



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Rifaxiheal-550	A.R. No.	FG/G/24A1598
Generic Name	Rifaximin Tablets IP 550 mg	Sample Quantity	60 Tablets
Batch No.:	AGT41189A	Sample Received on	02/12/2024
Batch Size:	1.40 Lac	Analysis Date	02/12/2024
Mfg. Date.	11/2024	Release Date	08/12/2024
Exp. Date	10/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	Brick red colour, elongated biconvex, scored mark on one side and other side plain, film coated tablet.	Brick red colour, elongated biconvex, scored mark on one side and other side plain, film coated tablet.		
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 weight	916.00 mg $\pm$ 3%	915.67 mg		
4.	Uniformity of weight	$\pm$ 5% of its average weight.	Min: 900.19 mg ; Max: 922.54 mg - 1.69% ; +0.75%		
5.	Disintegration	Not more than 30 minutes.	02 minutes 41 seconds.		
6.	Hardness	NLT 4.0 Kg/cm ² ;	8.91 Kg/cm ²		
7.	Dissolution	Not less than 70.00 % (Q)	Min. 95.85%, Max. 100.24%, Mean 97.54%		
8.	Assay:				
	Each film coated tablet contains:	Claim	Limit	mg	%
	Rifaximin IP	550 mg	Between 95.0 % to 105.0 % of labeled amount. (Between 522.5 mg to 577.5 mg)	542.87 mg	98.70%
9.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g		45 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	Kuljeet Kaur	Kavita Nandwani
Designation	Executive	Head QC	QA Manager
Signature			
Date	08/12/2024	08/12/2024	08/12/2024