



Certificate of Analysis

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|-----------------------|-------------|-------------------------|-------------|
| Product name | Varenicline | Manufacture date | Nov.15.2023 |
| Batch number | SW231115 | Analysis date | Nov.16.2023 |
| Batch quantity | 10kg | Expiry date | Nov.16.2025 |

| Items | Specification | Results |
|-----------------------------|---------------------------------|----------|
| Appearance | White or off-white solid powder | Complies |
| Identification | By HPLC | Complies |
| Melting Point | 138.5 °C | 138.5 °C |
| Loss on Drying | ≤1.00% | 0.21% |
| Heavy Metals | ≤10ppm | Complies |
| Sulfated Ash | ≤ 0.10% | 0.03% |
| Content | 17.5%~19.55 | 19.3% |
| Content | ≤ 0.1ppm | 0.09ppm |
| Microbiological Test | Coliforms: Negative | Negative |
| | Salmonella: Negative | Complies |
| | Total plate count: ≤1000cfu/g | Pass |
| | Yeast & Mold: ≤50cfu/g | Pass |
| Related Substances | Impurity A: ≤0.30% | 0.18% |
| | Other unknow impurity: ≤0.10% | 0.075 |
| | Total impurities: ≤0.50% | 0.42% |
| Assay | ≥98.0%~ | 99.34% |
| Reference Standard | USP Standard | |

| | |
|-----------------------------|---|
| Packing description: | Sealed export grade drum & double of sealed plastic bag |
| Storage: | Store in cool & dry place not freeze., keep away from strong light and heat |
| Shelf life: | 2 years when properly stored |

Quality Assurance Officer: 李强

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