



ALVENTA PHARMA LIMITED

VILL. KISHANPURA, TEHSIL BADDI- NALAGARH ROAD, DISTT.- SOLAN (H.P) 174101

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Primosterone-N	A.R. No.	FG/B/24A0025A
Generic Name	Norethisterone Tablets IP 5 mg	Sample Quantity	120 Tablets
Batch No.:	ABT40606	Sample Received on	13/06/2024
Batch Size:	3.0 Lac	Analysis Date	13/06/2024
Mfg. Date.	06/2024	Release Date	19/06/2024
Exp. Date	05/2027	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	White colour, round shaped, biconvex having, both side plain, uncoated tablet.	White colour, round shaped, biconvex having, both side plain, uncoated tablet.		
2.	Identification	The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with reference solution.	Complies		
3.	Average weight	151.00 mg ± 3.0%	151.55 mg		
4.	Uniformity of weight	± 7.5% of its average weight.	Min: 146.84 mg ; Max: 154.65 mg -3.21% ; +2.05%		
5.	Disintegration	Not more than 15 minutes.	05 minutes 24 seconds.		
6.	Friability	Not more than 1.0% w/w.	0.35%w/w		
7.	Hardness	NLT 4.0 Kg/cm ²	5.75 Kg/cm ²		
8.	Uniformity of content	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	2.17		
9.	Assay:				
	Each uncoated tablet contains:	Claim	Limit	mg	%
	Norethisterone IP	5 mg	Between 90.0 % to 110.0 % of stated amount (Between 4.5 mg to 5.5 mg)	4.9269 mg	98.54%
10.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g		25 cfu/g	
ii.	Total yeast and mould count	NMT 100 cfu/g		Less than 10 cfu/g	
iii.	Pathogens: Escherichia coli	Should be absent/g		Absent/g	

Remarks: The above test parameters are complies/ not complies as per IP/BP/USP & In-House Specification.

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	19/06/2024	19/06/2024	19/06/2024