



## CERTIFICATE OF ANALYSIS

Product Name	: Omeprazole Pellets 8.5% w/w		
Reference	: Customer/ In-house	Drug License No.	: 18/RR/AP/2006/F/R
Batch No.	: OMP/P/2/2023111731	Date of Manufacturing	: November 2023
Batch Qty.	: 750.30 kg	Date of Expiry	: October 2026
Dispatch Qty.	: 750.00kg	Date of Release	: 30.11.2023
Customer Name	: M/s. Unifarma S.A	Market mode	: Export
Storage Condition	: <i>Preserve in tight, light-resistant containers. Stored at 25°C (excursions allowed between 15° and 30°C)</i>		

S.No.	Test	Specification	Result
1.	Description	A white to an off white spherical pellets	A white spherical pellets
2.	Identification by HPLC	The principal peak in the chromatogram obtained with the test solution corresponds to the principal peak in the chromatogram obtained with the reference solution of the Assay test.	Conforms
3.	Dissolution by HPLC (% w/w)		
	Acid resistance test	NMT 10.0% of the labeled amount of Omeprazole released in 0.1N HCL after 2 hours	0.2
	Buffer stage	NLT 80.0% of labeled amount of Omeprazole release in pH 6.8 buffer within 45 minutes.	90.5
4.	Chromatographic Purity (%)		
	a) Thioxopyrido conversion product	NMT 0.5	ND
	b) 5-methoxy -1H-benzimidazole-2-thiol	NMT 0.5	ND
	c) Any other individual impurity	NMT 0.5	0.09
	d) Total impurities	NMT 1.5	0.41
5.	Assay (% w/w) (Content of Omeprazole)	NLT 8.1 and NMT 8.9	8.7
6.	Moisture content by KF (% w/w)	NMT 1.5	0.9
7.	Bulk Density (g/ml)	Between 0.70 and 0.90	0.84
8.	Particle Size (ASTM)(%)	NLT 95.0% Pellets pass through 12 mesh and NMT 5.0% Pellets pass through 18 mesh	98.4 Nil
9.	Residual solvents GC-HS		
	a) Methanol	NMT 3000 ppm	41
	b) Ethanol	NMT 5000 ppm	ND
	c) Acetone	NMT 5000 ppm	ND
10.	Microbiology Test (cfu/g)		
	a) Total Microbial count	NMT 1000	Less than 10
	b) Total Fungal count	NMT 100	Less than 10
	c) Total Pathogens	Should Absent	Absent

**Remarks:** The material conforms to above specifications. Specification No: CS/OMP/SP/260.Revision No-00

Compiled by: R. Lakshmi Prasanna Designation :Sr. Chemist-QC Signature :	Checked by: V.S.L. Bhavani Designation : Dy. Manager-QC Signature :	Approved by : K. Prabhakar Designation : Sr. Manager-QA Signature :
Date : 30/11/2023	Date : 30/11/2023	Date : 30/11/2023

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Volume • Quality