

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Clopidrill-75	A.R. No.	FG/G/24A0256
Generic Name	Clopidogrel Tablets IP 75 mg	Sample Quantity	60 Tablets
Batch No.:	AGT403101	Sample Received on	04/04/2024
Batch Size:	3.0 Lac	Analysis Date	04/04/2024
Mfg. Date.	03/2024	Release Date	10/04/2024
Exp. Date	02/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	Brick red colour, roundshaped, 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	300.00 mg ± 3%	309.103 mg		
4.	Uniformity of weight	± 5.0% of its average weight.	Min: 303.68 mg ; Max: 318.38 mg - 1.75% ; + 3.00%		
5.	Disintegration	Not more than 30 minutes.	05 Minutes 38 Seconds.		
6.	Hardness	Not less than 4.0 Kg/cm ²	5.65 Kg/cm ²		
7.	Dissolution	Not less than 80.00 % (Q)	Minimum = 94.68 % Maximum = 102.89 % Average = 98.89 %		
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	73.76 mg	98.35%
9.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g		40 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	Gaurtan Singh
Designation	Executive	As Head	Head- QA
Signature			
Date	10/04/2024	10/04/2024	10/04/2024