



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. : 252622439

Ref. STS No.	265	Product Code	FG07912
Product Name	TAB. GLYZEE M1 SR		
Generic Name	Metformin Hydrochloride PR & Glimepiride Tablets IP		
Batch No.	425-1426	Date Of Sampling	04/07/2025
Batch Size	120000.000 Tab	Sample Quantity	60.000 Tab
Mfg. Date	06/2025	Exp. Date	05/2028
A. R. No.	ZL25FG05132	Date Of Release	09/07/2025

S NO.	Tests	Specification	Results
1	Description	White & light pink colour, bilayer biconvex, uncoated tablets, scored on one side.	Complies
2	Identification	Should be positive for Glimepiride & Metformin Hydrochloride.	Complies
3	Average Weight of Tablet	900 mg \pm 5%	897.0 mg
4	Uniformity of Weight	Average weight of tablet \pm 5.0%.	-0.56% to + 0.55 %
5	Friability Test	NMT 1.0 % w/w	0.18%
6	Dissolution Test (A)	NLT 20.0% and NMT 60.0% in 1Hours	46% to 48 %
7	Dissolution Test (B)	NLT 40.0% and NMT 90.0% in 3Hours	81% to 82 %
8	Dissolution Test (C)	Q Not less than 70% of the labeled amount of Metformin Hydrochloride dissolves in 10th Hours at 100 rpm in 900 ml Phosphate Buffer pH 6.8 as dissolution medium.	97% to 99 %
9	Dissolution Test	Q Not less than 70.0% of the labeled amount of Glimepiride dissolves in 90 minutes at 100 rpm in 900 ml Buffer Solution.	47% to 49 %
10	Uniformity of Content	Should be Complies with I.P.	Complies %
11	Assay Each Uncoated tablet contains Metformin Hydrochloride I.P. 500.0 mg (As sustained Release)	NLT 90.0% and NMT 110.0%	99.6 %
12	Glimepiride I.P. 1 mg	NLT 90.0% and NMT 110.0%	96.3 %

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	29/07/2025	29/07/2025	29/07/2025
Name:	Rajyuees	Dherenks	Thakur Deen Singh
Designation:	Officer @ QC	Assistant Manager	QC Manager

