



BIOALTUS PHARMACEUTICALS PVT.LTD.

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

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Product Name	Glimepiride 1 mg, Voglibose 0.3 mg & Metformin Hydrochloride 500 mg (Sustained Release) Tablets (GLIMSMART-MV 1.3)	A.R. No.	BRDII/02/26/BD/373TF
Master/FG.B.No.	BD260380/BD260380A	Master/FG.B.Size	1.50 Lac/1.0 Lac
Mfd. By	Self	Sample Qty.	100 Tablets
MFD.	FEB.2026	Date of Receipt	21/02/2026
EXP.	JAN.2028	Date of Release	21/02/2026

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 layer & other side yellow coloured layer with central breakline.	Bilayered elongated shaped biconvex uncoated tablets with one side white layer & other side yellow coloured layer with central breakline.
02.	Identification	Complies	To Comply
03.	Average weight	0.75052 gm	0.75052 gm \pm 3.0%
04.	Uniformity of weight	Min. 0.7315 gm, Max. 0.7653 gm	\pm 5.0% of average weight
05.	Friability	0.23 % w/w	NMT 1.0 % w/w
06.	Hardness	Min. 7.0 Kg/cm ² Max. 8.0 Kg/cm ²	NLT 2.0 Kg/cm ²
07.	Uniformity of content (By HPLC) For Glimepiride *For Voglibose	Min. 99.13 %, Max. 101.39 % average content 1.01 mg Min. 96.96 %, Max. 100.35 % average content 0.29679 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. 40.31 %, Max. 42.00 % Mean 41.08 % Min. 70.88 %, Max. 72.80 % Mean 71.93 % Min. 99.41 %, Max. 100.65 % Mean 100.03 %	NLT 20 % & NMT 50 % NLT 50 % & NMT 75 % NLT 75 %
09.	Assay Each uncoated bilayered tablet contains: Glimepiride IP 1 mg *Voglibose IP 0.3 mg Metformin Hydrochloride IP 500 mg (As sustained release)	0.993 mg (99.3 %) 0.307 mg (102.2 %) 493.96 mg (98.8 %)	NLT 0.90 mg & NMT 1.10 mg (NLT 90.0 % & NMT 110.0 %) NLT 0.27 mg & NMT 0.33 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/266U1

*Test complies as per AAS Lab. Report No. AAFP/A1202-006/26

	Prepared By	Checked By	Approved By
Name	Sham Rana	Sapam	Navsh Kumar
Designation	ac officer	Reviewer	Manager Qc
Sign/Date	 21/02/2026	 21/02/2026	 21/02/2026