



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-A 10/75	A.R. No.	FG/G/24A0128
Generic Name	Aspirin Gastro-Resistant & Rosuvastatin Capsules IP	Sample Quantity	60 Capsules
Batch No.:	AGC40804	Sample Received on	12/08/2024
Batch Size:	1.0 Lac	Analysis Date	12/08/2024
Mfg. Date.	08/2024	Release Date	18/08/2024
Exp. Date	07/2026	Page No.:	Page 1 of 2

Sr. No.	Test Parameter	Acceptance Criteria	Result
1.	Description	Pink colour cap and transparent body filled with blue and white colour spherical pellets, size "2" hard gelatin capsule.	Pink colour cap and transparent body filled with blue and white colour spherical pellets, size "2" hard gelatin capsule.
2.	Identification	In the assay, the principal peak in the chromatogram obtained with the test solution should be corresponds to the peak in the chromatogram obtained with the reference solution.	Complies
3.	Average filled weight	270.00 mg $\pm$ 5.0%.	272.51 mg
4.	Uniformity of filled weight	$\pm$ 10 % of average filled weight.	Min: 262.55 mg ; Max: 278.43 mg - 3.65% ; + 2.17%
5.	Disintegration	Not more than 30 minutes.	01 minutes 55 seconds.
6.	Dissolution:		
	For Aspirin:		
	Acid Medium	NMT 10.0% in Acid of stated amount of Aspirin.	Average = 6.74%
	Buffer Medium	NLT 75.0% (Q) of the stated amount of Aspirin.	Average = 92.72%
	For Rosuvastatin calcium	NLT 70.0% (Q) of the stated amount of Rosuvastatin calcium.	Average = 100.98%
7.	Uniformity of content (For Rosuvastatin calcium)	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	5.35

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Tanvej	Gautam Singh
Designation	Executive	Sr. Executive	Head- QA
Signature			
Date	18/08/2024	18/08/2024	18/08/2024



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Product Name	Rosufree-A 10/75	A.R. No.	FG/G/24A0128
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8.	Assay:				
	Each hard gelatin capsule contains:	Claim	Limit	mg	%
	Rosuvastatin calcium IP Eq. to Rosuvastatin (As Pellets)	10 mg	Between 90.0% to 110.0% of the Stated amount (Between 9.0 mg to 11.0 mg)	9.95 mg	99.54%
	Aspirin IP (As Enteric coated Pellets)	75 mg	Between 90.0% to 110.0% of the Stated amount (Between 67.5 mg to 82.5 mg)	74.15 mg	98.86%
9.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g		40 cfu/g	
ii.	Total yeast & mould count	NMT 100 cfu/g		Less than 10 cfu/g	
iii.	Pathogen: E. 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	Braveen Kumar	Tanvej	Gautam Singh
Designation	Executive	Sr. Executive	Head-QA
Signature			
Date	18/08/2024	18/08/2024	18/08/2024