



CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)
(The Drugs & Cosmetics Act 1940 at the under form 39)

Work Order No. :

Document No. : 252613678

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| Ref. STS No. | 45 | Product Code | FG03539 |
| Product Name | TAB. GLIBENTEL-PM | | |
| Generic Name | GLIBENCLAMIDE, PIOGLITAZONE & METFORMIN TABLETS | | |
| Batch No. | 425-755 | Date Of Sampling | 01/05/2025 |
| Batch Size | 50000.000 Tab | Sample Quantity | 60.000 Tab |
| Mfg. Date | 04/2025 | Exp. Date | 03/2028 |
| A. R. No. | ZL25FG03162 | Date Of Release | 07/05/2025 |

| S NO. | Tests | Specification | Results |
|-------|--|---|-------------------|
| 1 | Description | Red colour, elongated, biconvex extended tablets, scored on one side. | Complies |
| 2 | Identification | Should be positive for Glibenclamide, Pioglitazone & Metformin Hydrochloride. | Complies |
| 3 | Average Weight of Tablet | 920.0 mg \pm 5% | 929.8 mg |
| 4 | Uniformity of Weight | Average weight of tablet \pm 5.0%. | -0.62% to + 0.44% |
| 5 | Dissolution test (A) | NLT 20.0% NMT 60.0% | 46.8% to 49.8 % |
| 6 | Dissolution test (B) | NLT 40.0% NMT 90.0% | 68.2% to 71.8 % |
| 7 | Dissolution test (C) | NLT 70.0% | 96.5% to 97.7 % |
| 8 | Assay Each film coated tablet contains Glibenclamide I.P. 5 mg | NLT 90.0% and NMT 110.0% of the labeled amount of Glibenclamide. | 98.46 % |
| 9 | Pioglitazone HCL I.P. Eq. To Pioglitazone 15 mg | NLT 90.0% and NMT 110.0% of the labeled amount of Pioglitazone. | 108.42 % |
| 10 | Metformin HCL I.P. 500.0 mg (As Extended Release) | NLT 90.0% and NMT 110.0% of the labeled amount of Metformin Hydrochloride. | 97.6 % |

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.

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| Particulars | Prepared By | Checked By | Approved By |
| Sign & Date | 07/05/2025 | 07/05/2025 | 07/05/2025 |
| Name: | Rachna | Dheeraj | Dr. Deen Singh |
| Designation: | Officer | Analyst | DCM |