



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/24A0357 |
| Generic Name | Vildagliptin Tablets IP 50 mg | Sample Quantity | 120 Tablets |
| Batch No.: | AGT40485B | Sample Received on | 04/05/2024 |
| Batch Size: | 0.65 Lac | Analysis Date | 04/05/2024 |
| Mfg. Date. | 04/2024 | Release Date | 11/05/2024 |
| Exp. Date | 03/2026 | 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 | 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%. | 177.55 mg | | |
| 4. | Uniformity of weight | \pm 7.5% of its average weight. | Min: 175.14 mg ; Max: 181.44 mg -1.36% ; +2.19% | | |
| 5. | Disintegration | Not more than 15 minutes. | 04 minutes 20 seconds. | | |
| 6. | Friability | Not more than 1.0%w/w | 0.27 %w/w | | |
| 7. | Hardness | Not less than 4.0 Kg/cm ² | 6.42 Kg/cm ² | | |
| 8. | Dissolution | Not less than 80.00% (Q) of labeled amount is released in 30 minutes. | Minimum = 91.63% Maximum = 96.67% Average = 93.53% | | |
| 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) | 52.27 mg | 104.54% |
| 10. | Microbial Limit Tests: | | | | |
| i. | Total aerobic microbial count | NMT 1000 cfu/g | | 40 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 | Chauhan Singh |
| Designation | Executive | Sr. Executive | Head-QA |
| Signature | | | |
| Date | 11/05/2024 | 11/05/2024 | 11/05/2024 |