



ALVENTA PHARMA LIMITED

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

Quality Control Department

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Vildafox-M 50/500	A.R. No.	FG/G/26A0494
Generic Name	Vildagliptin & Metformin Hydrochloride Tablets IP 50 mg/500 mg	Sample Quantity	60 Tablets
Batch No.:	AGT60233	Sample Received on	09/03/2026
Batch Size:	3.0 Lac	Analysis Date	09/03/2026
Mfg. Date.	02/2026	Release Date	14/03/2026
Exp. Date	01/2028	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%.	1125.95 mg		
4.	Uniformity of weight	\pm 5.0 % of its average weight.	Min: 1117.48 mg ; Max: 1134.29 mg -0.75% ; +0.74%		
5.	Disintegration	Not more than 30 minutes.	11 minutes 25 seconds.		
6.	Dissolution:				
	For Metformin HCl	Not less than 80.00% (Q)	Min. = 102.01% ; Max. = 108.40% Avg = 104.70%		
	For Vildagliptin	Not less than 80.00% (Q)	Min. = 85.72% ; Max. = 98.16% Avg = 91.27%		
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)	51.163 mg	102.33%
	Metformin Hydrochloride IP	500 mg	Between 95.0 % to 105.0 % of labeled amount. (Between 475.0 mg to 525.0 mg)	520.593 mg	104.12%

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Komal Rout	Subodh Kumar
Designation	Executive	Executive	Head QC
Signature			
Date	14/03/2026	14/03/2026	14/03/2026



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Sr. No.	Test Parameter	Acceptance Criteria	Result
9.	Microbial Limit Tests:		
i.	Total aerobic microbial count	NMT 1000 cfu/g	45 cfu/g
ii.	Total yeast and mould count	NMT 100 cfu/g	Less than 10 cfu/g
iii.	Pathogens: Escherichia coli	Should be absent/g	Absent/g

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

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Kamal Kaur	Subhash Kumar
Designation	Executive	Executive	Head QC
Signature			
Date	14/03/2026	14/03/2026	14/03/2026