

ZEE LABORATORIES

47, Industrial Area, Gondpur Paonta Sahib Sirmour HP INDIA 173025

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

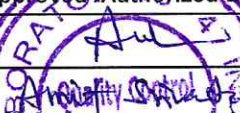
(The Drugs & Cosmetics Act 1940 at the under form 39)

Work Order No. : 252610974

Document No. : 252611862

Ref. STS No.	2373	Product Code	FG04807
Product Name	CAP. ESZONE-DSR		
Generic Name	ENTERIC COATED ESOMEPRAZOLE & DOMPERIDONE (SR) CAPSULES I.P.		
Batch No.	525-124	Date Of Sampling	06/05/2025
Batch Size	150000.000 CAP	Sample Quantity	100.000 CAP
Mfg. Date	04/2025	Exp. Date	03/2027
		Date Of Analysis	06/05/2025
A. R. No.	ZL25FG02044	Date Of Release	08/05/2025
S NO.	Tests	Specification	Results
1	Description	A pink coloured cap and clear transparent body, hard gelatin capsule containing orange and white colour spherical pellets.	Complies
2	Identification	Positive for Esomeprazole and Domperidone	Complies
3	Av. wt. of filled capsule	345 mg $\pm$ 7.5%	344.25 mg
4	Av. weight of filling	280 mg $\pm$ 10.0%	278.11 mg
5	Uniformity of weight	Average Weight of tablet $\pm$ 7.5%	Complies
6	Dissolution (Esomeprazole)	NMT 10 % (in acidic medium 0.1 M HCl)	2.75%
7	Dissolution (Esomeprazole)	NLT D + 70.0% (in phosphate buffer pH 7.4)	88.52 %
8	Dissolution (Domperidone)	NLT 15.0% and NMT 30.0% in 1 Hours	23.14 %
9	Dissolution (Domperidone)	NLT 25.0% and NMT 40.0% in 4 Hours	35.16 %
10	Dissolution (Domperidone)	NLT 45.0% and NMT 55.0% in 8 Hours	49.14 %
11	Dissolution (Domperidone)	NLT 80.0% in 12 Hours	88.53 %
12	Assay: Each hard gelatin capsule contains: Esomeprazole Magnesium I.P. Eq. to Esomeprazole 40 mg (As enteric coated pellets)	NLT 90.0% and NMT 110.0% of labeled amount	99.63 %
13	Domperidone I.P. 30 mg (As sustained release pellets)	NLT 90.0% and NMT 110.0% of labeled amount	98.74 %

Remarks The above sample complies/does not comply with prescribed standards of Quality with respect to above tests as per IP/BP/USP/In-house specification.

Particulars	Prepared / Analysed by	Reviewed By	Approved / Authorized By
Signature:			
Name:	Amarjeet Kumar	Sunil Kohal	Quality Control Manager
Designation:	QC Executive	Astt. QCM	QCM
Date	08/05/2025	08/05/2025	08/05/2025