

# 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. : 252612130

Document No.: 252615036

|              |                                                 |                  |                |
|--------------|-------------------------------------------------|------------------|----------------|
| Ref. STS No. | 7147                                            | Product Code     | FG01414        |
| Product Name | TAB. PANTORIDE-40 (ZLP)                         |                  |                |
| Generic Name | PANTOPRAZOLE GASTRO RESISTANT TABLETS I.P. 40MG |                  |                |
| Batch No.    | 425-436                                         | Date of Sampling | 30/06/2025     |
| Batch Size   | 700000.000 TAB                                  | Cumulative Qty.  | 694120.000 TAB |
| Mfg. Date    | 06/2025                                         | Exp. Date        | 05/2027        |
| A. R. No.    | PL25FG02056                                     | Date of Release  | 30/06/2025     |

| S NO. | Tests                                               | Specification                                                                                                                      | Results                                                       |
|-------|-----------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|
| 1     | Description                                         | An orange colour round shape biconvex enteric coated tablets.                                                                      | An orange colour round shape biconvex enteric coated tablets. |
| 2     | Identification                                      | Should be positive for Pantoprazole sodium.                                                                                        | Complies                                                      |
| 3     | Average weight                                      | 240 mg $\pm$ 7.5% of average weight                                                                                                | 225.36 mg                                                     |
| 4     | Uniformity of weight                                | $\pm$ 7.5% of Average weight.                                                                                                      | -1.41% to 1.96 %                                              |
| 5     | Disintegration Time                                 | NLT 120 minutes (In 0.1 M HCL)                                                                                                     | Pass                                                          |
| 6     | Disintegration Time                                 | NMT 60 minutes (In 6.8 pH M.P.B.)                                                                                                  | 11 minutes 28 seconds                                         |
| 7     | Dissolution                                         | Not less than 80.00%                                                                                                               | 95.38 % to 98.32%                                             |
| 8     | Composition: Each enteric coated tablet contains:   | Limit                                                                                                                              | Assay                                                         |
| 9     | Pantoprazole sodium I.P. eq. to Pantoprazole 40 mg. | Pantoprazole Gastro resistant Tablets contain not less than 90.0 % and not more than 110.0 % of the stated amount of pantoprazole. | 103.55 %                                                      |

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 30/06/2025

Checked By

Date 30/06/2025



Appendix No.:-

Confidential

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