



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 (PR) 500 mg Tablets IP (Glycoheal G 502)	A.R. No.	BRDII/08/24/BD/0797TF
Master/FGB. No.	BD241488/ BD241488	Master/FGB.Size	15.0 Lac/15.0 Lac
Mfd. By	Self	Sample Qty.	75 Tablets
MFD.	AUG.2024	Date of Receipt	31/08/2024
EXP.	JUL.2026	Date of Release	31/08/2024
RESULTS OF ANALYSIS			
Reference to Protocol : IP			
S.No.	Test	Results	Specification
01.	Description	Bilayered elongated shaped biconvex uncoated tablets with one side white plain layer & other side yellow colored layer, with central break line.	Bilayered elongated shaped biconvex uncoated tablets with one side white plain layer & other side yellow colored layer, with central break line.
02.	Identification For Glimepiride (By HPLC) For Metformin Hydrochloride (By UV)	Complies Complies	To Comply To Comply
03.	Average weight	0.75513 gm	0.7500 gm $\pm$ 3.0%
04.	Uniformity of weight	Min.0.7388 gm, Max.0.7697 gm	$\pm$ 5.0% of average weight
05.	Friability	0.20 % w/w	NMT 1.0 % w/w
06.	Hardness	Min. 6.0Kg/cm ² Max.7.0Kg/cm ²	NLT 2.0 Kg/cm ²
07.	Uniformity of content (By HPLC) For Glimepiride	Min. 98.84 %, Max. 102.98 % average content 2.08 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. 37.28 %, Max. 39.72 % Mean 38.54 % Min. 67.01 %, Max. 69.79 % Mean 68.75 % Min. 94.75 %, Max. 98.75 % Mean. 96.58 % Min. 80.61 %, Max.85.44 % Mean 82.89 %	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 IP500 mg (As Prolonged release form)(By UV)	1.997 mg (99.8 %) 509.19 mg (101.8 %)	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/170U1)			
Prepared By		Checked By	
Date	31/08/2024	Date	31/08/2024
Approved By			
Date	31/08/2024		

