



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-20	A.R. No.	FG/G/24A0975
Generic Name	Esomeprazole Gastro-resistant Tablets IP 20 mg	Sample Quantity	120 Tablets
Batch No.:	AGT40627	Sample Received on	03/07/2024
Batch Size:	1:50 Lac	Analysis Date	03/07/2024
Mfg. Date.	06/2024	Release Date	12/07/2024
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	185.0 mg ± 3.0%.	188.94 mg		
4.	Uniformity of weight	± 7.5% of its average weight.	Min: 183.01 mg ; Max: 193.91 mg -3.14% ; +2.63%		
5.	Hardness	Not less than 4.0 Kg/cm ²	6.92 Kg/cm ²		
6.	Disintegration	Should not dissolved in 2 hours.	Complies		
		NMT 60 minutes in Buffer.	18 Minutes 57 Sec.		
7.	Dissolution:				
	In acid stage	NMT 10.0%	Min. = -2.80% ; Max. = 6.41% Avg. = 2.02%		
	In Buffer stage	NLT 70.0% (Q)	Min. = 83.25% ; Max. = 86.38% Avg. = 84.52%		
8.	Assay:				
	Each enteric coated tablet contains:	Claim	Limit	mg	%
	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)	19.7232 mg	98.62%
9.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g		35 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	Gautam Singh
Designation	Executive	QC Head	Head-QA
Signature			
Date	12/07/2024	12/07/2024	12/07/2024