



# ALVENTA PHARMA LIMITED

VILL. KISHANPURA, TEHSIL BADDI- NALAGARH ROAD, DISTT.- SOLAN (H.P) 174101

## Quality Control Department

### CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Vildagfox-M 50/500	A.R. No.	FG/G/25A2256
Generic Name	Vildagliptin & Metformin Hydrochloride Tablets IP 50 mg/500 mg	Sample Quantity	60 Tablets
Batch No.:	AGT51187	Sample Received on	17/12/2025
Batch Size:	3.80 Lac	Analysis Date	17/12/2025
Mfg. Date.	11/2025	Release Date	22/12/2025
Exp. Date	10/2027	Page No.:	Page 1 of 2

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	Brick red colour, elongated biconvex, scored mark on one side and other side plain, film coated tablet.	Brick red colour, elongated biconvex, scored mark on one side and other side plain, film coated tablet.		
2.	Identification	In the assay, 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.	Average weight	1123.00 mg $\pm$ 3.0%.	1122.59 mg		
4.	Uniformity of weight	$\pm$ 5.0 % of its average weight.	Min: 1107.13 mg ; Max: 1131.70 mg -1.38% ; +0.81%		
5.	Disintegration	Not more than 30 minutes.	05 minutes 59 seconds.		
6.	Dissolution:				
	For Metformin HCl	Not less than 80.00% (Q)	Min. = 105.01% ; Max. = 108.18% Avg = 106.64%		
	For Vildagliptin	Not less than 80.00% (Q)	Min. = 102.70% ; Max. = 109.02% Avg = 104.89%		
7.	Related Substances:				
	Vildagliptin impurity B	Not more than 2.0%	Not Detected		
	Vildagliptin impurity A	Not more than 1.0%	Not Detected		
	Vildagliptin impurity C	Not more than 1.0%	Not Detected		
	Any secondary impurity	Not more than 0.2%	Not Detected		
	Total Impurities	Not more than 3.5%	Not Detected		
8.	Assay:				
	Each film coated tablet contains:	Claim	Limit	mg	%
	Vildagliptin IP	50 mg	Between 95.0 % to 105.0 % of labeled amount. (Between 47.5 mg to 52.5 mg)	49.129 mg	98.26%
	Metformin Hydrochloride IP	500 mg	Between 95.0 % to 105.0 % of labeled amount. (Between 475.0 mg to 525.0 mg)	489.126 mg	97.83%

Particulars	Prepared By	Checked By	Approved By
Name	Braveen Kumar	Kamal Kout	Subheet Kumar
Designation	Executive	Executive	Head QC
Signature			
Date	22/12/2025	22/12/2025	22/12/2025



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Sr. No.	Test Parameter	Acceptance Criteria	Result
9.	<b>Microbial Limit Tests:</b>		
i.	<b>Total aerobic microbial count</b>	NMT 1000 cfu/g	30 cfu/g
ii.	<b>Total yeast and mould count</b>	NMT 100 cfu/g	Less than 10 cfu/g
iii.	<b>Pathogens: Escherichia coli</b>	Should be absent/g	Absent

**Remarks:** The above test parameters are complies/ not complies as per IP/BP/USP & In-House Specification.

Particulars	Prepared By	Checked By	Approved By
<b>Name</b>	Praveen Kumar	Kamal Kant	Kuljeet Kaur
<b>Designation</b>	Executive	Executive	Head QC
<b>Signature</b>			
<b>Date</b>	22/12/2025	22/12/2025	22/12/2025