



Compounding
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Certificate of analysis

Remdesivir

| | | | |
|-------------|--------------|------------------|--------------|
| CAS No | 1809249-37-3 | Code | BIOJREM001 |
| Batch No | 23051301 | Manufacture Date | May.13, 2023 |
| Retest Date | May.12, 2026 | Quantity | 1KG |

| Testing Items | Specifications | Results |
|---------------------|---|--------------------|
| Appearance | White or off-white powder | White powder |
| Identification | HPLC: The retention time of main peak of test product is consistent with that of standard | Conform |
| Solubility | Insoluble in water and soluble in ethanol | Conform |
| Water | $\leq 1.0\%$ | 0.04% |
| Residue on ignition | $\leq 0.2\%$ | 0.10% |
| Specific rotation | $-18^{\circ} \sim -25^{\circ}$ | -22.2° |
| Heavy metal | $\leq 10\text{ppm}$ | Conform |
| Related substance | Rp-Isomer $\leq 0.1\%$ | 0.06% |
| | Nitrophenol $\leq 0.1\%$ | Not detected |
| | RD-3.1 $\leq 0.1\%$ | Not detected |
| | RD-C $\leq 0.1\%$ | Not detected |
| | RD-D $\leq 0.1\%$ | Not detected |
| | RD-E $\leq 0.1\%$ | Not detected |
| | Any unspecific individual impurity $\leq 0.1\%$ | 0.06% |
| | Total impurities $\leq 1.0\%$ | 0.18% |
| Purity(HPLC) | $\geq 99.0\%$ | 99.82% |
| Residual solvents | Methylene dichloride $\leq 0.06\%$ | Not detected |
| | n-Heptane $\leq 0.5\%$ | Not detected |
| | Acetonitrile $\leq 0.041\%$ | Not detected |
| | Ethyl acetate $\leq 0.5\%$ | Not detected |
| | Acetone $\leq 0.5\%$ | Not detected |
| | Isopropyl ether $\leq 0.5\%$ | Not detected |
| | Isopropyl acetate $\leq 0.5\%$ | Not detected |
| | 2,2-dimethoxypropane $\leq 0.1\%$ | Not detected |
| | N,N-Diisopropylethylamine $\leq 0.1\%$ | Not detected |
| | Isopropanol $\leq 0.5\%$ | Not detected |
| | Tetrahydrofuran $\leq 0.072\%$ | Not detected |
| Microbial limit | Total aerobic bacteria NMT 100cfu/g | $< 10\text{cfu/g}$ |
| | Total number of moulds and yeasts NMT 100cfu/g | $< 10\text{cfu/g}$ |
| Bacterial endotoxin | $\leq 0.5\text{EU/mg}$ | Conform |
| Assay(HPLC) | 98.0%~102.0% | 99.1% |
| Conclusion | This product conforms to In-house standard | |

***Storage condition: Store below 25°C, Protect from moisture and light.**