

Lanark Laboratories

NEAR ELECTRICITY SUB DIVISION, GONDPUR, PAONTA SAHIB DISTT.SIRMOUR HP INDIA 173025

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

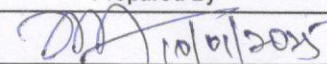
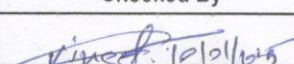
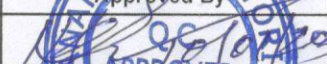
(The Drugs & Cosmetics Act 1940 at the under form 39)

Work Order No.: 242517948

Document No.: 242524543

Ref. STS No.	8619	Product Code	FG01826
Product Name	CAP. RABERIDE-DSR (ZLP)		
Generic Name	ENTERIC COATED RABEPRAZOLE 20MG + DOMPERIDONE 30MG CAPSULE 280MG		
Batch No.	524-379	Date Of Sampling	07/01/2025
Batch Size	1600000.000 CAP	Cumulative Qty.	1596120.000 CAP
		Sample Quantity	60.000 CAP
Mfg. Date	12/2024	Exp. Date	11/2027
		Quantity Release	1596060.000 CAP
A. R. No.	PL25FG00122	Date Of Release	10/01/2025

S NO.	Tests	Specification	Results
1	Description	A brown and orange colour pellets filled in red colour cap and body hard gelatin capsule shells.	A brown and orange colour pellets filled in red colour cap and body hard gelatin capsule shells.
2	Identification	Should be positive for Rabeprazole Sodium with Domperidone.	COMPLIES
3	Average fill weight	280mg \pm 3% of Average fill weight	279.3 mg
4	Uniformity of fill weight	\pm 10% of Average fill weight	-3.79%, +4.22%
5	Dissolution for Rabeprazole sodium	Limit	Result
6	Acid medium	Not more than 10.00%	1.71% to 2.88%
7	Buffer medium	Not less than 75.00%	83.56% to 89.33%
8	Dissolution for Domperidone	Limit	Result
9	After 1 hour	15.00% to 40.00%	21.48% to 37.47%
10	After 4 hour	30.00% to 60.00%	48.99% to 52.95%
11	After 8 hour	55.00% to 85.00%	72.14% to 81.88%
12	After 12 hour	Not less than 70.00%	86.48% to 99.49%
13	Composition: Each hard gelatin capsule contains:	Limit	Assay
14	Rabeprazole Sodium I.P. 20 mg. (as enteric coated pellets)	90.0 110.0% w/w of the stated amount of Rabeprazole Sodium.	94.13 %
15	Domperidone I.P. 30 mg. (As sustained release)	90.0 110.0% w/w of the stated amount of Domperidone.	102.48 %

Particulars	Prepared By	Checked By	Approved By
Sign & Date	 10/01/2025		
Name:	Neha	Neel Shukla	Neha
Designation:	QC Analyst	QC Analyst	QC Analyst

