

**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/26/023
Generic Name	Rabeprazole Injection IP 20mg	Sampled qty.	45 Vials
Batch No.	ARN2614A	Sampled by	Aakash
Batch Size	50,000 Vials	Sampled on	29/05/2026
Mfg. Date	05/2026	Date of Testing	30/05/2026
Exp. Date	04/2028	Date of Release	13/06/2026

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 $\pm 10\%$	-5.04% & +4.15%		
4.	Average weight	Informative $\pm 2\%$.	82.7 mg		
5.	pH	10.8 to 12.5	11.77		
6.	Related Substances (by HPLC)				
	Rabeprazole sulphide	NMT 1.0%	Not detected		
	Rabeprazole Sulphone	NMT 1.0%	0.342%		
	Any secondary peak	NMT 0.5%	0.407%		
	Sum of all secondary peaks	NMT 2.5%	1.832%		
7.	Water (By K.F.)	NMT 7.0%w/w.	2.61%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.	80/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	19.2756 mg	96.38%	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 per The Drug & Cosmetic Act 1940 and the rules made there under. Complies/ not complies as per IP/EP/USP/Ph. E.

Analysis by

NAME: NIKHIL SHARMA

Checked by

NAME: SUFIYAN ANSARI

Qualification: M.Sc. Clinical Microbiology
Registration No.: 580406039538
Approved by
NAME: MRS. SWATI DHAWAN
Punjab Technical University, Jalandhar