



Pacebiotech Pharma (India) Pvt. Ltd.

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

CERTIFICATE OF FINISH PRODUCT ANALYSIS

Product Name:	Ranican Injection (RANITIDINE INJECTION IP 25 mg/ml)		
Batch No.	25AF096B	A.R. No.	PV250560
Batch Size	100200 AMPS	Sample Quantity	60 Nos
Mfg. Date	06/2025	Date of Testing	17/06/2025
Exp. Date	05/2027	Date of Release	02/07/2025
Reference Batch No	25AF096	MFG. Lic. No.	N-MB/2023/263

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 6.7 to 7.3	6.39
4.	Related Substance A.) The any secondary impurity B.) The two other secondary impurity C.) Two further secondary impurity D.) The principal impurity	NMT (2.0 per cent) NMT (1.0 per cent) NMT (0.5 per cent) NMT (0.2 per cent)	Complies
5.	Extractable Volume	NLT 2 ml	2 ml



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6.	Bacterial Endotoxins	NMT 7.0 Endotoxin units per mg of ranitidine	Less than 7.0 Endotoxin unit per mg of ranitidine
7.	Sterility	Should be complies	Sterile
8.	Assay: Each ml contains: Ranitidine hydrochloride (25 mg)	(90.0% to 110.0%) (22.5mg to 27.5mg)	(101.06 %) (25.27 mg)

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

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