



# AMERICAN REMEDIES HEALTHCARE PVT. LTD.

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

## Title : Certificate of Analysis Finished Product

Product Name	RABEZCAN Injection	A.R. No.	ARN/FP/25/107
Generic Name	Rabeprazole Sodium Injection IP	Sampled qty.	45 Vials
Batch No.	ARN25119A	Sampled by	Rakesh
Batch Size	50,000 Vials	Sampled on	25/03/2026
Mfg. Date	03/2026	Date of Testing	26/03/2026
Exp. Date	02/2028	Date of Release	09/04/2026

S. No.	Tests	Specifications	Observations
1.	Description	A white or off white dry powder filled in amber glass vial.	A white dry powder filled in amber glass vial.
2.	Identification (By HPLC)	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.	Uniformity of weight	Average weight $\pm 10\%$	-2.65% & +2.24%
4.	Average weight	Informative $\pm 2\%$ .	81.8mg
5.	pH	10.8 to 12.5	11.69
6.	Related Substances (by HPLC)		
	Rabeprazole sulphide	NMT 1.0%	Not detected
	Rabeprazole Sulphone	NMT 1.0%	Not detected
	Any secondary peak	NMT 0.5%	0.38%
	Sum of all secondary peaks	NMT 2.5%	0.38%
7.	Water (By K.F.)	NMT 7.0%w/w.	2.04%w/w
8.	Particulate Matter	NMT 6000/vial NMT 600/vial The reconstituted solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	43/vial 1/vial Complies
	(A) Light Obscuration		
	Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$		
	(B.) Visual Particle		
9.	Sterility	No microbial growth should be observed.	Complies
10.	Bacterial Endotoxins	NMT 5 EU/mg of Rabeprazole Sodium.	Less than 5 EU/mg Rabeprazole Sodium.
11.	Assay: (By HPLC) Each glass vial contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Rabeprazole Sodium (Sterile) IP (Lyophilized)	20 mg	19.1101 mg	95.55%	90.0% to 110.0%

**Remarks:** In the opinion of the undersigned the sample referred to above is/ is not of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/ not complies as per IP/BP/USP/HS.

Analysis by: L. Choudhary      Checked by: [Signature]      Approved by: [Signature]