



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Raniheal-150	A.R. No.	FG/G/24A0951
Generic Name	Ranitidine Tablets IP 150 mg	Sample Quantity	90 Tablets
Batch No.:	AGT40665	Sample Received on	28/06/2024
Batch Size:	6.0 Lac	Analysis Date	28/06/2024
Mfg. Date.	06/2024	Release Date	03/07/2024
Exp. Date	05/2026	Page No.:	Page 1 of 2

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	Orange colour, round shaped, biconvex, having both side plain, film coated tablet.	Orange colour, round shaped, biconvex, having both side plain, film coated tablet.		
2.	Identification:				
	a) By IR	The IR spectrum of the residue matches with the reference spectrum Ranitidine hydrochloride or with the spectrum obtained with reference standard or working standard of Ranitidine hydrochloride.	Complies		
	b) By HPLC	The principal peak in the chromatogram obtained with the test solution should corresponds to the peak in the chromatogram obtained with the reference solution as obtained in assay.	Complies		
3.	Average weight	275.00 mg $\pm$ 3%	276.33 mg		
4.	Uniformity of weight	$\pm$ 5% of its average weight.	Min: 268.64 mg ; Max: 282.34 mg - 2.86% ; + 2.18%		
5.	Disintegration	Not more than 30 minutes.	10 minutes 05 seconds.		
6.	Hardness	NLT 4.0 Kg/cm ²	7.75 Kg/cm ²		
7.	Dissolution	Not less than 80.00 % (Q)	Minimum = 90.64% Maximum = 95.12% Average = 92.82%		
8.	Assay:				
	Each film coated tablet contains:	Claim	Limit	mg	%
	Ranitidine Hydrochloride IP equivalent to Ranitidine	150 mg	135.00 mg to 165.00 mg per tablet. (90.00 % to 110.00 % of labeled amount)	150.74 mg	100.49%

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	DURGESH KUMAR	Gaurav Singh
Designation	Executive	QC Head	Head-BIA
Signature			
Date	03/07/2024	03/07/2024	03/07/2024



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9.	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	Chaitan Singh
Designation	Executive	QC Head	Head- QA
Signature			
Date	03/07/2024	03/07/2024	03/07/2024