

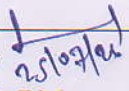
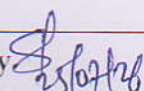
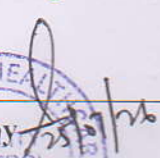
Title : Certificate of Analysis Finished Product

Product Name	ESOMECAN Injection	A.R. No.	ARN/FP/26/036
Generic Name	Esomeprazole Sodium for Injection 40mg	Sampled qty.	45 Vials
Batch No.	ARN2635A	Sampled by	Rakesh
Batch Size	49,440 Vials	Sampled on	09/07/2026
Mfg. Date	07/2026	Date of Testing	10/07/2026
Exp. Date	06/2028	Date of Release	25/07/2026

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 $\pm 10\%$	-6.72% & +7.03%
4.	Average weight	Informative $\pm 2\%$.	122.2 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.	1,227/vial 7/vial Complies
6.	Water (By K.F)	NMT 5%w/w	1.35%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	42.42 mg	106.05%	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: SURJEET KAUR	Approved by  NAME: MRS. SWATI DHAWAN
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