



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Clopidrill-75	A.R. No.	FG/G/24A1115
Generic Name	Clopidogrel Tablets IP 75 mg	Sample Quantity	90 Tablets
Batch No.:	AGT407127	Sample Received on	03/08/2024
Batch Size:	1.0 Lac	Analysis Date	03/08/2024
Mfg. Date.	07/2024	Release Date	09/08/2024
Exp. Date	06/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	Brick red colour, round shaped, biconvex, both side plain, film coated tablet.	Brick red colour, round shaped, biconvex, both side plain, film coated tablet.		
2.	Identification	In the assay, the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	Complies		
3.	Average weight	307.00 mg ± 3%	307.734 mg		
4.	Uniformity of weight	± 5.0% of its average weight.	Min: 301.18 mg ; Max: 312.76 mg - 2.13% ; + 1.63%		
5.	Disintegration	Not more than 30 minutes.	14 minutes 52 seconds.		
6.	Hardness	Not less than 4.0 Kg/cm ²	8.0 Kg/cm ²		
7.	Dissolution	Not less than 80.00 % (Q)	Minimum = 91.35 % Maximum = 93.76 % Average = 92.35 %		
8.	Assay:				
	Each film coated tablet contains:	Claim	Limit	mg	%
	Clopidogrel Bisulphate IP Eq. to Clopidogrel	75 mg	Between 90.00 % to 110.00 % of label amount. Between 67.50 mg to 82.50 mg	72.81 mg	97.08%
9.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g		30 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	Tanvej	Gautam Singh
Designation	Executive	Sr. Executive	Head-QA
Signature			
Date	09/08/2024	09/08/2024	09/08/2024