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Pace Biotech

Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title	:	Certificate of Analysis Finished Product

Product Name	**ESOMECAN 40** Injection	**A.R. No.**	NB/FP/24/001
Generic Name	Esomeprazole Sodium For Injection 40mg	**Sampled qty.**	45 Vials
Batch No.	N23457H	**Sampled by**	Arvind
Batch Size	15,000 Vials	**Sampled on**	04/04/2024
Mfg. Date	03/2024	**Date of Testing**	04/04/2024
Exp. Date	02/2026	**Date of Release**	19/04/2024

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 %	-2.98% & +3.25%
4.	Average weight	Informative.	118.9 mg
5.	Particulate Matter		
	(a.) Sub-Visible particle count		
	(1.) Particles ≥10µm	NMT-6000/vial	3051/vial
	(2.) Particles ≥25µm	NMT-600/vial	13/vial
	(b.) Visual	The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	Complies
6.	Water (By K.F)	NMT- 5% w/w	1.80% 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: Each vial Contains		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Esomeprazole Sodium (Sterile) Eq. to Esomeprazole (suitably buffered) (Lyophilized)	40 mg	39.82 mg	99.55%	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	Checked by	Approved by