



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. : 232455259

Ref. STS No.	254	Product Code	FG05600
Product Name	TAB. GLYZEE-M2 SR FORTE		
Generic Name	METFORMIN HYDROCHLORIDE(PROLONGED RELEASE) & GLIMEPIRIDE TABLETS I.P.		
Batch No.	424-634	Date Of Sampling	29/03/2024
Batch Size	375000.000 Tab	Sample Quantity	60.000 Tab
Mfg. Date	03/2024	Exp. Date	02/2027
A. R. No.	ZL24FG02762	Date Of Release	31/03/2024
S NO.	Tests	Specification	Results
1	Description	white & orange 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	1400.0 mg \pm 5%	1397.0 mg
4	Uniformity of Weight	NMT two of the individual weights deviate from the Average weight by more than the 5% and none deviates by more than 10%.	Complies
5	Dissolution A Metformin	NLT 40.0% & NMT 90.0% in 3Hours of the labeled amount of Metformin Hydrochloride	70.61%-72.81 %
6	Dissolution b Metformin	NLT 80.0% in 10Hours of the labeled amount of Metformin Hydrochloride	91.27%-96.13 %
7	Dissolution C	NLT 20% & NMT 60 of the labeled amount of Metformin Hydrochloride	39.71%-46.31 %
8	Dissolution Test	Q.Not less than 75.0% of the labeled amount of Glimepiride .	86.81%-93.49 %
9	Assay Each uncoated tablet contains Metformin Hydrochloride I.P. 1000 mg (As prolonged Release)	NLT 90.0% and NMT 110.0% of the stated amount of Metformin Hydrochloride.	100.20 %
10	Glimepiride I.P. 2.0 mg	NLT 90.0% and NMT 110.0% of the stated amount of Glimepiride.	105.44 %

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	31/03/2024	27/03/2024	31/03/2024
Name:	Rajkumar	Dheeraj	Dr. Deep Singh
Designation:	Officer in charge	Analyst	CCM