



# AMERICAN REMEDIES HEALTHCARE PVT. LTD.

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

## Title : Certificate of Analysis Finished Product

<b>Product Name</b>	RABEZCAN Injection	<b>A.R. No.</b>	ARN/FP/25/036
<b>Generic Name</b>	Rabeprazole Injection IP 20mg	<b>Sampled qty.</b>	45 Vials
<b>Batch No.</b>	ARN2550A	<b>Sampled by</b>	Anuj Verma
<b>Batch Size</b>	41,600 Vials	<b>Sampled on</b>	14/10/2025
<b>Mfg. Date</b>	10/2025	<b>Date of Testing</b>	15/10/2025
<b>Exp. Date</b>	09/2027	<b>Date of Release</b>	29/10/2025

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 $\pm 10\%$	-6.62% & +4.31%
4.	Average weight	Informative $\pm 2\%$ .	81.4 mg
5.	pH	10.8 to 12.5	11.86
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%	0.16%
	Sum of all secondary peaks	NMT 2.5%	0.16%
7.	Water (By K.F.)	NMT 7.0%w/w.	1.59%w/w
8.	Particulate Matter (A) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle	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.	1929/vial 5/vial Complies
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	21.75 mg	108.75%	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/ITS.

Analysis by *[Signature]* 29/10/25      Checked by *[Signature]* 29/10/25      Approved by *[Signature]*