

**Title**
**:**
**Certificate of Analysis Finished Product**

<b>Product Name</b>	OMEECAN 40 Injection	<b>A.R. No.</b>	ARN/FP/25/016
<b>Generic Name</b>	Omeprazole for Injection 40mg	<b>Sampled qty.</b>	45 Vials
<b>Batch No.</b>	ARN2525A	<b>Sampled by</b>	Rakesh
<b>Batch Size</b>	50,000 Vials	<b>Sampled on</b>	03/09/2025
<b>Mfg. Date</b>	08/2025	<b>Date of Testing</b>	04/09/2025
<b>Exp. Date</b>	07/2027	<b>Date of Release</b>	18/09/2025

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 $\pm 10\%$	-2.67% & +4.23%
4.	Average weight	Informative $\pm 2\%$ .	120.2 mg
5.	pH	10.30 to 11.30	10.55
6.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle	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.	1299.33/vial 110.00/vial Complies
7.	Water (By K.F.)	NMT 3.0%w/w	1.52%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: (By HPLC) Each glass vial contains:		

Ingredients	Labelled Claim	Found	% of labelled amount	Limits % of labelled amount
Omeprazole Sodium (Sterile ) IP (Lyophilized ) Equivalent to Omeprazole	40 mg	39.44 mg	98.60%	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/THIS.

Analysis by <i>18/09/25</i> NAME: NIKHIL SHARMA	Checked by <i>18/09/25</i> NAME: SUFIYAN ANSARI	Approved by <i>18/09/25</i> NAME: MRS. SWATI KUMAR
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