



# OM BIOMEDIC PVT LTD

PLOT NO : 68,69,82 & 83,SECTOR 6A,IIE,SIDCUL,HARIDWAR-249403  
REG.OFF.: 134/5 H.T.M ROAD NEAR SECTOR 1&4,RAIPUR LANE-HISAR HARYANA PIN-125001,HISAR-  
C.I.No. : U85110HR2005PTC040863

## QUALITY CONTROL DEPARTMENT

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THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

### FINISHED PRODUCT CERTIFICATE OF ANALYSIS

<b>Product Name</b> : OMEECAN-20 CAPSULES	<b>A.R. No.</b> : OMFPC241497
<b>Packing</b> : 20X15 CAP	<b>Rel. Dt.</b> : 10-12-2024
<b>Generic Name</b> : OMEPRAZOLE GASTRO-RESISTANT CAPSULES IP 20MG	<b>T.R. Slip No.</b> : FTRNBC4048
<b>Product Code</b> : OMEE01	<b>T.R. Slip Dt.</b> : 09-12-2024
<b>Batch No.</b> : CPK24-07	<b>Analysis Date</b> : 09-12-2024
<b>Actual Batch Size</b> : 300000 CAP(1000 BOX)	<b>Mfg. Dt.</b> : 11/2024
<b>Packing Batch Size</b> : 300000 CAP	<b>Exp. Dt.</b> : 10/2026
<b>Sample Size</b> : 50.000 CAP	<b>Test Packing</b> : 20X15
<b>Released Qty</b> : 300000.000 CAP (1000 BOX)	<b>Mfg. Lic No.</b> : 130/UA/2007
<b>Remarks</b> :	<b>Test As Per</b> : IP
	<b>Location</b> : HARIDWAR
	<b>Make</b> : OMBPL

Sr.	Test	Result	Specification
1	DESCRIPTION	Pink/CT colour hard gelatin capsule shell filled with white colour spherical pellets. Packed in Blister pack of 15 Capsules.	Pink/CT colour hard gelatin capsule shell filled with white colour spherical pellets. Packed in Blister pack of 15 Capsules.
2	IDENTIFICATION	Positive for: Omeprazole.	Positive for: Omeprazole.
3	AVERAGE WEIGHT OF FILLED CAPSULES	262.3mg	265.0mg
4	AVERAGE NET CONTENT OF CAPSULE	215.1mg	215.0mg
5	UNIFORMITY OF WEIGHT	-2.14% & +1.95%.	± 10.0% of Average net content.
6	DISSOLUTION	1) 1.84%, 2.16%, 1.56%, 1.95%, 2.38%, 1.38%. 2) 89.12%, 91.85%, 87.38%, 90.54%, 91.47%, 92.56%.	1) In 0.1M HCl: NMT10.0% of Stated Amount. 2) In Phosphate Buffer pH 6.8: NLT 70.0% (Q) of Stated Amount.
7	LOSS ON DRYING	1.74%.	NMT 3.0%.
8	ASSAY	19.96mg (99.80%)	Each Hard gelatin Capsule contains: Omeprazole IP 20.0mg (As enteric coated granules) [Limit: 18.0mg - 22.0mg][90.0% - 110.0%]

Conclusion : The above sample complies as per IP  
In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

Analysed By

Approved By