

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
		Batch No:	DEMC-25334A
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	NLT 90% in 2 Hours		100%
2) In Buffer Stage	NLT 75% in 45 minuts		82%
Domperidone			
1 st hour	Between 15% to 45%		25%
4 th hour	Between 35% to 65%		54%
8 th hour	Between 55% to 85%		74%
12 th hour	NLT 70%		90%

ASSAY			
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	(36 mg to 44 mg)
Domperidone (As sustained release pellets)	IP 30 mg	29.25 mg	(27 mg to 33 mg)

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

	TESTED BY	REVIEWED BY	APPROVED BY
SIGNATURE	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
DATE	16-08-2025	16-08-25	16-08-

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

