



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

**CERTIFICATE OF ANALYSIS**

|                  |                                                                                                     |                   |                       |
|------------------|-----------------------------------------------------------------------------------------------------|-------------------|-----------------------|
| Product Name     | Glimepiride 1 mg, Voglibose 0.3 mg & Metformin Hydrochloride 500 mg (SR) Tablets (HEALMARYL MV 1.3) | A.R. No.          | BRDII/12/24/BD/1630TF |
| Master/FG B. No. | BD242426/ BD242426                                                                                  | Master/FG B. Size | 2.0 Lac/2.0 Lac       |
| Mfd. By          | Self                                                                                                | Sample Qty.       | 100 Tablets           |
| MFD.             | DEC.2024                                                                                            | Date of Receipt   | 30/12/2024            |
| EXP.             | NOV.2026                                                                                            | Date of Release   | 02/01/2025            |

**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 layer & other side yellow coloured layer with central breakline. | Bilayered elongated shaped biconvex uncoated tablets with one side white layer & other side yellow coloured layer with central breakline.                                      |
| 02.   | Identification                                                                                                                                                          | Complies                                                                                                                                  | To Comply                                                                                                                                                                      |
| 03.   | Average weight                                                                                                                                                          | 0.74996 gm                                                                                                                                | 0.7500 gm $\pm$ 3.0%                                                                                                                                                           |
| 04.   | Uniformity of weight                                                                                                                                                    | Min. 0.7371gm, Max. 0.7633 gm                                                                                                             | $\pm$ 5.0% of average weight                                                                                                                                                   |
| 05.   | Friability                                                                                                                                                              | 0.23 % w/w                                                                                                                                | NMT 1.0 % w/w                                                                                                                                                                  |
| 06.   | Hardness                                                                                                                                                                | Min. 6.0 Kg/cm <sup>2</sup><br>Max. 7.0 Kg/cm <sup>2</sup>                                                                                | NLT 2.0 Kg/cm <sup>2</sup>                                                                                                                                                     |
| 07.   | Uniformity of content (By HPLC)<br>For Glimepiride<br><br>*For Voglibose                                                                                                | Min. 99.46 %, Max. 100.78 %<br>average content 0.99 mg<br>Min. 93.28 %, Max. 108.80 %<br>average content 0.3006 mg                        | NLT 85% & NMT 115% of the average content<br>NLT 85% & NMT 115% of the average content                                                                                         |
| 08.   | Dissolution (By UV)<br>For Metformin Hydrochloride<br>Release in 1 <sup>st</sup> Hour<br><br>Release in 3 <sup>rd</sup> Hours<br><br>Release in 8 <sup>th</sup> Hours   | Min. 37.00 %, Max. 39.82 %<br>Mean 38.73%<br>Min. 67.69 %, Max. 70.84 %<br>Mean 69.08 %<br>Min. 98.03 %, Max. 100.29 %<br>Mean 99.18 %    | NLT 20 % & NMT 50 %<br><br>NLT 50 % & NMT 75 %<br><br>NLT 75 %                                                                                                                 |
| 09.   | Assay<br>Each uncoated bilayered tablet contains:<br>Glimepiride IP 1 mg<br><br>*Voglibose IP 0.3 mg<br><br>Metformin Hydrochloride IP 500 mg<br>(As sustained release) | 0.973 mg (97.3%)<br><br>0.3 mg (100.0 %)<br><br>495.53 mg (99.1%)                                                                         | NLT 0.90 mg & NMT 1.10 mg<br>(NLT 90.0 % & NMT 110.0 %)<br>NLT 0.27 mg & NMT 0.33 mg<br>(NLT 90.0 % & NMT 110.0 %)<br>NLT 450.0 mg & NMT 550.0 mg<br>(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 **In House Specification No. BRD II/QC/FPS/266U1**

\*Test complies as per Aashirvad Lab Report No. AAFP/A2312-019/24

|             | Prepared By  | Checked By | Approved By                  |
|-------------|--------------|------------|------------------------------|
| Name        | Prateek Kaur | Priganta   | Name: Gyan Prakash Yadav     |
| Designation | QC Officer   | Reviewer   | Designation: Manager Q.A.    |
| Sign/Date   | P 02/01/2025 | 02/01/2025 | Sign./Date: 02/01/2025       |
|             |              |            | Qualification: B.Pharm       |
|             |              |            | Registration No.: 30373      |
|             |              |            | State of Registration: -U.P. |