



AMERICAN REMEDIES HEALTHCARE PVT. LTD.

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

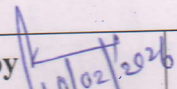
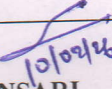
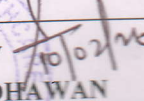
Title : Certificate of Analysis Finished Product

Product Name	ESOMEKAN Injection	A.R. No.	ARN/FP/25/088
Generic Name	Esomeprazole Sodium for Injection 40mg	Sampled qty.	45 Vials
Batch No.	ARN2592A	Sampled by	Anuj Verma
Batch Size	50,000 Vials	Sampled on	25/01/2026
Mfg. Date	01/2026	Date of Testing	26/01/2026
Exp. Date	12/2027	Date of Release	10/02/2026

S. No.	Tests	Specifications	Observations
1.	Description	A white dry powder filled in clear colour glass vial.	A white dry powder filled in clear colour glass vial.
2.	Identification (By HPLC)	In the chromatogram obtained the retention time of major peak in test solution is correspondence with RT of major peak in working standard solution.	Complies
3.	Uniformity of weight	Average weight $\pm 10\%$	-4.60% & +4.11%
4.	Average weight	Informative $\pm 2\%$.	120.5 mg
5.	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 observed on visual inspection.	133/vial 2/vial Complies
6.	Water (By K.F)	NMT 5%w/w	1.58%w/w
7.	Sterility	No microbial growth should be observed.	Complies
8.	Bacterial Endotoxins	NMT 5.0 EU/mg of Esomeprazole.	Less than 5.0 EU/mg of Esomeprazole.
9.	Assay: (By HPLC) Each vial contains:		

Ingredients	Labelled Claim	Found	% of labelled amount	Limits % of labelled amount
Esomeprazole Sodium (Sterile) Eq. to Esomeprazole (suitably buffered) (Lyophilized)	40 mg	41.16 mg	102.90%	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
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