AMERICAN REMEDIES HEALTHCARE PVT. LTD.

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

Title	:	Certificate of Analysis Finished Product

Product Name	**ESOMECAN 40** Injection	**A.R. No.**	ARN/FP/25/047
Generic Name	Esomeprazole Sodium for Injection 40mg	**Sampled qty.**	45 Vials
Batch No.	ARN2542A	**Sampled by**	Rakesh
Batch Size	30,000 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 ± 10%	-3.42% & +2.07%
4.	Average weight	Informative ±2%.	120.0 mg
5.	Particulate Matter		
	(A.) Light Obscuration Particle Count Test		
	(1.) Particles ≥10µm	NMT 6000/vial	108/vial
	(2.) Particles ≥25µm	NMT 600/vial	1/vial
	(B.) Visual Particle	The reconstituted solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be observed on visual inspection.	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	Checked by 14/11/25	Approved by
NAME: NIKHIL SHARMA	NAME: SUFIYAN ANSARI	NAME: MRS. SWATI DHAWAN 14/11/25

AMERICAN REMEDIES HEALTHCARE PVT. LTD. CONTROL MANAGER