



# 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-50	A.R. No.	FG/G/24A1247
Generic Name	Vildagliptin Tablets IP 50 mg	Sample Quantity	90 Tablets
Batch No.:	AGT408100	Sample Received on	03/09/2024
Batch Size:	2.25 Lac	Analysis Date	03/09/2024
Mfg. Date.	08/2024	Release Date	09/09/2024
Exp. Date	07/2027	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	White colour, round shaped, biconvex, both side plain, uncoated tablet.	White colour, round shaped, biconvex, both side plain, uncoated 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 (a).	Complies		
3.	Average weight	180.00 mg $\pm$ 3.0%.	179.74 mg		
4.	Uniformity of weight	$\pm$ 7.5% of its average weight.	Min: 175.80 mg ; Max: 184.12 mg -2.19% ; +2.44%		
5.	Disintegration	Not more than 15 minutes.	04 minutes 25 seconds.		
6.	Friability	Not more than 1.0%w/w	0.10 %w/w		
7.	Hardness	Not less than 4.0 Kg/cm <sup>2</sup>	5.5 Kg/cm <sup>2</sup>		
8.	Dissolution	Not less than 80.00% (Q) of labeled amount is released in 30 minutes.	Minimum = 92.02% Maximum = 98.93% Average = 95.16%		
9.	Assay:				
	Each uncoated 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)	50.32 mg	100.65%
10.	Microbial Limit Tests:				
i.	Total aerobic microbial count	NMT 1000 cfu/g		35 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	Tanvej	Gautam Singh
Designation	Executive	Sr. Executive	Head- QA
Signature			
Date	09/09/2024	09/09/2024	09/09/2024