

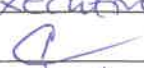
Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Ranoheal 500	A.R. No.	FG/G/24A0328
Generic Name	Ranolazine Sustained Release Tablets	Sample Quantity	60 Tablets
Batch No.:	AGT40471	Sample Received on	26/04/2024
Batch Size:	1.0 Lac	Analysis Date	26/04/2024
Mfg. Date.	04/2024	Release Date	03/05/2024
Exp. Date	03/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	Orange colour, elongated shaped, biconvex, scored mark on one side and other side plain, film coated tablet.	Orange 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	1022.00 mg ± 3%	1023.962 mg		
4.	Uniformity of weight	± 5% of its average weight.	Min: 1002.92 mg ; Max: 1034.88 mg - 2.06% ; + 1.07%		
5.	Hardness	NLT 4.0 Kg/cm ²	15.7 Kg/cm ²		
6.	Dissolution:				
	30 Minutes	Between 15.00% to 40.00%	Min. 16.28%, Max. 18.41%, Mean 16.81%		
	4 hours	Between 45.00% to 80.00%	Min. 53.68%, Max. 65.60%, Mean 59.29%		
	12 hours	Not less than 80.00%	Min. 92.66%, Max. 101.51%, Mean 96.19%		
7.	Assay:				
	Each film coated sustained release tablet contains:	Claim	Limit	mg	%
	Ranolazine	500 mg	Between 90.0 % to 110.0 % of labeled amount. (Between 450.0 mg to 550.0 mg)	508.93 mg	101.79%
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	Gaurav Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	03/05/2024	03/05/2024	03/05/2024