



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. : 252617835

Ref. STS No.	252	Product Code	FG03985
Product Name	TAB. TENLIZEM-M 1000SR		
Generic Name	TENELIGLIPTIN 20MG & METFORMIN HYDROCHLORIDE 1000MG (SUSTAINED RELEASE) TABLETS		
Batch No.	425-1036	Date Of Sampling	30/05/2025
Batch Size	120000.000 Tab	Sample Quantity	60.000 Tab
Mfg. Date	05/2025	Exp. Date	04/2028
A. R. No.	ZL25FG04092	Date Of Release	03/06/2025
S NO.	Tests	Specification	Results
1	Description	One side light Yellow and other side white colour, elongated, biconvex, Sustained Released tablets, scored on one side.	Complies
2	Identification A	In the Assay for teneligliptin, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference Solution.	Complies
3	Identification B	In the Assay for 'metformin, hydrochloride' the absorbance maxima obtained with the test solution corresponds to the absorbance maxima at same wavelength obtained with the reference solution.	Complies
4	Average Weight of Tablet	1450.0 mg \pm 5.0 %	1415.0 mg
5	Uniformity of Weight	Average weight of tablet \pm 5.0 %.	-0.35% to 0.35%
6	Friability Test	NMT 1.0 %	0.06 %
7	Dissolution A	NLT 20.0% and NMT 60.0% in 1 Hours.	41% to 45 %
8	Dissolution B	NLT 50.0% and NMT 90.0 % in 3 Hours.	74% to 79 %
9	Dissolution C	NLT 80 % in 10 Hours. At 100 RPM of labeled amount of Metformin HCl Dissolve 900 ml Phosphate Buffer pH-6.8.	98% to 99 %
10	Assay Each uncoated bilayer tablet contains: Teneligliptin Hydrochloride Hydrate I.P. Eq. to Teneligliptin 20mg	NLT 90.0 % and NMT 110.0 % of the labeled amount	96.0 %
11	Metformin Hydrochloride I.P. 1000 mg (in sustained release from)	NLT 90.0 % and NMT 110.0 % of the labeled amount	98.6 %

Particulars	Prepared By	Checked By	Approved By
Sign & Date	20/06/2025	20/06/2025	20/06/2025
Name:	Rachna	Dheerendra	Thakur Deen Singh
Designation:	Officer in Charge	Analyst	Chem



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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	203/06/2025	203/06/2025	203/06/2025
Name:	Rajyuee	Dherenks	Manu Deep Singh
Designation:	Officer in	Anti-Monopoly	CO. PM