

瑾 岚 医 药 技 术 开 发 有 限 公 司

JINLAN PHARM-DRUGS TECHNOLOGY CO., LIMITED Hangzhou ROYAL Import & Export Co.,Ltd.

CERTIFICATE OF ANALYSIS

| Product Name | Nicorandil | Batch NO. | 19RY0403 |
|---------------------|---------------------|---|---------------------|
| Production date | 2019.04.03 | Expired Date | 2021.04.02 |
| CAS NO. | 65141-46-0 | Standard | Enterprise standard |
| Tests | | Limits | Test results |
| Appearance | White or off- | white, crystalline powder | Conforms |
| Melting point | | 88.5~93.5℃ | |
| | Color reaction: th | Color reaction: the test solution should present brown | |
| Identification | | Maxium absorbance at 262nm:present maxium absorbance at 262nm | |
| | | IR: the infrared spectrum of the test substance corresponds to the standard.spectrum. | |
| Loss on drying | | ≤0.5% | |
| Residue on ignition | | ≤0.1% | |
| Sulphates | | ≤0.02% | |
| Related substances | | ≤1.0% | |
| Acidity | The test | The test solution should present pink | |
| Heavy metals | | ≤0.0020% | |
| Residual solvent | To | Toluol ≤0.089% | |
| | Ac | Acetone ≤0.50% | |
| | Et | Ethanol ≤0.50% | |
| Microbial limit | Total aerobic m | Total aerobic microbial count≤1000CFU/g | |
| | Molds and y | Molds and yeasts count≤100CFU/g | |
| | Esche | Escherichia coli: absent | |
| Assay | 98 | 98.5%~101.0% | |
| | Conclusion: This ba | tch meets enterprise standard. | NUTHIS |

Tested by:

Esther

Checked by: Alice

Approved by: Mich