

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Clopidrill-75	A.R. No.	FG/G/24A0962
Generic Name	Clopidogrel Tablets IP 75 mg	Sample Quantity	60 Tablets
Batch No.:	AGT406104	Sample Received on	01/07/2024
Batch Size:	2.0 Lac	Analysis Date	01/07/2024
Mfg. Date.	06/2024	Release Date	12/07/2024
Exp. Date	05/2026	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 $\pm$ 3%	304.497 mg		
4.	Uniformity of weight	$\pm$ 5.0% of its average weight.	Min: 297.35 mg ; Max: 311.13 mg - 2.35% ; + 2.18%		
5.	Disintegration	Not more than 30 minutes.	05 minutes 10 seconds.		
6.	Hardness	Not less than 4.0 Kg/cm ²	8.08 Kg/cm ²		
7.	Dissolution	Not less than 80.00 % (Q)	Minimum = 91.66 % Maximum = 99.24 % Average = 95.45 %		
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	73.62 mg	98.16%
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	Harveen Kumar	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head- QA
Signature			
Date	12/07/2024	12/07/2024	12/07/2024