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/23A1011
Generic Name	Vildagliptin & Metformin Hydrochloride Tablets IP 50 mg/500 mg	**Sample Quantity**	60 Tablets
Batch No.:	AGT31139	**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**	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 (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.	Complies
3.	**Average weight**	1123 mg ± 3.0%.	1125.63 mg
4.	**Uniformity of weight**	± 5.0 % of its average weight.	Min: 1115.61 mg ; Max: 1130.78 mg -0.89% ; +0.46%
5.	**Disintegration**	Not more than 30 minutes.	06 minutes 49 seconds.
6.	**Hardness**	Not less than 4.0 Kg/cm^2	8.67 Kg/cm^2
7.	**Dissolution:**		
	For Metformin HCl	Not less than 80.00% (Q)	Min. = 102.18% ; Max. = 104.32% Avg = 103.35%
	For Vildagliptin	Not less than 80.00% (Q)	Min. = 92.18% ; Max. = 95.88% Avg = 93.39%
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)	50.129 mg	100.26%
Metformin Hydrochloride IP	**500 mg**	Between 95.0 % to 105.0 % of labeled amount. (Between 475.0 mg to 525.0 mg)	512.502 mg	102.50%

9.	**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