

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Rifaxiheal-400	A.R. No.	FG/G/24A0480
Generic Name	Rifaximin Tablets 400 mg	Sample Quantity	60 Tablets
Batch No.:	AGT40594	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 shaped, biconvex, scored mark on one side and other side plain, film coated tablet.	Brick red colour, elongated shaped, 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%	818.78 mg
4.	Uniformity of weight	$\pm$ 5% of its average weight.	Min: 795.55 mg ; Max: 838.49 mg - 2.92% ; + 2.41%
5.	Disintegration	Not more than 30 minutes.	05 minutes 47 seconds.
6.	Hardness	NLT 4.0 Kg/cm ²	15.75 Kg/cm ²
7.	Assay:		
	Each film coated tablet contains:	Claim	Limit
	Rifaximin Ph. Eur.	400 mg	Between 90.0 % to 110.0 % of labeled amount. (Between 360.0 mg to 440.0 mg)
			mg %
			394.36 mg 98.59%
8.	Microbial Limit Tests:		
i.	Total aerobic microbial count	NMT 1000 cfu/g	35 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