



**EMIL
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An ISO 9001:2008 Certified Company

PACK PRODUCT ANALYTICAL REPORT

Product Name: **Omeprazole Capsules 20 mg**

Batch No: **EO9L131**

Buyer Order No. & Date: 6562 DTD 30-07-2019

Code No. : **MH/DRUGS/KD-669-A**

Batch Size : 18,72,470 Capsules	Pack Size : 6 x 10's	Q.C. Report No.: M/19-C164-131
Sample Size : 6 x 10's	Mfg Date : Nov-19	Exp. Date : Oct-22
Shelf Life : 36 Months	Date of Sampling : 27/11/2019	Sampled by : Ms. Sonali
Analysis Date : 27/11/2019	Analyst : Mr. Deepak	Report Date : 14/12/2019

Test	Specification	Result
Release Specifications:		
Description	Hard gelatin capsules; size "2" having pink cap and transparent body.	Hard gelatin capsules; size "2" having pink cap and transparent body
Identification	The retention time of the major peak in the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.	The retention time of the major peak in the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.
Average Weight	0.305 g to 0.355 g	0.332 g
Avg. Net Content	0.247 g to 0.287 g	0.270 g
Water Content By KF	N.M.T 3.0% w/w	1.5% w/w
Uniformity of Weight	± 7.5% of average weight	Complies
Organic Impurities		
Thioxopyrido conversion product ^a	NMT: 0.5%	0.005%
5-Methoxy-1H-benzimidazole-2-thiol	NMT: 0.5%	0.003%
Any other individual impurity	NMT: 0.5%	0.079%
Total impurities	NMT: 2.0%	0.386%
Uniformity of Dosage Unit	Acceptance value : NMT 15.0 when determined on 10 individual units	7.9

Dissolution (Test-2)				
By HPLC	Acid resistance: NMT 10% in 2 hrs.	1) 2% 4) 7%	2) 7% 5) 5%	3) 6% 6) 2%
By UV	Phosphate buffer: NLT 75% (Q) in 45 min.	1) 94% 4) 94%	2) 93% 5) 94%	3) 93% 6) 94%
Assay	Label Claim	Limits (%)	Results (mg/Cap.)	% of Label Claim
Omeprazole USP	20 mg.	90.00% to 110.00%	20.61 mg	103.1%

Quality Specifications:		
Weight of 20 filled capsules	6.100 g to 7.100 g	6.659 g
Length of filled capsules	17.0 mm – 17.60 mm	17.32 mm

Microbial Limit Test : According to in House Method

Total aerobic microbial count :		
Bacterial Counts	N.M.T. 1000 cfu/g	40 cfu/g
Fungi	N.M.T. 100 cfu/g	Nil

Test for specified microorganisms:		
<i>Escherichia coli</i>	Absent in 1 g	Absent in 1 g
<i>Salmonella</i>	Absent in 10 g	Absent in 10 g
<i>Pseudomonas</i>	Absent in 1 g	Absent in 1 g
<i>Staphylococcus aureus</i>	Absent in 1 g	Absent in 1 g

OPINION : The sample **Complies** as per Standard Specification.

Deepak

Analysed by :

Mr. Deepak

QC Officer

Date : 14/12/2019

S. Rote

Checked By :

Mr. S. Rote

QC Manager

Date : 14/12/2019



S. M. Daptardar

Approved by :

Mr. S. M. Daptardar

QA Manager

Date : 14/12/2019