



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Naproheal D-500	A.R. No.	FG/G/24A0890
Generic Name	Naproxen and Domperidone Tablets	Sample Quantity	60 Tablets
Batch No.:	AGT40601	Sample Received on	09/06/2024
Batch Size:	1.0 Lac	Analysis Date	09/06/2024
Mfg. Date.	06/2024	Release Date	15/06/2024
Exp. Date	05/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	Yellow colour, elongated shaped, biconvex, break line on one side and other side plain, film coated tablet.	Yellow colour, elongated shaped, biconvex, break line on one side and other side plain, film coated tablet.		
2.	Identification	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	Complies		
3.	Average weight	663.00 mg ± 3%	663.97 mg		
4.	Uniformity of weight	± 5.0 % of its average weight.	Min: 645.82 mg ; Max: 680.28 mg -2.81% ; + 2.46%		
5.	Disintegration	Not more than 30 minutes.	05 minutes 22 seconds.		
6.	Hardness	NLT 4.0 Kg/cm ²	15.25 Kg/cm ²		
7.	Uniformity of content (Domperidone)	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	4.24		
8.	Assay:				
	Each film coated tablet contains:	Claim	Limit	mg	%
	Naproxen IP	500 mg	Between 90.0 % to 110.0 % of stated amount (Between 450.0 mg to 550.0 mg)	498.55 mg	99.71%
	Domperidone Maleate IP eq. to Domperidone	10 mg	Between 90.0 % to 110.0 % of stated amount (Between 9.0 mg to 11.0 mg)	9.94 mg	99.40%
9.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g	35 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	15/06/2024	15/06/2024	15/06/2024