



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Rifaxi heal-550	A.R. No.	FG/G/24A0481
Generic Name	Rifaximin Tablets 550 mg	Sample Quantity	60 Tablets
Batch No.:	AGT40595	Sample Received on	06/06/2024
Batch Size:	0.50 Lac	Analysis Date	06/06/2024
Mfg. Date.	05/2024	Release Date	13/06/2024
Exp. Date	04/2026	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%	815.73 mg		
4.	Uniformity of weight	$\pm$ 5% of its average weight.	Min: 794.25 mg ; Max: 836.56 mg - 2.70% ; +2.55%		
5.	Disintegration	Not more than 30 minutes.	08 minutes 42 seconds.		
6.	Hardness	NLT 4.0 Kg/cm ²	11.0 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)	555.92 mg	101.08%
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	Praveen Kumar	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	13/06/2024	13/06/2024	13/06/2024