



Compounding
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Certificate of Analysis

Sirolimus

| | | | |
|-------------|--------------|------------------|--------------|
| CAS No. | 53123-88-9 | Code | BIOJSRL001 |
| Batch No | 260419 | Manufacture Date | Apr.19, 2026 |
| Retest Date | Apr.18, 2029 | Quantity | 10G |

| Testing Items | Specifications | Results |
|-------------------------------------------|----------------------------------------------------------------------------------------------------------|----------|
| Appearance | White or off-white crystalline powder | Complies |
| Specific rotation (on anhydrous basis) | -147° ~ -157° | -154° |
| Identification | HPLC: The retention time of major peak of test solution should correspond to that of comparison solution | Complies |
| | IR: Spectrum of test sample should confirm to that of reference standard spectrum | Complies |
| Related substances | Isomer A ≤ 1.0% | 0.077% |
| | Isomer C ≤ 3.5% | 2.06% |
| | Seco-sirolimus and 32-O-desmethyl sirolimus ≤ 1.0% | 0.32% |
| | Prolylsirolimus ≤ 1.0% | 0.067% |
| | 12-ethyl sirolimus ≤ 1.0% | 0.61% |
| | Individual impurity ≤ 0.2% | 0.1% |
| | Total impurities (Excluding C isomers) ≤ 3.0% | 1.2% |
| Residual solvents | Hexane ≤ 0.029% | Complies |
| | Diethyl ether ≤ 0.5% | Complies |
| | MTBE ≤ 0.5% | Complies |
| | Acetone ≤ 0.5% | Complies |
| | Dichloromethane ≤ 0.06% | Complies |
| Water | ≤ 1.0% | 0.22% |
| Residue on ignition | ≤ 0.5% | 0.2% |
| Chloridum | ≤ 0.05% | Complies |
| Assay | 98.0~102.0% (Calculated isomer B & C, on anhydrous basis) | 98.89% |
| Conclusion | This product conforms to In-house standard | |

***Storage condition: Store between 2°C~8°C, Protect from moisture and light.**