BIOALTUS

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 (SR) Tablets (GLYCOHEAL TRIO 2)**	**A.R. No.**	BRDII/06/24/BD/0503TF
Master/FG B. No.	BD241132/BD241132	**Master/FG B. Size.**	2.0 Lac/2.0 Lac
Mfd. By	Self	**Sample Qty.**	100 Tablets
MFD.	JUN.2024	**Date of Receipt**	02/07/2024
EXP.	MAY 2026	**Date of Release**	02/07/2024

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 coloured layer with central breakline.	Bilayered elongated shaped biconvex uncoated tablets with one side white plain layer & other side Blue coloured layer with central breakline.
02.	**Identification**	Complies	To Comply
03.	**Average weight**	0.75320 gm	0.7500 gm ± 3.0%
04.	**Uniformity of weight**	Min. 0.7496 gm, Max.0.7585gm	±5.0% of average weight
05.	**Friability**	0.13 % 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. 99.53%, Max. 100.61 % average content 1.93 mg Min. 93.89 %, Max. 106.35 % average content 0.20010mg	 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 1st Hour Release in 3rd Hours Release in 8th Hours	 Min. 37.36 %, Max. 41.11% Mean 39.27% Min. 66.90 %, Max.70.09% Mean 68.44 % Min. 95.88 %, Max. 98.97% Mean 97.28 %	 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)**	 0.2037 mg (101.8%) 1.958 mg (97.9 %) 505.31 mg (101.1 %)	 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. OALB240628242

Prepared By		**Checked By**		**Approved By**	
Date	02/07/2024	**Date**	02/07/2024	**Date**	02/07/2024