

**WINDLAS BIOTECH LIMITED**

40/1 Mohabewala Industrial Area Dehradun-248110 (Uttarakhand)

Approved by: FDA Uttarakhand, GLP certified Lab

FORM 39 [See rule 150E(f)]

Report of Analysis by Approved Institution

Lic. No.: 1/UA/CTL*/2024

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

Product Name	VILDAFOX - M 50/500 TABLET (SALE)		
Generic Name/ Dosage Form Strength (mg)	Vildagliptin 50 mg & Metformin Hydrochloride 500 mg Tablets IP		
Batch No.	VXV26001	Booking ID/A.R. No.	QC/FG/26/11113
Batch Size	20000 STRIP	Pack Size	01 X 15 TABLET
Mfg. Date	07/2026	Exp. Date	06/2028
Reference	IP	Sample Qty.	1x125 TABLET
Sample Received on	25/07/2026	Manufacturer Lic. No	34/UA/2013,55/UA/SC/P-2013
Protocol/STP No.	WBL/STP/FG/0088	Ref. SPS No.	WBL/FPS/FG/9107
Date of Analysis started on	14/08/2026	Date of Analysis completed on	24/08/2026
Sample Send by and Address	WINDLAS BIOTECH LIMITED (PLANT-2) ,Khasra No. 141 to 143 & 145, Mohabewala Industrial Area, Dehradun-248110 UK		
Manufactured By	WINDLAS BIOTECH LIMITED (PLANT-2)		Page No. 01 of 05

S.No.	Test	Specification	Result
1	Description	Orange coloured, oval shaped, biconvex, film coated tablets, plain on both sides.	Orange coloured, oval shaped, biconvex, film coated tablets, plain on both sides.
2	Identification	In the Assay, the Vildagliptin and Metformin peak in the chromatogram obtained with test solution (a) and test solution (b) corresponds to the Vildagliptin and Metformin peak in the chromatogram obtained with reference solution (a).	Complies
3	Disintegration Time	Not more than 30 minutes	05 Min 57 Sec
4	Average weight	620.80 to 659.20 mg	637.22 mg
5	Uniformity of weight	Not more than 2 tablets in 20 deviates from the average weight by more than 5.0%. No tablet deviate from the average weight by more than 10.0%.	-0.13% to +0.85%
6	Dissolution		

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By- Person-in-charge
Name	Ambika	Ravi Kumar	Rajeev Kumar	Jogendra Singh
Designation	Trainee	Assistant Manager	Sr. Executive	G. M.
Date	24/08/2026	25/08/2026	25/08/2026	25/08/2026

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S.No.	Test	Specification	Result
6a.	Vildagliptin IP	Not less than 80% (Q) of the stated amount in 30 minutes Stage: S1 Number tested: 6 Each unit is not less than Q+5 percent of the labelled content. Stage: S2 Number tested: 6 Average of 12 units (S1+S2) is equal to or greater than Q, and no unit is less than Q-15 percent of the labelled content. Stage: S3 Number tested: 12 Average of 24 units (S1+S2+S3) is equal to or greater than Q, not more than 2 units are less than Q-15 percent of the labelled content and no unit is less than Q-25 percent of the labelled content.	Min-99.2% Max-101.7% Avg-100.0%

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S.No.	Test	Specification	Result
6b.	Metformin Hydrochloride IP	Not less than 80% (Q) of the stated amount in 30 minutes Stage: S1 Number tested: 6 Each unit is not less than Q+5 percent of the labelled content. Stage: S2 Number tested: 6 Average of 12 units (S1+S2) is equal to or greater than Q, and no unit is less than Q-15 percent of the labelled content. Stage: S3 Number tested: 12 Average of 24 units (S1+S2+S3) is equal to or greater than Q, not more than 2 units are less than Q-15 percent of the labelled content and no unit is less than Q-25 percent of the labelled content.	Min-96.5% Max-99.3% Avg-97.7%
7	Uniformity of Dosage Units		
7a.	(By Content Uniformity) Vildagliptin IP	Acceptance value should be less than 15	3.19

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S.No.	Test	Specification	Result
7b.	(By Weight Variation) Metformin Hydrochloride IP	Acceptance value should be less than 15	1.30
8	1-amino-adamantan-3-ol (By GC)	Not more than 0.4%	Not Detected
9	Related substances		
9a.	Impurity A Vildagliptin IP	Not more than 1.0%	Not Detected
9b.	Impurity B Vildagliptin IP	Not more than 2.0%	Not Detected
9c.	Impurity C Vildagliptin IP	Not more than 1.0%	Not Detected
9d.	Any other secondary impurity Vildagliptin IP	Not more than 0.2%	Not Detected
9e.	Total Impurities Vildagliptin IP	Not more than 3.5%	Not Detected
9f.	Dicyandiamide impurity Metformin Hydrochloride IP	Not more than 0.02%	Not Detected

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S.No.	Test	Specification	Result
9g.	Any other secondary impurity Metformin Hydrochloride IP	Not more than 0.1%	Not Detected
9h.	Total Impurities Metformin Hydrochloride IP	Not more than 0.6%	Not Detected
10	Assay Each film coated tablet contains:		
10a.	Vildagliptin IP...50mg	95.0 to 105.0% of labeled amount	100.0%
10b.	Metformin Hydrochloride IP...500mg	95.0 to 105.0% of labeled amount	99.7%

Remarks : The results of analysis relate only to the analysis applied.

In the opinion of the undersigned, the sample referred to above is of standard Quality as defined in the Act and the rules made thereunder for the reason given below.

	Prepared By-QC	Checked By-QC	Reviewed By-Lab.-QA	Approved By- Person-in-charge
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