

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

Product Name	VILDAFOX 100 SR	Product code	700810
Batch No.	SIBP24438B	Sample Quantity	02 blister
Batch Size	135000.00 Nos	Date of Analysis	26/09/24
Mfg. Date	09/2024	Exp. Date:	08/2026
Specification No.	BP/FPS/V11-00	Date of Release	27/11/24
Manufacture Name	Bioaltus Pharmaceuticals Pvt. Ltd.	Analytical Report No.	BP/FP24/J31/0004
Sampling Date	26/09/24	STP. No.	BP/FP24/V11-00
Supplier Name	American Remedies Healthcare Pvt. Ltd.	Pack Size	10×15'S
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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	330.0 mg ± 3.0 %	338.70 mg
4.	Diameter	9.50 mm ± 0.20 mm	9.61 mm
5.	Thickness	4.60 mm ± 0.30 mm	4.84 mm
6.	Uniformity of Weight	± 4.0 % of average weight.	Max: +0.77 % Min: -0.92 %
7.	Hardness	NLT 55 N	69.20 N
8.	Friability	NMT 1.0 %	0.02 %
9.	Dissolution	Limit	Avg.
	30 Min.	NMT 20.0 %	9.07 %
	2 Hour	NLT 15.0 % and NMT 40.0 %	25.26 %
	6 Hour	NLT 35.0 % and NMT 60.0 %	48.20 %
	18 Hour	NLT 70.0 %	87.77 %
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 %	99.52 mg 99.52 %

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

Particulars	Prepared By	Checked By	Approved By
Name	Sudhanshu	Rejesh K. P. P. P.	Prashant Yadav
Designation	Officer	Executive	Asst. Manager
Sign & Date	 27/11/24	 27/11/24	 27/11/24