



ZEE LABORATORIES LTD
Behind 47, Industrial Area, Gondpur Paonta Sahib Sirmour HP INDIA 173025

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

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

Work Order No. :

Document No. : 252613678

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 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.

Particulars	Prepared By	Checked By	Approved By
Sign & Date	20/05/2025	Dhruvlos	MANAGER
Name:	Neetu Singh	Dheeraj	20/05/2025
Designation:	QC Executive	Amit Bansal	Manager Production