

**BIOALTUS PHARMACEUTICALS (P) LTD., SIKKIM****DEPARTMENT: QUALITY CONTROL****CERTIFICATE OF ANALYSIS**

Product Name	GLIMSMART MV 3.3	Product code	700936
Batch No.	SIBP24391B	Sample Quantity	02 blister
Batch Size	1.0 Lacs	Date of Analysis	04/09/24
Mfg. Date	08/2024	Exp. Date:	07/2026
Specification No.	BP/FPS/M26-00	Date of Release	09/09/24
Manufacture Name	Bioaltus Pharmaceuticals Pvt. Ltd.	Analytical Report No.	BP/FP24/I07/0004
Sampling Date	04/09/24	STP. No.	BP/FPT/M26-00
Supplier Name	American Remedies Healthcare Pvt. Ltd	Pack Size	10×10'S
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Sl. No.	Tests	Specification	Results
1.	Description	Capsule shaped, biconvex, bilayer uncoated tablet having breakline on one side and plain on another side, where Glimepiride and Voglibose layer is blue colour and Metformin layer is white to off white colour.	Capsule shaped, biconvex, bilayer uncoated tablet having breakline on one side and plain on another side, where Glimepiride and Voglibose layer is blue colour and Metformin layer is off white colour.
2.	Identification		
	Glimepiride(BY HPLC)	The retention time of the Glimepiride and Voglibose in the test solution chromatogram should be similar to that of the standard solution chromatogram obtained in the Assay.	Complies
	Metformin HCL (BY UV)	The absorbance of the Metformin HCL in the test solution should correspond to that of Metformin HCL in the standard solution obtained in the assay.	Complies
3.	Average weight	750.0 mg ± 2.0 %	748.47 mg
4.	Length	15.50 mm to 15.60 mm	15.56 mm
5.	Width	9.50 mm to 9.60 mm	9.56 mm
6.	Thickness	6.10 mm ± 0.30 mm	5.93 mm
7.	Uniformity of Weight	± 4.0 % of average weight	Max: +0.59 % Min: -0.58 %
8.	Uniformity of content	NLT 85 % to NMT 115 % of Average content	Max: 107.24 % Min: 106.27 %
9.	Hardness	NLT 70 N	85.20 N
10.	Friability	NMT 1.0 %	0.01 %
11.	Assay		
	Each uncoated bilayered tablet contains:		
	Glimepiride IP : 3 mg	NLT 2.7 mg and NMT 3.3 mg NLT 90.0 % and NMT 110.0 %	3.14 mg 104.67 %
	Metformin HCL IP: 500 mg	NLT 450 mg and NMT 550 mg NLT 90.0 % and NMT 110.0 %	500.33 mg 100.07 %

Particulars	Prepared By	Checked By	Approved By
Name	Umesh Prasad	Aslan Chhetri	Prakash Yadav
Designation	Sr. Officer	Executive - QC	Asst. Manager
Sign & Date	 09/09/24	 09/09/24	 09/09/24

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12.	Dissolution	Limit	Avg.	Max.	Min.
	Metformin HCL 1 st Hour	NMT 55 %	38.51 %	39.87 %	35.93 %
	3 rd Hours	NLT 50 %	71.12 %	73.09 %	69.15 %
	10 th Hours	NLT 80 %	97.45 %	99.42 %	96.22 %

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/M26-00**.

Particulars	Prepared By	Checked By	Approved By
Name	Umesh Prayogochi	Ashish Chhetri	Sudhanshu Yadav
Designation	Sr. Officer	Executive - QC	Asst. Manager
Sign & Date	 09/09/24	 09/09/24	 09/09/24