

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Esoheal-D	A.R. No.	FG/G/24A0065
Generic Name	Esomeprazole (EC) & Domperidone (SR) Capsule	Sample Quantity	60 Capsules
Batch No.:	AGC40506	Sample Received on	09/05/2024
Batch Size:	1.0 Lac	Analysis Date	09/05/2024
Mfg. Date.	05/2024	Release Date	15/05/2024
Exp. Date	04/2026	Page No.:	Page 1 of 2

Sr. No.	Test Parameter	Acceptance Criteria	Result
1.	Description	Pink color cap and clear transparent body filled with white and orange colour spherical pellets, size "2" hard gelatin capsule.	Pink color cap and clear transparent body filled with white and orange colour spherical pellets, size "2" hard gelatin capsule.
2.	Identification	In the assay, the principal peaks in the chromatogram obtained with the test solution should be correspond to the peaks in the chromatogram obtained with the reference solution.	Complies
3.	Average filled weight	275.00 mg $\pm$ 5.0%.	281.88 mg
4.	Uniformity of filled weight	$\pm$ 10 % of average filled weight	Min: 274.97 mg ; Max: 289.76 mg -2.45 % ; +2.80 %
5.	Dissolution:		
	For Esomeprazole:		
	Acid Medium	Not more than 10.0 %	Minimum = 0.75% Maximum = 4.66% Average = 2.43%
	Buffer Medium	Not less than 70.0 % (Q)	Minimum = 79.71% Maximum = 89.06% Average = 82.56%
	For Domperidone (As sustained release Pellets)		
	1 st Hour	15.0 % to 40.0 %	Minimum = 21.43% Maximum = 38.95% Average = 29.53%
	4 th Hours	30.0 % to 60.0 %	Minimum = 54.91% Maximum = 58.13% Average = 56.25%
	8 th Hours	55.0 % to 85.0 %	Minimum = 64.37% Maximum = 81.91% Average = 75.55%

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	DURGESH KUMAR	Gautam Singh
Designation	Executive	QC Head	Head- QA
Signature			
Date	15/05/2024	15/05/2024	15/05/2024



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-D	A.R. No.	FG/G/24A0065
Generic Name	Esomeprazole (EC) & Domperidone (SR) Capsule	Sample Quantity	60 Capsules
Batch No.:	AGC40506	Sample Received on	09/05/2024
Batch Size:	1.0 Lac	Analysis Date	09/05/2024
Mfg. Date.	05/2024	Release Date	15/05/2024
Exp. Date	04/2026	Page No.:	Page 2 of 2

Sr. No.	Test Parameter	Acceptance Criteria		Result	
	12 th Hours	Not less than 70.0 %		Minimum = 70.29%	
				Maximum = 102.45%	
				Average = 93.72%	
6.	Assay:				
	Each hard gelatin capsule contains:	Claim	Limit	mg	%
	Esomeprazole Magnesium Trihydrate IP Eq. to Esomeprazole (As enteric coated pellets)	40 mg	Between 90.0% to 110.0% of the Stated amount Between 36.0 mg to 44.0 mg	39.63 mg	99.08 %
	Domperidone IP (As sustained release pellets)	30 mg	Between 90.0% to 110.0% of the Stated amount Between 27.0 mg to 33.0 mg	30.51 mg	101.69 %
7.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g		40 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/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
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Signature			
Date	15/05/2024	15/05/2024	15/05/2024