



MEDOZ PHARMACEUTICALS PVT LTD
VILL.CHANAL MAJRA, NEAR MANPURA, TEH. NALAGARH ,DIST. SOLAN (H.P.)

QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS FINISHED PRODUCT

Name of product.	OVER-ALL TAB Levonorgestrel & Ethinyloestradiol Tablets IP	A.R. Number	FHTS/23/066
		MFG Date	DEC.2023
		EXP. Date	NOV.2025
Batch Number	MHTS-23066	Date of Received	11/01/2024
Batch Size.	315000 Tabs	Date of Analysis	11/01/2024
Sample Qty.	60 tabs	Date of Released	12/01/2024
S. No	Test	Specification	Observation
1.	Description	White coloured round shaped biconvex uncoated tablets plain on both side.	White coloured round shaped biconvex uncoated tablets plain on both side.
2.	Identification	To Comply	Complies
3.	Avg. wt. of tablet	100.0 mg $\pm$ 7.5 %	101.91mg
4.	Uniformity of weight	Not more than 2 of the individual weights of tablets deviate from the average weight by more than $\pm$ 7.5% & none deviates from the average weight by more than $\pm$ 15 %	Complies
5.	Hardness	Not less than 3.0 kg/cm ²	4.500 kg/cm ²
6.	Friability	Not more than 1.0% w/w	0.23% w/w
7.	Disintegration Time	Not more than 15 minutes	04 minutes 13 seconds
8.	Dissolution time	Ethinyloestradiol 75%(Q) Levonorgestrel 80%(Q)	Min-84.86%, Max-92.65% Min-88.34%, Max-97.15%
9.	Uniformity of content	Limit 85% to 115%	Complies
10.	Assay: Each Uncoated tablet contains:		
	Levonorgestrel IP 0.15mg Ethinyloestradiol IP 0.03 mg	Limit: 90% to 110 % of stated amount	0.1601 mg 106.75 % 0.0285 mg 95.06 %

Remark: In the opinion of the undersigned, the sample complies/~~does not comply~~ with the prescribed standard of quality with respect to the above test as per IP specification.

Prepared by:

12/01/2024

Checked by:

12/01/2024

Approved by:

12/01/2024