

**BIOALTUS PHARMACEUTICALS PVT.LTD.**

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

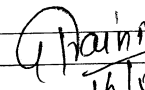
QUALITY CONTROL DEPARTMENT**CERTIFICATE OF ANALYSIS**

Product Name	Voglibose 0.2 mg, Glimepiride 2 mg & Metformin Hydrochloride 500 mg (Sustained Release) Tablets (GLYCOHEAL TRIO 2)	A.R. No.	BRDII/04/24/BD/0087TF
Batch No.	BD240674/ BD240674	Batch Size	2.0 Lac/2.0 Lac
Mfd. By	Self	Sample Qty.	100 Tablets
MFD.	APR.2024	Date of Receipt	16/05/2024
EXP.	MAR.2026	Date of Release	16/05/2024

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 blue colored layer, with central breakline.	Bilayered elongated shaped biconvex uncoated tablets with one side white plain layer & other side blue colored layer, plain on both sides.
02.	*Identification	Complies	To Comply
03.	Average weight	0.75295 gm	0.7500 gm $\pm$ 3.0%
04.	Uniformity of weight	Min. 0.7438 gm, Max. 0.7600 gm	$\pm$ 5.0% of average weight
05.	Friability	0.18 % w/w	NMT 1.0 % w/w
06.	Hardness	Min. 9.0 Kg/cm ² Max. 10.0 Kg/cm ²	NLT 2.0 Kg/cm ²
07.	Uniformity of content (By HPLC) For Glimepiride *For Voglibose	Min. 99.25 %, Max. 100.56 % average content 2.06 mg Min. 96.03 %, Max. 104.87 % average content 0.2075 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. 37.37 %, Max.41.09 % Mean 39.45 % Min. 68.33 %, Max.71.82 % Mean 70.05 % Min. 97.14 %, Max. 100.07 % Mean 98.42 %	NLT 20 % & NMT 50 % NLT 50 % & NMT 75 % NLT 75 %
09.	Assay Each uncoated bilayered tablet contains: *Voglibose IP 0.2 mg Glimepiride IP 2 mg Metformin Hydrochloride IP 500 mg (As sustained release) (By UV)	0.1974 mg (98.7 %) 2.084 mg (104.2 %) 497.71 mg (99.5 %)	NLT 0.18 mg & NMT 0.22 mg (NLT 90.0 % & NMT 110.0 %) NLT 1.80 mg & NMT 2.20 mg (NLT 90.0 % & NMT 110.0 %) NLT 450.0 mg & NMT 550.0 mg (NLT 90.0% & 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/161U1**
*Test complies as per Oxigen Lab. Report No. OALB240419084

Prepared By		Checked By		Approved By	
Date	16/05/2024	Date	16/05/2024	Date	16/05/2024