

**BIOALTUS PHARMACEUTICALS PVT. LTD.,****DEPARTMENT: QUALITY CONTROL****CERTIFICATE OF ANALYSIS**

Product Name	VILDAFOX 100 SR	Product code	600117
Batch No.	SIBP24606	Sample Quantity	100 Tablets
Batch Size	205000 Nos	Date of Analysis	02/01/25
Mfg. Date	12/2024	Exp. Date:	11/2026
Specification No.	BP/IPS/V11-00	Date of Release	07/01/25
Manufacture Name	Bioaltus Pharmaceuticals Pvt. Ltd.	Analytical Report No.	BP/IP25/A06/0009
Sampling Date	02/01/25	STP. No.	BP/IPT/V11-00
Supplier Name	American Remedies Healthcare Pvt. Ltd.	Pack Size	NA
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Sl. No.	Tests	Specification	Results
1.	Description	White to off white colour, round shape, biconvex, uncoated sustained release tablets, having plain on both side.	Off white colour, round shape, biconvex, uncoated sustained release tablets, having plain on both side.
2.	Identification For Vildagliptin	The retention time observed in the chromatogram of the test solution should be similar to that of the standard solution chromatogram in Assay.	Complies.
3.	Average weight	340.0 mg + 3.0 %	338.44 mg
4.	Diameter	9.50 mm ± 0.20 mm	9.50 mm
5.	Thickness	4.60 mm ± 0.30 mm	4.80 mm
6.	Uniformity of Weight	± 4.0 % of average weight.	Max: +1.23 % Min: -0.90 %
7.	Hardness	NLT 50 N	66.0 N
8.	Friability	NMT 1.0 %	0.02 %
9.	Dissolution	Limit	Avg.
	30 Min.	NMT 20.0 %	14.65 %
	2 Hour	NLT 15.0 % and NMT 40.0 %	32.46 %
	6 Hour	NLT 40.0 % and NMT 70.0 %	62.96 %
	18 Hour	NLT 80.0 %	94.57 %
10.	Assay Each uncoated sustained release tablet contains:		
	Vildagliptin IP: 100 mg	NLT 90.0 mg and NMT 110.0 mg NLT 90.0 % and NMT 110.0 %	100.43 mg 100.43 %

Remarks: The above sample complies/ does not comply to the prescribed standards of quality in respect of the above Tests as per In-process Product Specification No: **BP/IPS/V11-00**.

Particulars	Prepared By	Checked By	Approved By
Name	Sudhanshu Raiput	Taneta	trishant yadav
Designation	officer	Sr-Executive QCC	Asst. Manager
Sign & Date	 07/01/25	 07/01/25	 07/01/25