

**BIOALTUS PHARMACEUTICALS PVT.LTD.**

At: 19-20 Industrial Area, Baddi -173205 Distt. Solan

QUALITY CONTROL DEPARTMENT**CERTIFICATE OF ANALYSIS**

Product Name	Glimepiride 1 mg, Voglibose 0.2 mg & Metformin Hydrochloride 500 mg (Sustained Release) Tablets (GLYCOHEAL TRIO 1)	A.R. No.	BRDII/11/24/BD/1527TF
Master/FG B. No.	BD242359/ BD242359	Master/FG B. Size	3.0Lac/3.0Lac
Mfd. By	Self	Sample Qty.	100 Tablets
MFD.	NOV.2024	Date of Receipt	10/12/2024
EXP.	OCT.2026	Date of Release	10/12/2024

RESULTS OF ANALYSIS**Reference to Protocol : In House Specification**

S.No.	Test	Results	Specification
01.	Description	Bilayered elongated shaped biconvex uncoated tablets with one side white plain layer & other side orange coloured layer with central breakline.	Bilayered elongated shaped biconvex uncoated tablets with one side white plain layer & other side orange coloured layer with central breakline.
02.	Identification	Complies	To Comply
03.	Average weight	0.75265 gm	0.7500 gm $\pm$ 3.0%
04.	Uniformity of weight	Min. 0.7448 gm, Max. 0.7623gm	$\pm$ 5.0% of average weight
05.	Friability	0.26 % w/w	NMT 1.0 % w/w
06.	Hardness	Min. 8.0 Kg/cm ² Max. 9.0 Kg/cm ²	NLT 2.0 Kg/cm ²
07.	Uniformity of content (By HPLC) For Glimepiride *For Voglibose	Min. 99.19 %, Max. 101.51 % average content 1.04 mg Min. 95.94,Max. 104.25 % average content 0.2007 mg	NLT 85% & NMT 115% of the average content NLT 85% & NMT 115% of the average content
08.	Dissolution (By UV) For Metformin Hydrochloride Release in 1 st Hour Release in 3 rd Hours Release in 8 th Hours	Min. 36.88 %, Max.39.89 % Mean 38.07% Min. 67.83 %, Max.70.29 % Mean 69.15 % Min. 97.11 %, Max.98.90 % Mean 98.39%	NLT 20 % & NMT 50 % NLT 50 % & NMT 75 % NLT 75 %
09.	Assay Each uncoated bilayered tablet contains: Glimepiride IP 1 mg (By HPLC) *Voglibose IP 0.2 mg (By HPLC) Metformin Hydrochloride IP 500 mg (As sustained release)(By UV)	1.041 mg (104.1%) 0.20 mg (100.0%) 493.93 mg (98.8 %)	NLT 0.90 mg & NMT 1.10 mg (NLT 90.0 % & NMT 110.0 %) NLT 0.18 mg & NMT 0.22 mg (NLT 90.0 % & NMT 110.0 mg) NLT 450.0 mg & NMT 550.0 mg (NLT 90.0% & NMT 110.0 %)

Remark: In the opinion of the undersigned, the sample referred to above is of **standard quality**/is not of standard quality as defined in the Act and the Rules made there under for the reasons given below:

Complies as per **In House Specification No. BRD II/QC/FPS/201U1**

*Test complies as per Aashirvad Lab Report No. AAFP/A0612-002/24

	Prepared By	Checked By	Approved By
Name	Priteek kaur	Priyanka	Harpreet kaur
Designation	QC officer	Reviewer	Manager QC
Sign/Date	 10/12/2024	 10/12/2024	 10/12/2024

B. Phatma
Reg No. 48650