



# 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. : 252627280

Ref. STS No.	5268	Product Code	FG03916
Product Name	TAB. VILDAZEM M1000		
Generic Name	VILDAGLIPTIN 50MG & METFORMIN HYDROCHLORIDE 1000MG TABLETS		
Batch No.	425-1661	Date Of Sampling	08/08/2025
Batch Size	300000.000 Tab	Sample Quantity	60.000 Tab
Mfg. Date	07/2025	Exp. Date	06/2028
A. R. No.	ZL25FG06182	Date Of Release	13/08/2025
S NO.	Tests	Specification	Results
1	Description	A Yellowish colour, elongated, biconvex, film coated tablets, scored on one side.	Complies
2	Identification	In the Assay, the principal peaks in the chromatogram obtained with test solution (a) and test solution (b) correspond to die principal peaks in the chromatogram obtained with reference solution (a).	Complies
3	Average Weight of Tablet	1400.0 mg $\pm$ 5.0%	1425.0 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%.	-0.35% to + 0.34%
5	Disintegration Test	Not more than 30 minutes	09:25 Min
6	Dissolution Test Vildagliptin	Q. Not less than 80 % of the stated amount of Vildagliptin	88% to 105 %
7	Dissolution Test Metformin Hydrochloride	Q. Not less than 80 % of the stated amount of Metformin Hydrochloride	86% to 94 %
8	Benzyltrimethylammonium hydroxide (By GC)	Not more than 0.4 %.	Complies
9	Related Substances (Vildagliptin)	Vildagliptin Impurity A NMT 1.0% Vildagliptin Impurity C NMT 1.0% Vildagliptin Impurity B NMT 2.0% The area of any other secondary peak NMT 0.2% The sum of the areas of all the secondary peaks NMT 3.5%	Complies
10	Assay Each Film coated tablet contains Vildagliptin 50.0 mg	NLT 90.0% and NMT 110.0% of the labeled amount of Vildagliptin	96.4 %
11	Metformin Hydrochloride I.P. 1000.0 mg	NLT 90.0% and NMT 110.0% of the labeled amount of Metformin Hydrochloride	102.1 %

**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	L 13/08/2025	21/8/2025	
Name:	Raj Kumar	Dheeraj	Thakur Deen Singh
Designation:	Officer Q.C.	Assistant	Chem



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Particulars	Prepared By	Checked By	Approved By
Sign & Date	13/08/2025	21/08/2025	13/08/2025
Name:	Rajhveer	Dheerendra	Thakur Deen Singh
Designation:	Officer in Charge	Assistant Manager	Officer in Charge