

	LIFEVISION HEALTHCARE Plot No. 138, EPIP, Phase-1, Jharmajri, Baddi, Distt.: Solan (H.P.)-174103		Page 01 of 01
	DEPARTMENT: QUALITY CONTROL		
	CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)		
Product Name	PERIODX - 35		
Generic Name	Cyproterone Acetate and Ethinylestradiol (micronized) Tablets		
Batch No.	LTH - 1295	A.R.No.	QC/FP/ LTH - 1295
Mfg. Date	AUG. 2025	Batch Size	63,000 Tablets
Exp. Date	JUL. 2028	Sample Quantity	105 Tablets
Date of Receipt	04-08-2025	Date of Release	06-08-2025
Date of Analysis	05-08-2025	Mfg. Lic. No.	MNB/09/804 & MB/09/805
Marketed By	MYGEN PHARMA LLP		

S. No.	TEST	SPECIFICATION	OBSERVATION
1	Description	Blue coloured, round shaped, biconvex, with break line on one side and plain on other side, film coated tablets	Blue coloured, round shaped, biconvex, with break line on one side and plain on other side, film coated tablets
2	Identification Cyproterone Acetate IP Ethinylestradiol IP	In assay by HPLC, the RT (Retention Time) of the sample solution should match with the RT of the standard solution. In assay by HPLC, the RT (Retention Time) of the sample solution should match with the RT of the standard solution.	In assay by HPLC, the RT (Retention Time) of the sample solution match with the RT of the standard solution. In assay by HPLC, the RT (Retention Time) of the sample solution match with the RT of the standard solution.
3	Average weight	95 mg ± 7.5 %	97.48 mg
4	Uniformity of weight	± 7.5 % of average weight	-2.44 % to +2.27 %
5	Disintegration test	Not more than 30 minutes	02 minute 17 seconds
6	Uniformity of content Cyproterone Acetate IP 2 mg (as micronized) Ethinylestradiol IP 0.035 mg (as micronized)	85.0 % to 115.0 % 85.0 % to 115.0 %	97.58 % to 104.23 % 95.74 % to 102.36 %
7	Physical Parameters: Diameter Thickness Hardness	6.15 mm ± 0.3 mm 3.05 mm ± 0.3 mm Not less than 4.0 Kg/cm ²	6.11 mm to 6.20 mm 3.01 mm to 3.10 mm 4.5 Kg/cm ² to 5.5 Kg/cm ²
8	Assay		
	Each film coated tablet contains:		
	Cyproterone Acetate IP 2 mg (as micronized)	1.80 mg to 2.20 mg (90.0 % to 110.0 %)	1.996 mg (99.80 %)
	Ethinylestradiol IP 0.035 mg (as micronized)	0.0315 mg to 0.0385 mg (90.0 % to 110.0 %)	0.0347 mg (99.14 %)
9	Additional Test		
	Dissolution Cyproterone Acetate IP 2 mg (as micronized)	Not less than 75.0 %	92.74 % to 96.05 %

Remark: The above finished product complies to as per In House specification

	Prepared by Officer-QC	Checked by Executive-QC	Approved by Manager-QC
Signature			
Date	06-08-2025	06-08-2025	06-08-2025