



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/25/048
Generic Name	Omeprazole for Injection 40 mg	Sampled qty.	45 Vials
Batch No.	ARN2554A	Sampled by	Anuj Verma
Batch Size	28,280 Vials	Sampled on	02/11/2025
Mfg. Date	10/2025	Date of Testing	03/11/2025
Exp. Date	09/2027	Date of Release	17/11/2025

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 $\pm 10\%$	-1.87% & +2.07%
4.	Average weight	Informative $\pm 2\%$.	122.0 mg
5.	pH	10.30 to 11.30	10.60
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.	77/vial 0/vial Complies
7.	Water (By KF)	NMT 3.0%w/w	0.61%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	41.32 mg	103.30%	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/IHS.

Analysis by
NAME: NIKHIL SHARMA

Checked by
NAME: SUFIYAN ANSARI

Approved by
NAME: MRS. SWATI DHAWAN