

| ITEMS | SPECIFICATION | RESULTS |
|---------------------------------------|---|------------------------------|
| [Characters] | Off-white or yellowish crystalline powder | Off-white crystalline powder |
| Solubility | Shall comply with requirement | Complies |
| [Identification] | | |
| Chemical identification | Shall be positive reaction | Complies |
| HPLC Identification | The retention time of the main peak of the sample solution shall be consistent with that of the reference solution | Complies |
| UV absorption | There is maximum absorption at the wavelength of 225nm and 257nm; minimum absorption at the wavelength of 244nm and 285nm | Complies |
| IR | Shall be consistent with the reference spectrum | Complies |
| Chloride identification | Shall be positive reaction | Complies |
| [Inspection] | | |
| Clarity and color of ethanol solution | Shall comply with requirement | Complies |
| PH | Shall be 4.0~6.0 | 5.2 |
| Related substance | Impurity A shall be NMT 0.10% | Not detected |
| | Impurity K shall be NMT 0.10% | Not detected |
| | Monomethylamine impurity shall be NMT 0.15% | 0.04% |
| | Impurity B shall be NMT 0.10% | Not detected |
| | Impurity C shall be NMT 0.10% | Not detected |
| | Impurity D shall be NMT 0.10% | 0.06% |
| | Impurity E shall be NMT 0.10% | Not detected |
| | Impurity G shall be NMT 0.10% | Not detected |
| | Maximum unknown single impurity shall be NMT 0.10% | 0.02% |
| Total impurities shall be NMT 1.0% | 0.13% | |

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|---|---|-----------|
| Residual solvent | | |
| Methanol, ethanol, acetone, tetrahydrofuran, carbon tetrachloride | Shall comply with requirement | Complies |
| Water | Shall be 3.0%~4.0% | 3.7% |
| Residue on ignition | NMT 0.2% | 0.07% |
| Heavy metals | NMT 10ppm | Complies |
| PSD | NA | D90=71.07 |
| Assay | Shall be 98.0%~102.0% | 99.6% |
| Conclusion | Comply with registration declaration standard | |

Analyzed by: Zhang Da

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