



ALVENTA PHARMA LIMITED

VILL. KISHANPURA, TEHSIL BADDI- NALAGARH ROAD, DISTT.- SOLAN (H.P) 174101

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Esoheal-40	A.R. No.	FG/G/24A0125
Generic Name	Esomeprazole Gastro-Resistant Tablets IP 40 mg	Sample Quantity	60 Tablets
Batch No.:	AGT40211	Sample Received on	17/02/2024
Batch Size:	3.0 Lac	Analysis Date	17/02/2024
Mfg. Date.	02/2024	Release Date	22/02/2024
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	170.0 mg ± 3.0%.	169.899 mg		
4.	Uniformity of weight	± 7.5% of its average weight.	Min: 167.52 mg ; Max: 172.75 mg -1.40% ;+1.67%		
5.	Hardness	Not less than 4.0 Kg/cm ²	10.5 Kg/cm ²		
6.	Disintegration	Should not dissolved in 2 hours.	Complies		
		NMT 60 minutes in Buffer.	15 Minutes 12 Sec.		
7.	Dissolution:				
	In acid stage	NMT 10.0%	Minimum = 0.00% Maximum = 0.00% Average = 0.00%		
	In buffer stage	NLT 70.0% (Q)	Minimum = 77.18% Maximum = 94.18% Average = 90.59%		
8.	Assay (By HPLC):				
	Each enteric coated tablet contains:	Claim	Limit	mg	%
	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)	39.315 mg	98.29%
9.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g		20 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	DURGESH KUMAR	Gauram Singh
Designation	Executive	QC Head	Head- QA
Signature			
Date	22/02/2024	22/02/2024	22/02/2024