

## CERTIFICATE OF ANALYSIS

| PRODUCT                        | METFORMIN HYDROCHLORIDE  |                     |               |
|--------------------------------|--|---------------------|---------------|
| BATCH NO.                      | A-22612307036  | GROSS WEIGHT        | 27.0Kg/Drum   |
| BATCH QUANTITY                 | 2000KGS  | NET WEIGHT          | 25.0Kg/Drum   |
| MANUFACTURE DATE               | July 12, 2023  | RETEST DATE         | Jun. 2026     |
| ANALYSIS DATE                  | July 13, 2023  | REPORT DATE         | July 16, 2023 |
| PHARMACOPOEIA                  | EP11.0   |                     |               |
| <b>Analytical results</b>      |  |                     |               |
| Items                          | Specifications   | Results             |               |
| Appearance                     | White or almost white crystals   | white crystals      |               |
| Identification                 | B: IR-spectrum: Consistent with the spectrum of metformin- hydrochloride CRS. (2.2.24) | Complies            |               |
|                                | E: reaction of chlorides: It gives reaction of chlorides. (2.3.1)                      | Complies            |               |
| Appearance of solution         | Clear(2.2.1) and colorless(2.2.2 Method II)  | clear and colorless |               |
| Related substances<br>(2.2.29) | Cyanoguanidine(imp.A) ≤0.02%   | 0.003%              |               |
|                                | Any other impurity≤0.05%   | 0.004%              |               |
|                                | Total impurities ≤0.2%   | 0.02%               |               |
|                                | Impurity F≤0.05%   | 0.002%              |               |
| NDMA                           | ≤0.03ppm   | <0.005ppm           |               |
| Loss on drying                 | ≤0.5% (2.2.32)   | 0.10%               |               |
| Sulphated ash                  | ≤0.1% (2.4.14)   | 0.03%               |               |
| Residual solvents              | Methanol ≤3000ppm  | 407ppm              |               |
| Assay% on dry basis            | 98.5-101% (2.2.20)   | 99.90%              |               |
| Particle Size                  | D90≤500 μm   | 195μm               |               |
| Conclusion                     | The commodity meets the standard of EP11.0.(R1-CEP 2008-043-Rev 07)                    |                     |               |

Inspector: Carlifor Wu

Verifier: Jack He