



# 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. : 242554203

Ref. STS No.	310	Product Code	FG03172
Product Name	TAB. METROSE-1000SR		
Generic Name	METFORMIN HYDROCHLORIDE SUSTAINED RELEASED TABLETS I.P.		
Batch No.	425-524	Date Of Sampling	21/03/2025
Batch Size	375000.000 Tab	Sample Quantity	60.000 Tab
Mfg. Date	03/2025	Exp. Date	02/2028
A. R. No.	ZL25FG02218	Date Of Release	25/08/2025

S NO.	Tests	Specification	Results
1	Description	White colour, elongated, biconvex Sustained Released tablets scored on one side.	Complies
2	Identification By IR	IR spectrophotometry compare the spetrum with that obtained with metformin Hcl WS or with the reference spectrum of metformin Hcl.	Complies
3	Identification By chemically	An Orange -red colour is produced which darkens on keeping.	Complies
4	Average Weight of Tablet	1400.0 mg $\pm$ 5.0 %	1405.8mg
5	Uniformity of Weight	Average weight of tablet $\pm$ 5.0 %.	Complies
6	Friability Test	NMT 1.0 %	0.14 %
7	Dissolution A	NLT 20.0% and NMT 60.0% in 1Hours	52.26% to 54.11 %
8	Dissolution B	NLT 40.0% and NMT 90.0% in 3Hours	86.77% to 87.20 %
9	Dissolution C	Not less than 70% of the labeled amount of Metformin Hydrochloride.	100.62% to 102.39 %
10	Related Substance	The area of the peak due to dicyandiamide 0.02%. the area of any other secondary peak 0.1%.	Complies
11	Assay Each Sustained Released tablet contains Metformin Hydrochloride I.P. 1000 mg	NLT 90.0 % and NMT 110.0 % of the labeled amount of Metformin Hydrochloride.	104.08 %

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	Q.C. MANAGER Approved By
Sign & Date	25/08/2025	25/08/2025	25/08/2025
Name:	Rayhaneer	Dheeraj	Thakur Deep Singh
Designation:	Officer Q.C.	Anti tamper Q.C.	Q.C.