

**BIOALTUS PHARMACEUTICALS PVT.LTD.**

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

QUALITY CONTROL DEPARTMENT**CERTIFICATE OF ANALYSIS**

Product Name	Glimepiride 2 mg and Metformin Hydrochloride (Prolonged Release) 500 mg Tablets IP (Glycoheal G 502)	A.R. No.	BRDII/11/24/BD/1494TF
Master/FG B. No.	BD242233/ BD242233A	Master/FG B. Size	18.0 Lac/15.0 Lac
Mfd. By	Self	Sample Qty.	75 Tablets
MFD.	NOV.2024	Date of Receipt	01/12/2024
EXP.	OCT.2026	Date of Release	01/12/2024

RESULTS OF ANALYSIS

Reference to Protocol : IP			
S.No.	Test	Results	Specification
01.	Description	Bilayered elongated shaped biconvex uncoated tablets with one side white plain layer & other side yellow coloured layer, with central breakline.	Bilayered elongated shaped biconvex uncoated tablets with one side white plain layer & other side yellow coloured layer, with central breakline.
02.	Identification For Glimepiride (By HPLC) For Metformin (By UV)	Complies Complies	To Comply To Comply
03.	Average weight	0.75021 gm	0.7500 gm $\pm$ 3.0%
04.	Uniformity of weight	Min. 0.7418 gm, Max. 0.7660gm	$\pm$ 5.0% of average weight
05.	Friability	0.24 % 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	Min. 98.72 %, Max. 104.88 % average content 2.12 mg	NLT 85% & NMT 115% of the average content
08.	Dissolution (By UV) For Metformin Hydrochloride Release in 1.0 Hour Release in 3.0 Hours Release in 8.0 Hours For Glimepiride (By HPLC)	Min. 37.84 %, Max. 40.08 % Mean 38.96 % Min. 67.95 %, Max. 70.19 % Mean 68.92 % Min. 95.83 %, Max. 99.41 % Mean 97.51 % Min. 85.88%, Max. 93.01 % Mean 88.85%	NLT 20 % & NMT 50 % NLT 50 % & NMT 75 % NLT 75 % Q.NLT 70 %
09.	Assay Each uncoated bilayered tablet contains: Glimepiride IP 2 mg (By HPLC) Metformin Hydrochloride IP 500mg (As Prolonged release form)(By UV)	2.063 mg (103.2 %) 495.59 mg (99.1 %)	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 IP (BRD II/QC/FPS/170 U1)

	Prepared By	Checked By	Approved By
Name	Puteek kaur	Priyanka	Harpreet kaur
Designation	QC officer	Reviewer	Manager QC
Sign/Dte	 01/12/2024	 01/12/2024	 01/12/2024

B. Pharma
Reg no. 48650