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 (SR) Tablets (GLYCOHEALTRIO 1)**	**A.R. No.**	BRDII/06/24/BD/0519TF
Master/FG B. No.	BD241184/BD241184	**Master/FG B. Size.**	3.0 Lac/3.0 Lac
Mfd. By	Self	**Sample Qty.**	100 Tablets
MFD.	JUN.2024	**Date of Receipt**	07/07/2024
EXP.	MAY 2026	**Date of Release**	07/07/2024

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 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**	0.75309gm	0.7500 gm ± 3.0%
04.	**Uniformity of weight**	Min. 0.7418 gm, Max. 0.7622 gm	±5.0% of average weight
05.	**Friability**	0.15 % 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. 99.37 %, Max. 100.66 % average content 0.95 mg Min. 94.67 %, Max. 105.75% average content 0.2002 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 1st Hour Release in 3rd Hours Release in 8th Hours	 Min. 36.25 %, Max. 40.25 % Mean 38.51% Min. 67.05 %, Max.70.17% Mean 68.94 % Min. 95.08 %, Max.99.19 % Mean 97.45 %	 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)**	 0.992 mg (99.2 %) 0.2005 mg (100.2 %) 511.40 mg (102.3 %)	 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 Oxigen Lab Report No. OALB240629047**

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