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/24A0150
Generic Name	Ranitidine Tablets IP 150 mg	**Sample Quantity**	60 Tablets
Batch No.:	AGT40258	**Sample Received on**	26/02/2024
Batch Size:	6.0 Lac	**Analysis Date**	26/02/2024
Mfg. Date.	02/2024	**Release Date**	02/03/2024
Exp. Date	01/2026	**Page No.:**	Page 1 of 1

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**	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**	276.00 mg ± 3%	275.604 mg
4.	**Uniformity of weight**	± 5% of its average weight.	Min: 273.54 mg ; Max: 280.49 mg - 0.75% ; + 1.77%
5.	**Disintegration**	Not more than 30 minutes.	09 minutes 46 seconds.
6.	**Hardness**	NLT 4.0 Kg/cm^2	10.5 Kg/cm^2
7.	**Dissolution**	Not less than 80.00 % (Q)	Minimum = 93.30% Maximum = 105.48% Average = 98.91%
8.	**Assay:**		

Each film coated tablet contains:	Claim	Limit	mg	%
Ranitidine Hydrochloride IP equivalent to Ranitidine	150 mg	Between 90.00 % to 110.00 % of stated amount (Between 135.0 mg to 165.0 mg)	147.74 mg	98.49%

9.	**Microbial Limit Tests:**		
i.	**Total aerobic microbial count**	NMT 1000 cfu/g	30 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	Baveen Kumar	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head- QA
Signature			
Date	02/03/2024	02/03/2024	02/03/2024