

# Pace

Add Pace To Health

## Pace Biotech

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

Title

:

Certificate of Analysis Finished Product

Product Name	Esomecan Injection	A.R. No.	NB/FP/23/423
Generic Name	Esomeprazole Sodium for Injection 40mg	Sampled qty.	45 Vials
Batch No.	N23415F	Sampled by	Vineet
Batch Size	15,000 Vials	Sampled on	04/03/2024
Mfg. Date	02/2024	Date of Testing	04/03/2024
Exp. Date	01/2026	Date of Release	19/03/2024

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 $\pm 10\%$	-2.21% & +2.78%
4.	Average weight	Informative.	120.3 mg
5.	Particulate Matter (a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (b.) Visual	NMT-6000/vial NMT-600/vial The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	791/vial 11/vial Complies
6.	Water (By K.F)	NMT- 5% w/w	2.53% 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