

Certificate of analysis Nizatidine

| CAS No | 76963-41-2 | Code | BIOJNIZ001 |
|-------------|-------------|------------------|--------------|
| Batch No | NZTD2009005 | Manufacture Date | Sep.05, 2020 |
| Expiry date | Aug.2024 | Quantity | 5Kg |

| Testing Items | Specifications | Results |
|--|---|----------|
| Appearance | White or almost white powder | Conform |
| | Spectrum is accordance with the spectrum obtained with the RS. | Conform |
| Identification | The retention time of the major peak of the test solution corresponds to that of the reference solution. | Conform |
| Delated substances (UDLC) | Any single impurity≤0.3% | 0.10% |
| Related substances (HPLC) | Total impurities<1.5% | 0.39% |
| Loss on drying | ≤1.0% | 0.16% |
| Residue on ignition | ≪0.1% | 0.06% |
| Heavy metals | ≤10ppm | Conform |
| Assay | 98.0%~101.0% (Calculated on the dried basis) | 98.7% |
| Conclusion This product conforms to USP42 standard | | standard |

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

