

DR. EDWIN MEDILABS PVT .LTD

PLOT NO. B-29, INDUSTRIAL FOCAL POINT, CHANALON, KURALI, MOHALI (PUNJAB)

TEST REPORT (CAPSULES)

Product Name:	ESOGRED DSR	Vendor COA AR NO	OPI-01/FP/25/0519
Pellets Mfg By	OPI PALLETS PVT.LTD.	Sample Submitted By	SHALINI
Pellets B.No.	OPI2539016	Sample Quantity:	100 Capsules
Generic Name:	Esomeprazole Magnesium (Enteric Coated) & Domperidone (Sustained Release) Capsules	Mother Batch No:	DEMC-25334
Manufactured By:	Dr. Edwin MediLabs PVT Ltd (Mohali)	Analytical Report No:	QC/DEMC- 25334/07
Mfg. Date:	07/2025	Exp. Date:	06/2027
Description:	Transparent Pink cap and Transparent body hard gelatin capsules filled with orange and white pellets.		
Identification:	Positive for Esomeprazole & Domperidone		
Average Weight	380 mg	(351.5 mg to 408.5 mg)	
Average fill:	308 mg	(284.9 mg to 331.1 mg)	
Uniformity of weight	Complies	Should complies within limit	
Dissolution			
a) Esomeprazole 1) In Acid Stage 2) In Buffer Stage	NLT 90% in 2 Hours NLT 75% in 45 minutes	100% 82%	
Domperidone			
1 st hour 4 th hour 8 th hour 12 th hour	Between 15% to 45% Between 35% to 65% Between 55% to 85% NLT 70%	25% 54% 74% 90%	
<u>ASSAY</u>			
Composition	CLAIM	OBTAINED	LIMITS
Each hard gelatin capsules contains-			
Esomeprazole Magnesium Trihydrate I.P Eq. to Esomeprazole (As enteric coated pellets)	IP	40 mg	38.47 mg
Domperidone (As sustained release pellets)	IP	30 mg	29.25 mg
			(36 mg to 44 mg) (27 mg to 33 mg)

Remark : The submitted sample complies for above test as per in house specification.

SIGNATURE	TESTED BY	REVIEWED BY	APPROVED BY
DATE	16-08-2025	16-08-25	DCML 16-08-25

* Refer vendor COA, Calculation Sheet Chromatogram & Raw Data attached here with here.