

**BIOALTUS PHARMACEUTICALS PVT.LTD.**

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

QUALITY CONTROL DEPARTMENT**CERTIFICATE OF ANALYSIS**

Product Name	Glimepiride 1 mg & Metformin Hydrochloride (PR)1000 mg Tablets IP (Glycoheal G 1001)	A.R. No.	BRDII/07/24/BD/0717TF
Master/FG B. No.	BD241391/BD241391E	Master/FG B. Size	4.50 Lac/2.0 Lac
Mfd. By	Self	Sample Qty.	70 Tablets
MFD.	JUL.2024	Date of Receipt	06/09/2024
EXP.	JUN.2026	Date of Release	06/09/2024

RESULTS OF ANALYSIS

Reference to Protocol : IP

S.No.	Test	Results	Specification
01.	Description	Bilayered elongated shaped biconvex film coated tablets with one side white layer & other side pink coloured layer with a central break line.	Bilayered elongated shaped biconvex film coated tablets with one side white layer & other side pink coloured layer with a central break line.
02.	Identification For Glimepiride (By HPLC) For Metformin Hydrochloride (By UV)	Complies Complies	To Comply To Comply
03.	Average weight	1.36975 gm	1.3730 gm $\pm$ 3.0%
04.	Uniformity of weight	Min. 1.3429 gm Max.1.3908gm	$\pm$ 5.0% of average weight
05.	Uniformity of content (By HPLC) For Glimepiride	Min. 98.12%, Max. 102.07 % average content 0.96 mg	NLT 85.0 % & NMT 115.0% of the average content
06.	Dissolution For Metformin Hydrochloride (By UV) Release in 1 st Hour Release in 3 rd Hours Release in 8 th Hours For Glimepiride (By HPLC)	Min. 36.52 %, Max. 40.75 % Mean 39.01 % Min. 66.59 %, Max. 70.60% Mean 68.78% Min. 95.76 %, Max. 99.10 % Mean 97.51 % Min. 84.31 %, Max. 89.99 % Mean 88.00 %	NLT 20 % & NMT 50 % NLT 50 % & NMT 75 % NLT 75 % Q.NLT 70 %
07.	Assay Each film coated bilayered tablet contains: Glimepiride IP 1 mg (By HPLC) Metformin Hydrochloride IP 1000 mg (As prolonged release form)(By UV)	0.989 mg (98.9%) 982.07 mg (98.2 %)	NLT 0.90 mg & NMT 1.10 mg (NLT 90.0 % & NMT 110.0 %) NLT 900.0 mg & NMT 1100.0 mg (NLT 90.0% & NMT110.0 %)

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/0152U3)

Prepared By		Checked By		Approved By	
Date	06/09/2024	Date	06/09/2024	Date	06/09/2024

