

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

Product Name	GLIMSMART MV 3.3	Product code	700936
Batch No.	SIBP25820E	Sample Quantity	02+02 Blister
Batch Size	100000 Nos	Date of Analysis	18/12/25
Mfg. Date	12/2025	Exp. Date:	11/2027
Specification No.	BP/FPS/M25-00	Date of Release	06/01/26
Manufacture Name	Bioaltus Pharmaceuticals Pvt. Ltd.	Analytical Report No.	BP/FP26/A05/0001
Sampling Date	18/12/25	STP. No.	BP/FPT/M25-00
Supplier Name	American Remedies	Pack Size	1×10'S
		Page No.	Page 1 of 2

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 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 %	742.23 mg
4.	Uniformity of Weight	± 4.0 % of average weight	Max: +1.59 % Min: -1.70 %
5.	Length	15.50 mm to 15.60 mm	15.56 mm
6.	Width	9.50 mm to 9.60 mm	9.57 mm
7.	Thickness	6.10 mm ± 0.30 mm	6.01 mm
8.	Hardness	NLT 70 N	88.50 N
9.	Friability	NMT 1.0 %	0.04 %
10.	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 %	2.92 mg 97.23 %
	Metformin HCL IP: 500 mg (as sustained release form)	NLT 450 mg and NMT 550 mg NLT 90.0 % and NMT 110.0 %	495.91 mg 99.18 %

Particulars	Prepared By	Checked By	Approved By
Name	Ankita Kumar	Arpan Chhetri	Varun Kr. Singh
Designation	Tx. Chemist - QC	Executive - QC	Sr. Executive - Q.C.
Sign & Date	 18/12/25	 06/01/26	 06/01/26

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11.	Dissolution	Limit	Avg.	Max.	Min.
	Metformin HCL				
	1 st Hour	NMT 55 %	36.9 %	39.1 %	34.8 %
	3 rd Hours	NLT 50 %	67.5 %	68.7 %	65.9 %
	10 th Hours	NLT 80 %	91.8 %	94.0 %	90.4 %

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/M25-00**.

Particulars	Prepared By	Checked By	Approved By
Name	Ankit Kumar	Aspan Chhetri	Vaibhav Kr. Singh
Designation	Asst. Chemist - QC	Executive - QC	Sr. Executive - QC
Sign & Date	 18/12/25	 06/01/26	 06/01/26