



# RAVOOS LABORATORIES LIMITED

Sy.No.542-544, Chivemla (V&M), Suryapet, Telangana,India.

RAVOOS LABORATORIES LTD  
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## CERTIFICATE OF ANALYSIS – FINISHED PRODUCT

# QC

Name of the Product: **OMEPRAZOLE PELLETS 8.5%W/W**

Batch No: <b>OME852101223</b>	Mfg. Date: <b>DEC 2023</b>	Exp. Date: <b>NOV 2026</b>	
Batch Size: <b>1005Kgs</b>	Analysis Started on	Analysis Completed on	COA prepared on
Dispatch Qty: <b>1000Kgs</b>	<b>27/12/2023</b>	<b>31/12/2023</b>	<b>31/12/2023</b>
Test Data ref. No: <b>AWS/ OME852101223</b>		AR. No.: <b>FPO85/210/23</b>	

Sr. No	TEST	SPECIFICATION	RESULTS
1.	Description	White to off- white spherical pellets	Complies
2.	Identification	The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation, as obtained in the assay.	Complies
3.	Moisture content by KF	Not more than 3.0%	2.20%
4.	Bulk density	Between 0.70 to 0.90g/ml	0.83g/ml
5.	Assay (By HPLC)	95.0 to 105.0% of the label claim 8.10 to 8.90% w/w	(100.82%) 8.57% w/w
6.	Pellets mesh size Retention on Mesh #12 Passing through Mesh#18	Not more than 10 %	Complies
7.	Acid Resistance Stage	Not more than 10.0% of label claim should dissolve after 2hours at 100rpm.	1.88%
8.	Dissolution (Phosphate buffer pH6.8)	Not less than 75.0%(Q) of label claim should dissolve after 30 minutes at 100rpm.	90.47%
Related Substances by HPLC			
9.	a) Omeprazole related compounds F&G	Not more than 0.5%	Not Detected
	b) 5-methoxy-1H benzimidazole-2thiol	Not more than 0.5%	Not Detected
	c) Individual impurity	Not more than 0.5%	0.089%
	d) Total impurities	Not more than 2.0%	0.380%
Microbiological Tests			
10.	Total Aerobic bacteria	Not more than 100 cfu/g	48 cfu/g
	Total Yeast & Mould	Not more than 10 cfu/g	Less than 10cfu/g
	E. coli	Must be absent	Absent
	Salmonella	Must be absent	Absent
	Staphylococcus aureus	Must be absent	Absent
	Pseudomonas aeruginosa	Must be absent	Absent

**Remarks:** The product complies as per above specifications

**Storage Condition:** Store in an airtight container, in a cool & dry place, protected from light.

Prepared by	Reviewed by	Approved by
<i>P. Laxmi</i> 31/12/2023	<i>V. Geetha</i> 31/12/2023	<i>N. L. P.</i> 31/12/2023
Sr. Executive – QC Sign & date	Manager – QC Sign & date	DGM QA & QC Sign & date

Format No.: RLL/QC/FRM099

Office Address: Flat No.201, S.V.S.S. Nivas, Czech Colony, opp. Gokul Theatre, Sanath Nagar, Hyderabad.

Tel.: +91 402381 0261, Fax: +91 402381 0461, Url: www.ravoos.com, e-mail: vijay@ravoos.net