



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/24A1146
Generic Name	Ranitidine Tablets IP 150 mg	Sample Quantity	90 Tablets
Batch No.:	AGT40747A	Sample Received on	10/08/2024
Batch Size:	9.0 Lac	Analysis Date	10/08/2024
Mfg. Date.	07/2024	Release Date	16/08/2024
Exp. Date	06/2026	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%	275.176 mg		
4.	Uniformity of weight	$\pm$ 5% of its average weight.	Min: 270.98 mg ; Max: 282.58 mg - 1.52% ; + 2.69%		
5.	Disintegration	Not more than 30 minutes.	06 minutes 20 seconds.		
6.	Hardness	NLT 4.0 Kg/cm ²	8.75 Kg/cm ²		
7.	Dissolution	Not less than 80.00 % (Q)	Minimum = 88.61% Maximum = 92.54% Average = 89.98%		
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)	150.99 mg	100.66%

Particulars	Prepared By	Checked By	Approved By
Name	Harveen Kumar	Tanvej	Chaitan Singh
Designation	Executive	Sr. Executive	Head-QA
Signature			
Date	16/08/2024	16/08/2024	16/08/2024



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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	Tanvej	Gautam Singh
Designation	Executive	Sr. Executive	Head-QA
Signature			
Date	16/08/2024	16/08/2024	16/08/2024