



# 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/24A1377
Generic Name	Vildagliptin & Metformin Hydrochloride Tablets IP 50 mg/500 mg	Sample Quantity	60 Tablets
Batch No.:	AGT409118	Sample Received on	05/10/2024
Batch Size:	1.70 Lac	Analysis Date	05/10/2024
Mfg. Date.	09/2024	Release Date	11/10/2024
Exp. Date	08/2027	Page No.:	Page 1 of 1

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%.	1125.64 mg		
4.	Uniformity of weight	$\pm$ 5.0 % of its average weight.	Min: 1097.58 mg ; Max: 1148.50 mg -2.56% ; +2.03%		
5.	Disintegration	Not more than 30 minutes.	09 minutes 46 seconds.		
6.	Hardness	Not less than 4.0 Kg/cm <sup>2</sup>	15.5 Kg/cm <sup>2</sup>		
7.	Dissolution:				
	For Metformin HCl	Not less than 80.00% (Q)	Min. = 99.27% ; Max. = 102.21% Avg = 100.56%		
	For Vildagliptin	Not less than 80.00% (Q)	Min. = 90.32% ; Max. = 104.48% Avg = 98.31%		
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)	51.508 mg	103.02%
	Metformin Hydrochloride IP	500 mg	Between 95.0 % to 105.0 % of labeled amount. (Between 475.0 mg to 525.0 mg)	487.696 mg	97.54%
9.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g		50 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	

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	Ankita Kumar, Executive	Balwinder Singh
Designation	Executive	Executive	Plant Head
Signature			
Date	11/10/2024	11/10/2024	11/10/2024