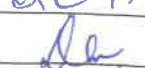


Quality Control Department
CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Esoheal-40	A.R. No.	FG/G/24A0929
Generic Name	Esomeprazole Gastro-Resistant Tablets IP 40 mg	Sample Quantity	120 Tablets
Batch No.:	AGT40628	Sample Received on	23/06/2024
Batch Size:	3.0 Lac	Analysis Date	23/06/2024
Mfg. Date.	06/2024	Release Date	28/06/2024
Exp. Date	05/2026	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result
1.	Description	Brick red colour, round shaped, biconvex, both side plain, enteric coated tablet.	Brick red colour, round shaped, biconvex, both side plain, enteric coated tablet.
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 weight	170.0 mg $\pm$ 3.0%.	171.22 mg
4.	Uniformity of weight	$\pm$ 7.5% of its average weight.	Min: 169.31 mg ; Max: 173.31 mg -1.13% ; +1.22%
5.	Hardness	Not less than 4.0 Kg/cm ²	10.5 Kg/cm ²
6.	Disintegration	Should not dissolved in 2 hours. NMT 60 minutes in Buffer.	Complies 20 Minutes 08 Sec.
7.	Dissolution:		
	In acid stage	NMT 10.0%	Minimum = 2.08% Maximum = 3.44% Average = 2.89%
	In buffer stage	NLT 70.0% (Q)	Minimum = 89.63% Maximum = 94.18% Average = 91.80%
8.	Assay:		
	Each enteric coated tablet contains:	Claim.	Limit
	Esomeprazole Magnesium Trihydrate IP eq. to Esomeprazole	40 mg	Between 90.0 % to 110.0 % of labeled amount. (Between 36.0 mg to 44.0 mg)
			mg %
			40.416 mg 101.04%
9.	Microbial Limit Tests:		
i.	Total aerobic microbial count	NMT 1000 cfu/g	30 cfu/g
ii.	Total yeast and mould count	NMT 100 cfu/g	Less than 10 cfu/g
iii.	Pathogens: Escherichia coli	Should be absent/g	Absent/g

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	DURGESH KUMAR	Gaurav Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	28/06/2024	28/06/2024	28/06/2024