

Pace

Add Pace To Health

Pace Biotech

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

Title

:

Certificate of Analysis Finished Product

Product Name	OMEECAN 40 Injection	A.R. No.	NB/FP/24/063
Generic Name	Omeprazole for Injection 40mg	Sampled qty.	45 Vials
Batch No.	N24040B	Sampled by	Vineet
Batch Size	50,000 Vials	Sampled on	26/05/2024
Mfg. Date	05/2024	Date of Testing	26/05/2024
Exp. Date	04/2026	Date of Release	10/06/2024

S. No.	Tests	Specifications	Observations
1.	Description	A white dry powder filled in amber glass vial.	A white dry powder filled in amber glass vial.
2.	Identification (By HPLC)	In the Assay, the principal peaks in the chromatogram obtained with the test solution correspond to the peak in the Chromatogram obtained with the working standard solution.	Complies
3.	Uniformity of weight	Average weight $\pm 10\%$	-3.57% & +3.60%
4.	Average weight	Informative.	121.3 mg
5.	pH	10.30 to 11.30	10.47
6.	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 Constitute the injection as directed on the label; The solution is essentially free from particles of foreign matter that can be seen on visual inspection.	240/vial 10/vial Complies
7.	Water (By KF)	NMT 3.0% w/w	2.40% w/w
8.	Sterility	Dry Injection should comply the test for sterility.	Complies
9.	Bacterial Endotoxins	NMT- 5.0 EU/mg of Omeprazole Sodium.	Less than- 5.0 EU/ mg of Omeprazole Sodium.
10.	Assay: Each glass vial Contains :		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Omeprazole Sodium (Sterile) IP (Lyophilized) Equivalent to Omeprazole	40 mg	40.46 mg	101.15%	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

