

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

Product Name	GLYCOHEAL GP 3/850	Product code	700799
Batch No.	SIBP24313	Sample Quantity	02 blister
Batch Size	200000 Nos	Date of Analysis	29/07/24
Mfg. Date	07/2024	Exp. Date:	06/2026
Specification No.	SP/FPS/G43-01	Date of Release	16/08/24
Manufacture Name	Bioaltus Pharmaceuticals Pvt. Ltd.	Analytical Report No.	SP/FP24/H16/0002
Sampling Date	29/07/24	STP. No.	SP/FPT/G43-01
Supplier Name	Healing Pharma India Pvt. Ltd.	Pack Size	10×10'S
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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	1273.0 mg $\pm$ 4.0 %	1266.64 mg
4.	Length	21.00 mm $\pm$ 0.20 mm	21.09 mm
5.	Width	9.00 mm $\pm$ 0.20 mm	9.09 mm
6.	Thickness	6.70 mm $\pm$ 0.30 mm	6.67 mm
7.	Uniformity of Weight	$\pm$ 4.0 % of average weight	Max: +0.82 % Min: -0.89 %
8.	Hardness	NLT 90 N	129.0 N
9.	Friability	NMT 1.0 %	0.01 %
10.	Uniformity of Content Glimepiride	NLT 85 % to NMT 115 % of Average content	Max: 100.36 % Min: 99.38 %
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 %	3.06 mg 102.00 %

Particulars	Prepared By	Checked By	Approved By
Name	Pushka r Raj	Rajesh Kr.	trishant yadav
Designation	Tr. Chemist	Executive	Asst. Manager
Sign & Date	 16/08/24	 16/08/24	 16/08/24

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	Metformin HCL IP: 850 mg (as prolonged release form)	NLT 765 mg and NMT 935 mg NLT 90.0 % and NMT 110.0 %	876.10 mg 103.07 %		
12.	Dissolution	Limit	Avg.	Max.	Min.
	Glimepiride	(Q) NLT 70 %	90.95 %	92.99 %	89.98 %
	Metformin HCL				
	1 Hour	NMT 55 %	35.29 %	36.15 %	34.78 %
	3 Hour	NLT 50 %	62.59 %	64.06 %	61.32 %
	10 Hour	NLT 80 %	93.98 %	95.48 %	91.06 %

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/G43-01**.

Particulars	Prepared By	Checked By	Approved By
Name	Pustkhar Raj	Rejesh Kr.	trishant yadav
Designation	Pr. Chemist	Executive	Asst. Manager
Sign & Date	 16/08/24	 16/08/24	 16/08/24