



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 40 Injection	A.R. No.	ARN/FP/25/047
Generic Name	Esomeprazole Sodium for Injection 40mg	Sampled qty.	45 Vials
Batch No.	ARN2542B	Sampled by	Rakesh
Batch Size	50,010 Vials	Sampled on	30/10/2025
Mfg. Date	10/2025	Date of Testing	31/10/2025
Exp. Date	09/2027	Date of Release	14/11/2025

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%	-3.42% & +2.07%
4.	Average weight	Informative \pm 2%.	120.0 mg
5.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles \geq 10 μ m (2.) Particles \geq 25 μ 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.	108/vial 1/vial Complies
6.	Water (By K.F)	NMT 5%w/w	1.43%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	39.30 mg	98.25%	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 14/11/2025
NAME: NIKHIL SHARMA

Checked by 14/11/2025
NAME: SUFIYAN ANSARI

Approved by 14/11/2025
NAME: MRS. SWATI DHAWAN

