



ZEE LABORATORIES LTD

Behind 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. : 252614285

Sample Rec No. : 252620590

QC No. : 252624990

Ref. STS No. 548 Product Code FG03221

Product Name TAB. ESZONE-40

Generic Name ESOMEPRAZOLE TABLETS I.P. 40MG

Batch No. 425-1137 Date Of Sampling 24/07/2025

Batch Size 120000.000 Tab Sample Quantity 60.000 Tab

Mfg. Date 05/2025 Exp. Date 04/2028

A. R. No. ZL25FG05719 Date Of Report 24/07/2025

S NO.	Tests	Specification	Results
1	Description	A brown colour, elongated, biconvex, enteric coated tablets both sides are plain	Complies
2	Identification	Should be positive for Esomeprazole Magnesium.	Complies
3	Average Weight of Tablet	407.0 mg $\pm$ 5.0 %	397.5 mg
4	Uniformity of Weight	Average weight of tablet $\pm$ 5%.	Complies
5	Disintegration Test (A)	a) Do not disintegrate in 0.1 M hydrochloric acid in 2 hours.	Complies
6	Disintegration Test (B)	b) Disintegrate in mixed phosphate buffer pH 6.8 in 60 minutes .	23:25Min
7	Dissolution Test (A)	A) Not more than 10% of the labeled amount of Esomeprazole dissolves in 120 minutes at 75 rpm in 1000ml 0.1 M HCl as dissolution medium.	Complies
8	Dissolution Test (B)	B) Q Not less than 70% of the labeled amount of Esomeprazole dissolves in 60 minutes at 75 rpm in 900 ml Phosphate Buffer pH 6.8 as dissolution medium.	82% to 98%
9	Assay Each enteric coated tablet contains Esomeprazole Magnesium I.P. Eq. to Esomeprazole 40 mg	NLT 90.0 % and NMT 110.0 % of the labeled amount of Esomeprazole	100.0 %

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 By	Checked By	Approved By
Sign & Date	24/07/2025	24/07/2025	24/07/2025
Name:	Maulik	Maulik	T. K. Datta
Designation:	QA Officer	QA Officer	QA Manager