

**BIOALTUS PHARMACEUTICALS PVT.LTD.**

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

QUALITY CONTROL DEPARTMENT**CERTIFICATE OF ANALYSIS**

Product Name	Glimepiride 2 mg, Voglibose 0.3 mg & Metformin Hydrochloride 500 mg (SR) Tablets (Glismart MV 2.3)	A.R. No.	BRDII/07/24/BD/0693TF
Master/FG B. No.	BD241354/BD241354A	Master/FG B. Size	3.0 Lac/1.0 Lac
Mfd. By	Self	Sample Qty.	100 Tablets
MFD.	JUL.2024	Date of Receipt	14/08/2024
EXP.	JUN.2026	Date of Release	14/08/2024

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 pink coloured layer with central breakline.	Bilayered elongated shaped biconvex uncoated tablets with one side white plain layer & other side pink coloured layer with central breakline.
02.	Identification	Complies	To Comply
03.	Average weight	0.74963 gm	0.7500 gm \pm 3.0%
04.	Uniformity of weight	Min. 0.7380gm, Max. 0.7632 gm	\pm 5.0% of average weight
05.	Friability	0.26% w/w	NMT 1.0 % w/w
06.	Hardness	Min. 6.0 Kg/cm ² Max. 7.0 Kg/cm ²	NLT 2.0 Kg/cm ²
07.	Uniformity of content (By HPLC) For Glimepiride *For Voglibose	Min. 99.16 %, Max. 102.85% average content 2.14 mg Min. 94.62 %, Max. 106.66 % average content 0.3012mg	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. 37.61 %, Max. 40.40% Mean 38.95 % Min. 67.74%, Max. 70.64 % Mean 69.19% Min. 95.87%, Max.98.88 % Mean 97.89%	NLT 20 % & NMT 50 % NLT 50 % & NMT 75 % NLT 75 %
09.	Assay Each uncoated bilayered tablet contains: Glimepiride IP 2 mg *Voglibose IP 0.3 mg Metformin Hydrochloride IP 500 mg (As sustained release) (By UV)	2.079mg (104.0 %) 0.3050 mg (101.7%) 493.51 mg (98.7%)	NLT 1.80 mg & NMT 2.20 mg (NLT 90.0 % & NMT 110.0 %) NLT 0.27 mg & NMT 0.33 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/299U2**

*Test complies as per **Oxygen Lab Report No. OALB240725145**

Prepared By		Checked By		Approved By	
Date	14/08/2024	Date	14/08/2024	Date	14/08/2024