

**AKUMS DRUGS & PHARMACEUTICALS LTD.**19,20,21, Sector-6A, I.I.E., SIDCUL, Ranipur
Haridwar-249403, Uttarakhand, INDIA**QUALITY CONTROL****CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)**

Product Name :	RANIHEAL-DC		
Generic Name :	Ranitidine Hydrochloride & Dicyclomine Hydrochloride Tablets		
Mfg. Lic. No. :	10/UA/2004	Market:	DOMESTIC
Batch No. :	H0AA09	A. R. No.:	F20241006009
Mfg. Date :	09/2024	Pack Size:	1x10 Tablets
Expiry date:	08/2026	Pack Type:	Strip
Batch Size :	200000 Tablets	Sampled On:	06/10/24
Product Code :	40046495	Sample Quantity:	90 Tablets
Specification No, Ver No.:	STS/FP/40046495-00	Sampled By:	CHAMAN SINGH
Ref. STP No. , Ver No.:	STP/FP/40046495-00	Analyzed By:	PRADEEP SHARMA
Manufactured For :	Healing Pharma India Pvt. Ltd.	Date of Analysis:	14/10/24
Manufactured By :	Akums Drugs (Plant-1)	Analysis Completion Date:	14/10/24

S.No.	TEST	ACCEPTANCE CRITERIA	RESULTS
1	Description	Yellow coloured, round, biconvex, plain on both sides & film coated tablets. 10 tablets packed in a strip of printed aluminium foil & plain aluminium foil.	Yellow coloured, round, biconvex, plain on both sides & film coated tablets. 10 tablets packed in a strip of printed aluminium foil & plain aluminium foil.
2	Identification	As below	As below
2.a	For Ranitidine Hydrochloride (By UV)	In the assay the test solution exhibits absorption maxima at 314 nm wavelength as that of the reference solution.	In the assay the test solution exhibits absorption maxima at 314 nm wavelength as that of the reference solution.
2.b	For Dicyclomine Hydrochloride (By Titration)	A permanent orange pink colour is produced in chloroform layer.	A permanent orange pink colour is produced in chloroform layer.
3	Dimension	As below	As below

	Prepared By QC	Reviewed By QC	Approved By QC
Date	14/10/24 19:44:18	14/10/24 19:45:21	14/10/24 19:46:45
Name	SUMIT DAWAS	RAVI KANT AGNIHOTRI	DHIRAJ KANDWAL
Designation	ASST.EXECUTIVE	EXECUTIVE	SR. MANAGER

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QA REVIEWED

Name : Suman ; Date : 15/10/2024 16:41:47

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S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
3.a	Diameter	9.7 mm $\pm$ 0.2 mm		9.67 mm
3.b	Thickness	4.2 mm $\pm$ 0.4 mm		4.13 mm
4	Average weight	318.0 mg $\pm$ 5.0%		316.77 mg
5	Uniformity of weight	Within $\pm$ 5.0 % of Average weight		-1.11% to +1.25%
6	Disintegration Time	Not more than 30 minutes		Passes (06 Minutes 10 Seconds)
7	Uniformity of Content for Dicyclomine Hydrochloride	85% to 115% of Average value		96.66% to 98.41%
8	Colour Identification	Positive for Quinoline Yellow WS & Titanium Dioxide IP		Positive for Quinoline Yellow WS & Titanium Dioxide IP
9	Assay - Each film coated tablet contains:	Shelf Life Limit	Release Limit	

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S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
9.a	Ranitidine Hydrochloride IP eq. to Ranitidine - 150 mg/Tab	NLT 135.0mg/Tab to NMT 165.0mg/Tab (NLT 90.0% to NMT110.0% of label claimed)	NLT 142.5mg/Tab to NMT 157.5mg/Tab (NLT 95.0% to NMT105.0% of label claimed)	154.1mg 102.7%

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S.No.	TEST	ACCEPTANCE CRITERIA		RESULTS
9.b	Dicyclomine Hydrochloride IP - 10 mg/Tab	NLT 9.00mg/Tab to NMT 11.00mg/Tab (NLT 90.0% to NMT110.0% of label claimed)	NLT 9.50mg/Tab to NMT 10.50mg/Tab (NLT 95.0% to NMT105.0% of label claimed)	10.02mg 100.2%

CONCLUSION : The Finished Product complies as per IH Specifications.

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