



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/24A0319
Generic Name	Rifaximin Tablets 550 mg	Sample Quantity	60 Tablets
Batch No.:	AGT40469	Sample Received on	24/04/2024
Batch Size:	0.50 Lac	Analysis Date	24/04/2024
Mfg. Date.	04/2024	Release Date	01/05/2024
Exp. Date	03/2026	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	816.00 mg $\pm$ 3%	822.097 mg		
4.	Uniformity of weight	$\pm$ 5% of its average weight.	Min: 807.09 mg ; Max: 832.16 mg - 1.83% ; +1.22%		
5.	Disintegration	Not more than 30 minutes.	09 minutes 20 seconds.		
6.	Hardness	NLT 4.0 Kg/cm ²	10.6 Kg/cm ²		
7.	Assay:				
	Each film coated tablet contains:	Claim	Limit	mg	%
	Rifaximin Ph. Eur.	550 mg	Between 90.0 % to 110.0 % of labeled amount. (Between 495.0 mg to 605.0 mg)	545.30 mg	99.15%
8.	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	Braveen Kumar	DURGESH KUMAR	Gautam Singh
Designation	Executive	AG Head	Head-QA
Signature			
Date	01/05/2024	01/05/2024	01/05/2024