BIOALTUS Innovative & Integrated Lifecare	BIOALTUS PHARMACEUTICALS PVT. LTD.,
	DEPARTMENT: QUALITY CONTROL

CERTIFICATE OF ANALYSIS

Product Name	VILDAFOX 100 SR			**Product code**	700810
Batch No.	SIBP24173			**Sample Quantity**	02 blister
Batch Size	105000 Nos			**Date of Analysis**	30/04/24
Mfg. Date	04/2024	**Exp. Date:**	03/2026	**Date of Release**	30/05/24
Specification No.	SP/FPS/V28-00			**Analytical Report No.**	SP/FP24/D30/0008
Manufacture Name	Bioaltus Pharmaceuticals Pvt. Ltd.			**STP. No.**	SP/FPT/V28-00
Sampling Date	30/04/24			**Pack Size**	10×10'S
Supplier Name	American Remedies Healthcare Pvt. Ltd.			**Page No.**	Page **1** of **1**

Sl. No.	Tests	Specification	Results		
1.	Description	White to off white colour, round shape, biconvex, uncoated sustained release tablets, having plain on both side.	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	350.0 mg ± 4.0 %	355.62 mg		
4.	Diameter	9.50 mm ± 0.20 mm	9.50 mm		
5.	Thickness	4.50 mm ± 0.30 mm	4.78 mm		
6.	Uniformity of Weight	± 4.0 % of average weight.	Max: +1.01 %	Min: -1.21 %	
7.	Hardness	NLT 55 N	128.00 N		
8.	Friability	NMT 1.0 %	0.02 %		
9.	Dissolution	Limit	Avg.	Max.	Min.
	1st Hour	NMT 55.0 %	23.78 %	28.86 %	18.71 %
	3rd Hour	NLT 50.0 %	56.80 %	58.67 %	52.98 %
	10th Hour	NLT 80.0 %	106.33 %	112.24 %	86.30 %
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 %	102.90 mg 102.90 %		

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: **SP/FPS/V28-00.**

Particulars	Prepared By	Checked By	Approved By
Name	Divya Patel	Rajesh Kr.	Prashant yadav
Designation	Tr-Chemist	Sr. officer	Asst. Manager
Sign & Date	DP 30/05/24	30/05/24	30/05/24

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