

**STEPAN LIFESCIENCES PVT. LTD.**PLOT No. 184, SECTOR-6, IMT MANESAR,
GURUGRAM, (HARYANA) 122050**QUALITY CONTROL DEPARTMENT****CERTIFICATE OF ANALYSIS****(FINISHED PRODUCT)****Page 1 of 2**

Product Name :	LUPREST Tablets		
Generic Name :	Dydrogesterone Tablets IP 10mg		
Product Code :	561	A. R. No. :	FPT/25/07/069
Batch No. :	SHT-561-13	Pack Size / Type:	1x10 Tablets
Batch Size :	30,000 Tablets	Sampled On :	16/07/2025
Mfg. Date :	06/2025	Sample Quantity:	60 Tablets
Exp. Date :	05/2027	Sampled By:	Priya
Reference No. :	SLQC/STP/FP/007	Mfg. Lic. No.	886-B(H) & 1170-OSP(H)
Manufactured For :	NA	Date of Analysis:	16/07/2025
Manufactured By:	Stepan Lifescience Pvt. Ltd.	Release Date:	21/07/2025

S.No.	TEST	SPECIFICATION	RESULTS
1.	Description	White coloured round shaped, biconvex film coated tablets, plain on both sides.	White coloured round shaped, biconvex film coated tablets, plain on both sides.
2.	Identification:		
	Identification A: (By IR)	The IR spectrum of sample should be concordant with IR spectrum obtained from reference and working standard of Dydrogesterone	The IR spectrum of sample is concordant with IR spectrum obtained from reference and working standard of Dydrogesterone.
	Identification B: (By HPLC)	In the assay of Dydrogesterone, the principle peak in the chromatogram obtained with the test solution corresponds to the principle peak in the chromatogram obtained with the reference solution.	In the assay of Dydrogesterone, the principle peak in the chromatogram obtained with the test solution corresponds to the principle peak in the chromatogram obtained with the reference solution.
3.	Average Weight	183.0mg	185.1mg
4.	Uniformity of Weight	$185.1\text{mg} \pm 7.5\%$ of the average weight	Max: +3.03 % Min: -2.05%
5.	Thickness	Mean: $3.54\text{mm} \pm 0.2\text{ mm}$	Max: 3.58mm Min: 3.52mm
6.	Dissolution (BY UV)	NLT: 85% .	Min: 95.66% Max: 98.44, Average=96.77%
7.	Uniformity of Content: (By HPLC)	NLT: 85.0% and NMT: 115.0%	Min: 101.41% Max: 103.29%, Average=101.96%

Analyzed By Officer/Executive (Sign & Date)	Checked By Head QC (Sign & Date)	Approved By Head QA (Sign & Date)
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STEPAN LIFESCIENCES PVT. LTD.

PLOT No. 184, SECTOR-6, IMT MANESAR,
GURUGRAM, (HARYANA) 122050

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

(FINISHED PRODUCT)

Page 2 of 2

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8.	Related Substances: (By HPLC)	Any Other Impurities, NMT: 0.5 % Total Impurities, NMT: 1.0 %	Not Detected Not Detected
9.	Assay: (By HPLC) Each Film coated tablet contains:		
	Dydrogesterone IP 10 mg	NLT: 9.25 mg to NMT: 10.75 mg (92.5% to 107.5%)	9.91mg 99.10%

10.	Microbial Contamination:		
	(i) Total Bacterial Count	Not more than 1000 cfu/g	75 cfu/g
	(ii) Total Fungal Count	Not more than 100 cfu/g	Nil
	(ii) Pathogen:		
	E. coli	Should be absent /g	Absent
	Salmonella	Should be absent /10g	Absent
	Staphylococcus aureus	Should be absent /g	Absent
	Pseudomonas aeruginosa	Should be absent /g	Absent
	Shigella	Should be absent /10g	Absent

CONCLUSION: The Finish Product ~~complies~~ /does not complies as per IP/BP/USP/IH Specification.

Analyzed By Officer/Executive <i>Umesh</i> (Sign & Date) <i>21/07/2025</i>	Checked By Head QC (Sign & Date) <i>Rajesh</i> <i>21/07/2025</i>	Approved By Head QA (Sign & Date) <i>Gaurav</i> <i>21/07/2025</i>
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