

402A, 4th floor, building 2, Shenzhen biological incubation base, No. 10, Gaoxin Zhongyi Road,
Maling community, Yuehai Street, Nanshan District, Shenzhen

Certificate of Analysis

| | | | |
|-----------------------|----------------------|-------------------------|------------|
| Product Name | Osimertinib mesylate | Manufacture Date | 2020-04-01 |
| Batch No. | 20200401 | Report Date | 2020-04-07 |
| Batch Quantity | 3kg | Retest Date | 2022-03-31 |
| CAS No. | 1421373-66-1 | Standard | In-house |

| Items | Specifications | Results |
|----------------------|---|------------------|
| Appearance | Off-white to yellow powder | Off-white powder |
| Identification | HPLC | Conforms |
| | NMR | Conforms |
| Water content (KF) | ≤1.0% | 0.18% |
| Residual on ignition | ≤0.1% | 0.08% |
| Residual solvents | Ethanol≤5000ppm | 674ppm |
| | Ethyl acetate≤0.5% | 206ppm |
| | Acetone≤5000ppm | N.D. |
| | Acetonitrile≤410ppm | N.D. |
| Related substances | Largest single impurity≤0.5% | 0.05% |
| | Total impurities≤1.0% | 0.11% |
| Heavy metal | ≤20ppm | Conforms |
| Chloride content | 5.5%~6.5% | Conforms |
| Assay | 98.0%~102.0% | 99.91% |
| Conclusion | The product conforms to the In-house standard. | |
| Storage condition | Preserve in tight containers, protected from light. | |

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