



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

**CERTIFICATE OF ANALYSIS**

|                  |                                                                                      |                   |                       |
|------------------|--------------------------------------------------------------------------------------|-------------------|-----------------------|
| Product Name     | Glimepiride 2mg & Metformin Hydrochloride (PR) 1000 mg Tablets IP (Glycoheal G 1002) | A.R. No.          | BRDII/08/24/BD/0892TF |
| Master/FG B. No. | BD241572/BD241572                                                                    | Master/FG B. Size | 2.0 Lac/2.0 Lac       |
| Mfd. By          | Self                                                                                 | Sample Qty.       | 70 Tablets            |
| MFD.             | AUG.2024                                                                             | Date of Receipt   | 30/08/2024            |
| EXP.             | JUL.2026                                                                             | Date of Release   | 30/08/2024            |

**RESULTS OF ANALYSIS**

Reference to Protocol : IP

| S.No. | Test                                                                                                                                                                                                   | Results                                                                                                                                                                        | Specification                                                                                                                                 |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|
| 01.   | Description                                                                                                                                                                                            | Bilayered elongated shaped biconvex film coated tablets with one side white layer & other side blue coloured layer with a central break line.                                  | Bilayered elongated shaped biconvex film coated tablets with one side white layer & other side blue coloured layer with a central break line. |
| 02.   | Identification<br>For Glimepiride (By HPLC)<br>For Metformin Hydrochloride (By UV)                                                                                                                     | Complies<br>Complies                                                                                                                                                           | To Comply<br>To Comply                                                                                                                        |
| 03.   | Average weight                                                                                                                                                                                         | 1.38528 gm                                                                                                                                                                     | 1.3720 gm $\pm$ 3.0%                                                                                                                          |
| 04.   | Uniformity of weight                                                                                                                                                                                   | Min. 1.3499 gm<br>Max. 1.4084 gm                                                                                                                                               | $\pm$ 5.0% of average weight                                                                                                                  |
| 05.   | Uniformity of content (By HPLC)<br>For Glimepiride                                                                                                                                                     | Min. 97.67 %, Max. 102.36 %<br>average content 2.07mg                                                                                                                          | NLT 85% & NMT 115% of the average content                                                                                                     |
| 06.   | Dissolution<br>For Metformin Hydrochloride (By UV)<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<br><br>For Glimepiride (By HPLC) | Min. 36.67 %, Max. 39.80 %<br>Mean 38.35%<br>Min. 67.19 %, Max. 69.43%<br>Mean 68.52 %<br>Min. 97.05%, Max. 99.06 %<br>Mean 97.96%<br>Min. 85.47 %, Max. 92.01%<br>Mean 88.58% | NLT 20 % & NMT 50 %<br><br>NLT 50 % & NMT 75 %<br><br>NLT 75 %<br><br>Q.NLT 70 %                                                              |
| 07.   | Assay<br>Each uncoated bilayered tablet contains:<br>Glimepiride IP 2 mg (By HPLC)<br>Metformin Hydrochloride IP 1000 mg (In Prolonged release form) (By UV)                                           | 2.039 mg (102.0 %)<br><br>999.36 mg (99.9%)                                                                                                                                    | NLT 1.80 mg & NMT 2.20 mg (NLT 90.0 % & NMT 110.0 %)<br>NLT 900.0 mg & NMT 1100.0 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/0144U3)

|             |            |            |            |             |            |
|-------------|------------|------------|------------|-------------|------------|
| Prepared By |            | Checked By |            | Approved By |            |
| Date        | 30/08/2024 | Date       | 30/08/2024 | Date        | 30/08/2024 |

