

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Esoheal-20	A.R. No.	FG/G/24A0122
Generic Name	Esomeprazole Gastro-resistant Tablets IP 20 mg	Sample Quantity	60 Tablets
Batch No.:	AGT40210	Sample Received on	15/02/2024
Batch Size:	1.50 Lac	Analysis Date	15/02/2024
Mfg. Date.	02/2024	Release Date	20/02/2024
Exp. Date	01/2026	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	185.0 mg $\pm$ 3.0%.	192.483 mg
4.	Uniformity of weight	$\pm$ 7.5% of its average weight.	Min: 189.40 mg ; Max: 195.50 mg -1.60% ; +1.57%
5.	Hardness	Not less than 4.0 Kg/cm ²	8.6 Kg/cm ²
6.	Disintegration	Should not dissolved in 2 hours. NMT 60 minutes in Buffer.	Complies 15 Minutes 46 Sec.
7.	Dissolution:		
	In acid stage	NMT 10.0%	Min. = 1.10% ; Max. = 7.51% Avg. = 3.23%
	In Buffer stage	NLT 70.0% (Q)	Min. = 82.12% ; Max. = 101.11% Avg. = 89.16%
8.	Uniformity of content	The acceptance value (AV) calculated using 10 dosage units must be less than or equal to 15 (L1 =15, L2 =25)	3.26
9.	Assay:		
	Each enteric coated tablet contains:	Claim	Limit
	Esomeprazole Magnesium Trihydrate IP Eq. to Esomeprazole	20 mg	Between 90.0 % to 110.0 % of labeled amount. (Between 18.0 mg to 22.0 mg)
			mg %
			19.7896 mg 98.95%
10.	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	Praveen Kumar	BURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	20/02/2024	20/02/2024	20/02/2024