**BIOALTUS PHARMACEUTICALS (P) LTD., SIKKIM**

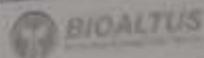
DEPARTMENT: QUALITY CONTROL

CERTIFICATE OF ANALYSIS

Product Name	GLISMART MV 3.3	Product code	700936
Batch No.	SIBP25397A	Sample Quantity	02+04 Blister
Batch Size	1.0 Lacs	Date of Analysis	24/06/25
Mfg. Date	06/2025	Exp. Date:	05/2027
Specification No.	BP/FPS/M25-00	Date of Release	02/07/25
Manufacture Name	Bioaltus Pharmaceuticals Pvt. Ltd.	Analytical Report No.	BP/FP25/G01/0001
Sampling Date	24/06/25	STP. No.	BP/FPT/M25-00
Supplier Name	American Remedies Healthcare Pvt. Ltd.	Pack Size	10x10'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 Glimpiride 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 Glimpiride and Voglibose layer is blue colour and Metformin layer is off white colour.
2.	Identification		
	Glimpiride(BY HPLC)	The retention time of the Glimpiride 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 \pm 2.0 %	748.65 mg
4.	Length	15.50 mm to 15.60 mm	15.54 mm
5.	Width	9.50 mm to 9.60 mm	9.53 mm
6.	Thickness	6.10 mm \pm 0.30 mm	5.85 mm
7.	Uniformity of Weight	\pm 4.0 % of average weight	Max: +0.94 % Min: -0.87 %
8.	Hardness	NLT 70 N	86.50 N
9.	Friability	NMT 1.0 %	0.03 %
10.	Assay		
	Each uncoated bilayered tablet contains:		

Particulars	Prepared By	Checked By	Approved By
Name	Pushanaj Raj	Ranjesh KR	Vijay K. Singh
Designation	Officer - QC	Executive	Sr. Executive
Sign & Date	 02/07/25	 02/07/25	 02/07/25

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

Product Name	GLIMSMART MV 3.3	Product code	700936
Batch No.	SIBP25397A	Sample Quantity	02+04 Blister
Batch Size	1.0 Lacs	Date of Analysis	24/06/25
Mfg. Date	06/2025	Exp. Date:	05/2027
Specification No.	BP/FPS/M25-00	Date of Release	02/07/25
Manufacture Name	Bioaltus Pharmaceuticals Pvt. Ltd.	Analytical Report No.	BP/FP25/G01/0001
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	Glimepiride IP : 3 mg	NLT 2.7 mg and NMT 3.3 mg	2.92 mg		
	Metformin HCL IP: 500 mg (as sustained release form)	NLT 90.0 % and NMT 110.0 %	97.29 %		
		NLT 450 mg and NMT 550 mg	514.18 mg		
		NLT 90.0 % and NMT 110.0 %	102.84 %		
11.	Dissolution	Limit	Avg.	Max.	Min.
	Metformin HCL				
	1 st Hour	NMT 55 %	40.58 %	42.39 %	38.78 %
	3 rd Hours	NLT 50 %	74.19 %	76.52 %	71.86 %
	10 th Hours	NLT 80 %	101.55%	103.14%	100.30%

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	Pushanac Roj	Rajesh Kr	Vaman Kr. Singh
Designation	Officer - QC	Executive	Senior Executive
Sign & Date	 02/07/25	 02/07/25	 02/07/25