



BIOALTUS PHARMACEUTICALS PVT.LTD.
19-20 Industrial Area, Baddi -173205 Distt. Solan
QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Product Name	Glimepiride 1 mg & Metformin Hydrochloride (PR) 500 mg Tablets IP (Glycoheal G 501)	A.R. No.	BRDII/08/24/BD/0868TF
Master/FG B.No.	BD241508/BD241508	Master/FG B. Size	15.0 Lac/15.0 Lac
Mfd. B	Self	Sample Qty.	75Tablets
MFD.	AUG.2024	Date of Receipt	30/08/2024
EXP.	JUL.2026	Date of Release	30/08/2024

RESULTS OF ANALYSIS

Reference to Protocol : IP

S.No.	Test	Results	Specification
01.	Description	Bilayered elongated shaped biconvex uncoated tablets with one side white layer & other side pink coloured layer with central breakline.	Bilayered elongated shaped biconvex uncoated tablets with one side white layer & other side pink coloured layer with central breakline.
02.	Identification For Glimepiride (By HPLC) For Metformin Hydrochloride (By UV)	Complies Complies	To Comply To Comply
03.	Average weight	0.75041 gm	0.7500 gm $\pm$ 3.0%
04.	Uniformity of weight	Min. 0.7423gm Max.0.7603 gm	$\pm$ 5.0% of average weight
05.	Friability	0.20 % 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. 97.77%, Max. 101.29 % average content 1.07 mg	NLT 85% & NMT 115% of the average content
08.	Dissolution For Metformin Hydrochloride (By UV) Release in 1 Hour Release in 3 Hours Release in 8 Hours For Glimepiride (By HPLC)	Min. 36.16 %, Max. 40.06 % Mean 38.41% Min. 67.88 %, Max. 69.99% Mean 68.90 % Min. 96.48 %, Max. 98.81% Mean 97.48 % Min. 93.16%, Max. 101.50 % Mean 96.27 %	NLT 20 % & NMT 50 % NLT 50 % & NMT 75 % NLT 75 % Q.NLT 70 %
09.	Assay Each uncoated bilayered tablet contains: Glimepiride IP 1 mg (By HPLC) Metformin Hydrochloride IP 500 mg (As prolonged release form) (By UV)	1.031 mg (103.1%) 491.43 mg (98.3%)	NLT 0.90 mg & NMT 1.10 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/156U1)

Prepared By		Checked By		Approved By	
Date	30/08/2024	Date	30/08/2024	Date	30/08/2024

