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Pace Biotech

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

Title : Certificate of Analysis Finished Product

Product Name	**OMEECAN** Injection	**A.R. No.**	NB/FP/23/339
Generic Name	Omeprazole for Injection 40mg	**Sampled qty.**	45 Vials
Batch No.	N23319A	**Sampled by**	Arvind
Batch Size	25,000 Vials	**Sampled on**	23/12/2023
Mfg. Date	11/2023	**Date of Testing**	23/12/2023
Exp. Date	10/2025	**Date of Conditionally Release**	28/12/2023

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 ±10%	-2.80% & +3.34%
4.	Average weight	Informative.	122.2 mg
5.	pH	10.30 to 11.30	10.33
6.	Particulate Matter		
	a.) Sub-Visible particle count		
	(1.) Particles ≥10µm	NMT-6000/vial	326/vial
	(2.) Particles ≥25µm	NMT-600/vial	6/vial
	(b.) Visual	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.	Complies
7.	Water (By KF)	NMT- 3.0% w/w	0.24% w/w
8.	Sterility	Dry Injection should comply the test for sterility.	Under process
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	38.82 mg	97.05%	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	Checked by	Approved by

PACE BIOTECH PAONTA SAHIB (H.P.) Quality Control Manager