

CERTIFICATE OF ANALYSIS

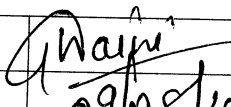
Product Name	Glimepiride 0.5 mg & Metformin Hydrochloride (PR) 500 mg Tablets IP (Glycoheal G Semi)	A.R. No.	BRDII/08/24/BD/0782TF
Master/FG B. No.	BD241477/BD241477	Master/FG B. Size	2.0 Lac/2.0 Lac
Mfd. By	Self	Sample Qty.	70 Tablets
MFD.	JUL.2024	Date of Receipt	09/08/2024
EXP.	JUN.2026	Date of Release	09/08/2024

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 pink coloured layer, with central breakline.	Bilayered elongated shaped biconvex uncoated tablets with one side white plain 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	0.75181 gm	0.7500 gm $\pm$ 3.0%
04.	Uniformity of weight	Min. 0.7407 gm Max. 0.7606 gm	$\pm$ 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. 98.98 %, Max. 102.04 % average content 0.50 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. 35.06 %, Max. 40.16 % Mean 38.15 % Min. 67.01 %, Max. 71.67 % Mean 68.55 % Min. 95.08 %, Max. 98.75 % Mean 97.03 % Min. 88.20 %, Max. 90.55 % Mean 89.77 %	 NLT 20 % & NMT 50 % NLT 50 % & NMT 75 % NLT 75 % Q.NLT 70 %
09.	Assay Each uncoated bilayered tablet contains: Glimepiride IP 0.5 mg (By HPLC) Metformin Hydrochloride IP 500 mg (as prolonged release form) (By UV)	0.494 mg (98.7 %) 506.87 mg (101.4 %)	NLT 0.45 mg & NMT 0.55 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/262U2)

Prepared By		Checked By		Approved By	
Date	09/08/2024	Date	09/08/2024	Date	09/08/2024