

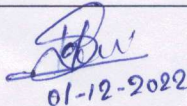
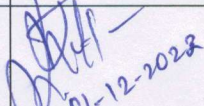
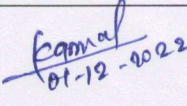

CERTIFICATE OF ANALYSIS

Batch No.	CJ2011A	Product Name	: OMEPRAZOLE CAPSULE 20MG
Batch size	: 3.82 Lac Capsules	Reference	: BP
Mfg. date	: 10-2022	Sampled Quantity	: 60 CAP
Exp. Date	: 09-2025	AR.No.	: NFP/2203243
Date of Analysis	: 22-11-2022	Date of Release	: 01-12-2022

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S. No.	Tests	Results	Specifications
1.	Description	Pink clear transparent hard gelatin capsule of size '3' containing off white pellets	Pink clear transparent hard gelatin capsule of size '3' containing off white pellets
2.	Identification (By HPLC)	Retention time of major peak in the chromatogram of the test preparation corresponds to that exhibited in the chromatogram of the standard preparation obtained as directed in the assay.	Retention time of major peak in the chromatogram of the test preparation should correspond to that exhibited in the chromatogram of the standard preparation obtained as directed in the assay.
3.	Average weight of filled capsules	253.43 mg	250.0 mg \pm 5.0 %
4.	Average weight of filled granules	202.635 mg	200 mg \pm 5.0 %
5.	Average weight of filled powder variations	50.795 mg	\pm 5 %
6.	Dissolution	2.48 % to 5.21% 89.64 % to 90.49%	NMT 15% in an acid media for 2 hours NLT 70% in buffer media for 45 Min
7.	Loss on drying	2.23%w/w	NMT 3.0% w/w
8.	Related substances	1.47% 3.0%	Individual-NMT 1.5% Total NMT 3.0%
9.	Microbiological count		
	Aerobic Bacterial count	65cfu/gm	Aerobic Bacterial count: NMT 10^3 cfu/gm
	Yeast & fungal count	Nil	Yeast & fungal count: NMT 10^2 cfu/gm
	Pathogens E. coli count	Absent	Pathogens E. coli. Salmonella etc: absent/gm
10.	Assay Each hard gelatin capsule Contains: Omeprazole BP 20.0mg	20.164mg (100.82%)	18.0to 22.0 mg. / capsule (90.0 to 110.0%) of label claim
11.	Storage	Store in a dry place protect from light, at the tem. Exceeding 25°.	Store in a dry place protect from light, at the tem. Exceeding 25°.
12.	Self life	3 years	3 years from the date of manufacture

Remarks: Conforms to the Specification

Particulars	Prepared By	Checked By		Approved By
Name	Hasib Ansari	Kunal Ratan	Kamaljeet	Bhaskar Shinagare
Designation	Officer QC	Microbiologist QC	Executive QC	Manager QC
Sign & Date	 01-12-2022	 01-12-2022	 01-12-2022	 01-12-2022