



# American Remedies Healthcare Pvt. Ltd.

Surajpur, Nahan Road Paonta sahib Dist. Sirmour (H.P)

## QUALITY CONTROL DEPARTMENT

### CERTIFICATE OF FINISHED PRODUCT ANALYSIS

<b>Product Name:</b>	Ranican-2ml Injection (Ranitidine Injection IP 25mg/ml)		
<b>Batch No.</b>	26AR001	<b>A.R. No.</b>	AFP260006
<b>Batch Size</b>	104761 Vials	<b>Sample Quantity</b>	60 Nos
<b>Mfg. Date</b>	01/2026	<b>Date of Testing</b>	12/01/2026
<b>Exp. Date</b>	12/2027	<b>Date of Release</b>	28/01/2026
<b>Reference Batch No</b>	26AR001	<b>MFG. Lic. No.</b>	HP-MB-LL-00235

Sr. No.	Test	Specification	Observation
1.	Description	A clear, colourless solution	Clear and colorless solution
2.	Identification	A.) Determine by infrared absorption spectrophotometry (2.4.6) compare the spectrum with that obtained with ranitidine hydrochloride IPRS or with the reference spectrum of ranitidine hydrochloride.  (B) In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	Complies
3.	pH	Between 4.5 to 7.0	5.56
4.	Related Substance		



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	<b>A.) The any secondary impurity</b> <b>B.) The two other secondary impurity</b> <b>C.) Two further secondary impurity</b> <b>D.) The principal impurity</b>	NMT (2.0 per cent)  NMT (1.0 per cent)  NMT (0.5 per cent)  NMT (0.2 per cent)	Complies
<b>5.</b>	<b>Extractable Volume</b>	NLT 2.0 ml	2.0 ml
<b>6.</b>	<b>Bacterial Endotoxins</b>	NMT 7.0 Endotoxin units per mg of ranitidine	Less than 7.0 Endotoxin unit per mg of ranitidine
<b>7.</b>	<b>Sterility</b>	Should be Sterile	Sterile
<b>8.</b>	<b>Assay:</b> <b>Each ml contains:</b> <b>Ranitidine hydrochloride (25 mg)</b>	(90.0% to 110.0%)  (22.5mg to 27.5mg)	(100.10 %)  (25.03 mg)






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Remark: The sample is complies as per IP /BP/ USP/IH specification.

	Prepared By	Checked By	Approved By
Sign/Date	 28/01/2026	 28/01/2026	 28/01/2026
Name	Prayash	Manisha Thakur	Bhupinder Navet
Designation	Officer QC	Executive-QC	Head-QC

