

**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**

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

Title	Certificate of Analysis Finished Product		
Product Name	OMEECAN Injection	A.R. No.	ARN/FP/25/083
Generic Name	Omeprazole for Injection 40mg	Sampled qty.	45 Vials
Batch No.	ARN2585A	Sampled by	Rakesh
Batch Size	99,200 Vials	Sampled on	30/12/2025
Mfg. Date	12/2025	Date of Testing	31/12/2025
Exp. Date	11/2027	Date of Release	15/01/2026

S.No.	Tests	Specifications	Observations
1.	Description	A 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 peaks in the chromatogram obtained with the test solution correspond to the peak in the Chromatogram obtained with the working standard solution.	Complies
3.	Uniformity of weight	Average weight $\pm 10\%$	-2.68% & +3.39%
4.	Average weight	Informative $\pm 2\%$.	123.7 mg
5.	pH	10.30 to 11.30	10.50
6.	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 Constitute the injection as directed on the label; The solution is essentially free from particles of foreign matter that can be seen on visual Inspection.	199/vial 0/vial Complies
7.	Water (By KF)	NMT 3.0%w/w	1.29%w/w
8.	Sterility	Dry Injection should comply the test for sterility.	Complies
9.	Bacterial Endotoxins	NMT 5.0 EU/mg of Omeprazole Sodium.	Less than 5.0 EU/ mg of Omeprazole Sodium.
10.	Assay: (By HPLC) Each glass vial contains:		

Ingredients	Labelled Claim	Found	% of labelled amount	Limits % of labelled amount
Omeprazole Sodium (Sterile) IP (Lyophilized) Equivalent to Omeprazole	40 mg	42.69mg	106.73%	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 NAME: NIKHIL SHARMA	Checked by NAME: SUFIYAN ANSARI	Approved by NAME: MRS. SWATI BHAWAN
------------------------------------	------------------------------------	--