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/23A1012
Generic Name	Vildagliptin Tablets IP 50 mg	**Sample Quantity**	60 Tablets
Batch No.:	AGT31138	**Sample Received on**	29/11/2023
Batch Size:	2.25 Lac	**Analysis Date**	29/11/2023
Mfg. Date.	11/2023	**Release Date**	NA
Exp. Date	10/2026	**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 (By HPLC)**	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 mg ± 3.0%.	180.014 mg
4.	**Uniformity of weight**	± 7.5% of its average weight.	Min: 178.40 mg ; Max: 182.11 mg -0.90% ; +1.16%
5.	**Disintegration**	Not more than 15 minutes.	00 minutes 48 seconds.
6.	**Friability**	Not more than 1.0%w/w	0.18 %w/w
7.	**Hardness**	Not less than 4.0 Kg/cm^2	5.25 Kg/cm^2
8.	**Dissolution**	Not less than 80.00% (Q) of labeled amount is released in 30 minutes.	Minimum = 95.33% Maximum = 101.17% Average = 98.75%
9.	**Assay (By HPLC):**		

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)	49.645 mg	99.29%

10.	**Microbial Limit Tests:**		
i.	**Total aerobic microbial count**	NMT 1000 cfu/g	Under Observation
ii.	**Total yeast and mould count**	NMT 100 cfu/g	Under Observation
iii.	**Pathogens: Escherichia coli**	Should be absent/g	Under Observation

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		Tanvej	
Date	05/12/2023	05/12/2023	05/12/2023