

**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/07/24/BD/0752TF
Master/FG B. No.	BD241448/BD241448	Master/FG B. Size	2.0 Lac/2.0 Lac
Mfd. By	Self	Sample Qty.	100 Tablets
MFD.	JUL.2024	Date of Receipt	05/08/2024
EXP.	JUN.2026	Date of Release	05/08/2024

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	0.74728gm	0.7500 gm $\pm$ 3.0%
04.	Uniformity of weight	Min. 0.7415 gm, Max.0.7569 gm	$\pm$ 5.0% of average weight
05.	Friability	0.17 % w/w	NMT 1.0 % w/w
06.	Hardness	Min. 7.0 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. 99.14%, Max. 101.42 % average content 1.95mg Min. 91.78 %, Max. 111.07 % average content 0.2043 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. 37.55%, Max. 41.16% Mean 39.13 % Min. 67.44 %, Max.72.85 % Mean 69.75 % Min. 96.76%, Max. 100.59% Mean 99.35%	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)	0.2034 mg (101.7%) 1.952 mg (97.6 %) 499.92mg (100.0 %)	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% & 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/161U1**

*Test complies as per Oxigen Lab Report No. OALB240801265

Prepared By	<i>Carima</i>	Checked By	<i>[Signature]</i>	Approved By	<i>[Signature]</i>
Date	05/08/2024	Date	05/08/2024	Date	05/08/2024