

CERTIFICATE OF ANALYSIS

Product Name	Glimepiride 0.5 mg & Metformin Hydrochloride Sustained Release 500 mg Tablets IP (Glycoheal G Semi)	A.R. No.	BRDII/10/24/BD/1271TF
Master/FG B. No.	BD242108/ BD242108	Master/FG B. Size	2.0 Lac/2.0 Lac
Mfd. By	Self	Sample Qty.	70 Tablets
MFD.	OCT.2024	Date of Receipt	08/11/2024
EXP.	SEP.2026	Date of Release	08/11/2024

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	0.75286 gm	0.7500 gm $\pm$ 3.0%
04.	Uniformity of weight	Min. 0.7460 gm Max. 0.7596 gm	$\pm$ 5.0% of average weight
05.	Friability	0.25 % 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. 97.81 %, Max. 101.93% average content 0.48 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. 38.02%, Max. 39.82 % Mean 38.85 % Min. 68.06 %, Max. 70.08 % Mean 69.39 % Min. 96.93 %, Max. 99.64 % Mean 98.70% Min. 87.23 %, Max. 94.66 % Mean 91.05%	 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 Sustained release form) (By UV)	0.512 mg (102.4%) 500.31 mg (100.1%)	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
Name	P. K. Kaur	Priyanka	Harpreet Kaur
Designation	QC Officer	Reviewer	Manager QC
Sign / Date	08/11/2024	08/11/2024	08/11/2024