



# RAVOOS LABORATORIES LIMITED

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

# QC

## CERTIFICATE OF ANALYSIS – FINISHED PRODUCT

Page No. 1

Name of the Product: <b>OMEPRAZOLE PELLETS- 8.5 % W/W</b>		
Batch No: <b>OMEP852060722</b>	Mfg. Date : <b>JULY/2022</b>	Exp. Date: <b>JUNE/2025</b>
Batch Qty: <b>1005 Kgs</b>	Retested on : <b>06/07/2022</b>	Test Data ref. No:
	Completed on : <b>10/07/2022</b>	<b>AWS OMEP852060722</b>
Dispatch Qty: <b>1000 Kgs</b>	COA prepared on : <b>18/07/2022</b>	AR. No: <b>FPO85/206/22</b>
LC No.31790ILC0005122		

Sr.No	TEST	SPECIFICATION	RESULT
01	Description	White to off-white spherical pellets	Complies
02	Identification	The retention time of the principal peak in the sample chromatogram must be same as that of the peak in the chromatogram obtained with standard.	Complies
03	Moisture content by KF	Not more than 5.0%	2.44%
04	Bulk density	Between 0.70 to 0.90g/ml	0.83g/ml
05	Assay For Omeprazole USP 8.5 % w/w	Between 95.0% to 105.0 % of the label claim (i.e., 8.07% w/w to 8.92% w/w of Omeprazole)	101.76% of the labeled claim (8.65% w/w)
06	Pellets mesh size#12#18 ASTM	Not more than 10 % Retention on #12# mesh: NMT 5%, Passing through #18# mesh: NMT 5%	Complies
07	Acid Resistance (USP Test I)	No individual value exceeds 15.0% of the Omeprazole dissolved in 0.1NHCl after 2 hours.	1.70%
08	Buffer stage (USP Test I)	Not less than 75.0% (Q) of labeled amount of Omeprazole shall dissolve in pH 6.8 phosphate buffer after 30 minutes.	89.38%
09	Related Substances by HPLC		
	a) Omeprazole related compounds F and G	Not more than 0.5%	Not detected
	b) 5-methoxy-1H benzimidazole-2-thiol	Not more than 0.5%	Not detected
	c) Any other individual impurity	Not more than 0.5%	0.088%
	d) Total impurities	Not more than 2.0%	0.174%



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10	Residual solvents		
	Isopropyl Alcohol	Not more than 5000 ppm	Not detected
	Dichloro Methane	Not more than 600 ppm	Not detected
11	Content uniformity	85% to 115% of label claim.	Complies
12	Microbiological analysis		
	A)Total recount aerobic microorganisms	Maximum 200 CFU/g	38 CFU/g
	B)Total recount molds and yeasts	Maximum 20 CFU/g	Nil
	C)Specific microorganisms Escherichia coli	Absent	Absent

**Remark:** According to the results provided, material being mentioned above complies with above specification.

**Storage Condition:** Store in Dry and Dark Place at below 30°C

Prepared by	Checked & Approved by	Authorized by
<i>P. Laxmi</i> 18/07/2022	<i>Nay</i> 18/07/2022	<i>M</i> 18/07/2022
Executive – Quality Control Sign & date	Manager – Quality Control Sign & date	Asst. Manager - QA Sign & date

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