

Lanark Laboratories

NEAR ELECTRICITY SUB DIVISION, GONDPUR, PAONTA SAHIB, DISTT.SIRMOUR-173025,H.P.(INDIA).

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

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

Work Order No.: 252610424

Document No.: 252611076

Ref. STS No.	7939	Product Code	FG01600
Product Name	CAP. RABERIDE-LS (ZLP)		
Generic Name	RABEPRAZOLE SODIUM (EC) & LEVOSULPIRIDE (SR) CAPSULES.		
Batch No.	525-74	Date Of Sampling	19/04/2025
Batch Size	150000 CAPS	Cumulative Qty.	149960 CAPS
Mfg. Date	04/2025	Sample Quantity	30 CAPS
	Exp. Date 03/2028	Quantity Release	149930 CAPS
A. R. No.	PL25FG01177	Date Of Release	24/04/2025

S NO.	Tests	Specification	Results
1	Description	A brown and white colour pellets filled in red colour body and black colour cap hard gelatine capsule shells.	Complies.
2	Identification	Should be positive for Rabeprazole sodium & Levosulpiride	Positive.
3	Average fill weight	270 mg. $\pm 10\%$	270.5 mg
4	Uniformity of fill weight	± 10 of Average fill weight	-2.11%, +2.24%
5	Dissolution for Rabeprazole sodium	Limit	Result
6	Acid medium	NMT 10.00 %	1.70% to 2.88%
7	Buffer medium	NLT 75.00 %	83.50% to 88.33%
8	Dissolution for Levosulpiride	Limit	Result
9	After 1 hour	15.0% to 40.0%	19.76% to 29.16%
10	After hour	30.0% to 60.0%	38.06% to 48.34%
11	After 8 hour	55.0% to 85.0%	60.50% to 73.58%
12	After 12 hour	NLT 70.00%	88.75% to 98.37%
13	Composition: Each hard gelatine capsule contains:	Limit	Assay
14	Rabeprazole Sodium I.P. 20 mg. (As enteric coated pellets)	90.0 to 110.0% w/w of the stated amount of Rabeprazole sodium.	103.69 %
15	Levosulpiride 75 mg. (As sustained release pellets)	90.0 to 110.0% w/w of the stated amount of Levosulpiride.	99.47 %

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.

Prepared By

Date 24/04/2025

Appendix No.: -

Checked By

Date 24/04/2025

Confidential

QCM

Approved By

Date 24/04/2025

