



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Rosufree-CV 10/75	A.R. No.	FG/G/24A0407
Generic Name	Rosuvastatin and Clopidogrel Tablets	Sample Quantity	90 Tablets
Batch No.:	AGT404112	Sample Received on	17/05/2024
Batch Size:	1.0 Lac	Analysis Date	17/05/2024
Mfg. Date.	04/2024	Release Date	25/05/2024
Exp. Date	03/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	White coloured, round shaped, biconvex both side plain, film coated tablet.	White coloured, round shaped, biconvex both side plain, film coated tablet.		
2.	Identification	In the assay, the principal peaks in the chromatogram obtained with the test solution should be correspond to the peaks in the chromatogram obtained with the reference solution.	Complies		
3.	Average weight	285.00 mg $\pm$ 3%	290.236 mg		
4.	Uniformity of weight	$\pm$ 5% of its average weight.	Min: 284.76 mg ; Max: 296.37 mg - 1.89% ; +2.11%		
5.	Disintegration	Not more than 30 minutes.	03 minutes 10 seconds.		
6.	Hardness	NLT 4.0 Kg/cm ²	5.32 Kg/cm ²		
7.	Uniformity of content (For Rosuvastatin)	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	2.89		
8.	Assay:				
	Each film coated tablet contains:	Claim	Limit	mg	%
	Rosuvastatin Calcium IP Eq. to Rosuvastatin	10 mg	Between 90.0 % to 110.0 % of labeled amount. (Between 9.0 mg to 11.0 mg)	9.801 mg	98.01%
	Clopidogrel Bisulphate IP eq. to Clopidogrel	75 mg	Between 90.0 % to 110.0 % of labeled amount. (Between 67.50 mg to 82.50 mg)	74.394 mg	99.19%
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	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	25/05/2024	25/05/2024	25/05/2024