

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

Product Name	GLYCOHEAL GP 3/850	Product code	700799
Batch No.	SIBP24139	Sample Quantity	02 blister
Batch Size	2.0 Lacs	Date of Analysis	26/03/24
Mfg. Date	03/2024	Exp. Date:	02/2026
		Date of Release	23/04/24
Specification No.	SP/FPS/G43-00	Analytical Report No.	SP/FP24/D23/0003
Manufacture Name	Bioaltus Pharmaceuticals Pvt. Ltd.	STP. No.	SP/FPT/G43-00
Sampling Date	26/03/24	Pack Size	10×10'S
Supplier Name	Healing Pharma India Pvt. Ltd.	Page No.	Page 1 of 2

Sl. No.	Tests	Specification	Results
1.	Description	Capsule shaped, biconvex, bilayer uncoated tablet where Glimepiride layer is yellow having break line and Metformin layer is white to off white colour having plain side.	Capsule shaped, biconvex, bilayer uncoated tablet where Glimepiride layer is yellow having break line and Metformin layer is off white colour having plain side.
2.	Identification		
	Glimepiride	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	1270.0 mg $\pm$ 5.0 %	1263.66 mg
4.	Length	21.00 mm $\pm$ 0.20 mm	21.07 mm
5.	Width	9.00 mm $\pm$ 0.20 mm	9.09 mm
6.	Thickness	7.00 mm $\pm$ 0.30 mm	6.72 mm
7.	Uniformity of Weight	$\pm$ 5.0 % of average weight	Max: +0.64 % Min: -0.95 %
8.	Hardness	NLT 90 N	152.60 N
9.	Friability	NMT 1.0 %	0.01 %
10.	Uniformity of Content	85 to 115 % of Average content	Max: 101.74 % Min: 97.10 %
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 %	2.981 mg 99.36 %
	Metformin HCL IP: 850 mg (as prolonged release form)	NLT 765 mg and NMT 935 mg NLT 90.0 % and NMT 110.0 %	840.117 mg 98.84 %

Particulars	Prepared By	Checked By	Approved By
Name	Rajesh K.R.	Arpan Chhetri	Sreenat Ch. Das
Designation	Sr. officer	Sr. officer	Manager QA
Sign & Date	 23/04/24	 23/04/24	 23/04/24

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	Dissolution	Limit	Avg.	Max.	Min.
12.	Metformin HCL				
	1 st Hour	NMT 55 %	47.36 %	48.39 %	46.63 %
	3 rd Hour	NLT 50 %	74.28 %	74.96 %	73.46 %
	10 th Hour	NLT 80 %	98.60 %	100.04 %	98.03 %

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/G43-00**.

Particulars	Prepared By	Checked By	Approved By
Name	Rajesh K R	Arpan Chhetri	Shankar Choudhary
Designation	Sr. officer	Sr. officer	Manager, QA
Sign & Date	 23/04/24	 23/04/24	 23/04/24