49(0) 2369-9261950

La Chandra
Pharmalab Pvt Ltd

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Sr. No.	Test	Result	Specification
	Impurity-M	0.06 %	NMT 0.15%
	Impurity-H	Not detected	NMT 0.15%
	Unspecified Impurity	Below disregard limit	NMT 0.10%
	Total Impurities (Excluding Impurity-H)	0.44 %	NMT 1.0%
7.0	Assay (By HPLC)	99.40 % w/w	NLT 97.0% & NMT 102.0% w/w (On dried basis)
	Residual Solvents		
	Methanol	133 ppm	NMT 3000 ppm
	Acetone	Below detection limit	NMT 5000 ppm
	Acetonitrile	4 ppm	NMT 410 ppm
	Methylene Dichloride	4 ppm	NMT 600 ppm
	Di-Isopropyl Ether	Not detected	NMT 98 ppm
	Particle size		
9.0	D(99)	19.07	< 20 µm

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

Remark: 22/10/2022

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