

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Omforce-20	A.R. No.	FG/G/24A0042
Generic Name	Omeprazole Gastro-Resistant Capsules IP 20 mg	Sample Quantity	60 Capsules
Batch No.:	AGC40313	Sample Received on	27/03/2024
Batch Size:	10.0 Lac	Analysis Date	27/03/2024
Mfg. Date.	03/2024	Release Date	03/04/2024
Exp. Date	02/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result
1.	Description	Pink colored cap & transparent body filled with white colour pellets, size "2" hard gelatin capsule.	Pink colored cap & transparent body filled with white colour pellets, size "2" hard gelatin capsule.
2.	Identification	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	Complies
3.	Average filled weight	267.00 mg $\pm$ 5.0%.	269.25 mg
4.	Uniformity of filled weight	$\pm$ 10 % of average filled weight.	Min: 256.72 mg ; Max: 276.62 mg - 4.65% ; + 2.74%
5.	Disintegration	Not more than 30 minutes.	08 minutes 16 seconds.
6.	Dissolution:		
	Acid Medium:	NMT 10.0% in Acid of stated amount of Omeprazole.	Minimum = 0.18% Maximum = 3.56% Average = 1.91%
	Buffer Medium:	NLT 70.0% (Q) of the stated amount of Omeprazole.	Minimum = 80.35% Maximum = 85.22% Average = 84.23%
7.	Assay:		
	Each hard gelatin capsule contains:	Claim	Limit
	Omeprazole IP (as enteric coated granules)	20 mg	Between 90.0% to 110.0% stated amount of Omeprazole (Between 18.0 mg to 22.0 mg)
			mg
			%
8.	Microbial Limit Tests:		
i.	Total aerobic microbial count	NMT 1000 cfu/g	30 cfu/g
ii.	Total yeast & mould count	NMT 100 cfu/g	Less than 10 cfu/g
iii.	Pathogen: E. Coli	Should be absent/g	Absent

Remarks: The above test parameters are complies/ ~~not complies~~ as per IP/BP/USP & In-House Specification.

Particulars	Prepared By	Checked By	Approved By
Name	Harveen Kumar	Tanveer Alam	Gaurang Singh
Designation	Executive	Sr. Executive	Head- QA
Signature			
Date	03/04/2024	03/04/2024	03/04/2024