

CERTIFICATE OF ANALYSIS

Product Name	Voglibose 0.2 mg, Glimepiride 2 mg & Metformin Hydrochloride 500 mg (SR) Tablets (GLYCOHEAL TRIO 2)	A.R. No.	BRDII/06/24/BD/0503TF
Master/FG B. No.	BD241132/BD241132	Master/FG B. Size.	2.0 Lac/2.0 Lac
Mfd. By	Self	Sample Qty.	100 Tablets
MFD.	JUN.2024	Date of Receipt	02/07/2024
EXP.	MAY 2026	Date of Release	02/07/2024

RESULTS OF ANALYSIS

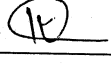
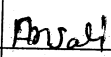
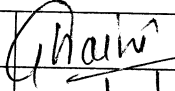
Reference to Protocol : In House Specification

S.No.	Test	Results	Specification
01.	Description	Bilayered elongated shaped biconvex uncoated tablets with one side white plain layer & other side Blue coloured layer with central breakline.	Bilayered elongated shaped biconvex uncoated tablets with one side white plain layer & other side Blue coloured layer with central breakline.
02.	Identification	Complies	To Comply
03.	Average weight	0.75320 gm	0.7500 gm $\pm$ 3.0%
04.	Uniformity of weight	Min. 0.7496 gm, Max.0.7585gm	$\pm$ 5.0% of average weight
05.	Friability	0.13 % w/w	NMT 1.0 % w/w
06.	Hardness	Min. 8.0 Kg/cm ² Max. 9.0 Kg/cm ²	NLT 2.0 Kg/cm ²
07.	Uniformity of content (By HPLC) For Glimepiride #For Voglibose	Min. 99.53%, Max. 100.61 % average content 1.93 mg Min. 93.89 %, Max. 106.35 % average content 0.20010mg	NLT 85% & NMT 115% of the average content NLT 85% & NMT 115% of the average content
08.	Dissolution (By UV) For Metformin Hydrochloride Release in 1 st Hour Release in 3 rd Hours Release in 8 th Hours	Min. 37.36 %, Max. 41.11% Mean 39.27% Min. 66.90 %, Max.70.09% Mean 68.44 % Min. 95.88 %, Max. 98.97% Mean 97.28 %	NLT 20 % & NMT 50 % NLT 50 % & NMT 75 % NLT 75 %
09.	Assay Each uncoated bilayered tablet contains: #Voglibose IP 0.2 mg Glimepiride IP 2 mg Metformin Hydrochloride IP 500 mg (As sustained release) (By UV)	0.2037 mg (101.8%) 1.958 mg (97.9 %) 505.31 mg (101.1 %)	NLT 0.18 mg & NMT 0.22 mg (NLT 90.0 % & NMT 110.0 %) 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% & 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 In House Specification No. BRD II/QC/FPS/161U1

#Test complies as per Oxigen Lab Report No. OALB240628242

Prepared By		Checked By		Approved By	
Date	02/07/2024	Date	02/07/2024	Date	02/07/2024