



CERTIFICATE OF ANALYSIS

|              |                          |           |          |
|--------------|--------------------------|-----------|----------|
| Product name | Tetracaine hydrochloride | Batch No. | 19020111 |
| Mfg.Date     | 2019-02-09               | Exp. Date | 2021-02  |
| Report Date  | 2019-02-17               | Quantity  | 525kg    |

| Inspection Items                           | Accepted Standard  | Results       |
|--|--|---------------|
| Appearance                                 | A white,crystalline power , No smell, slight bitterness; Its solution is neutral to the litmus; It has the wetting property; | Complies      |
| Identification                             | A.By IR, To match with working standard  | Complies      |
|  | B: HPLC, To match with working standard  | Complies      |
|  | C. Chloride,should match with standard.  | Complies      |
| Solubility                                 | Easily soluble in water, soluble in ethanol, insoluble in ether and benzene  | Complies      |
| Water                                      | ≤2.0%  | 0.32%         |
| Melting point                              | About 148°C  | 147.2-148.5°C |
| Related substance                          | Total impurities≤0.8%  | 0.10%         |
|  | Individual unspecified impurity≤0.4%   | 0.09%         |
|  | Impurity B≤0.4%  | 0.005%        |
|  | ImpurityC≤0.4%   | 0.005%        |
|  | Aminobenzoic acid≤0.4%   | Not detected  |
| Residue on ignition                        | ≤0.1%  | 0.04%         |
| Residual solvents                          | Acetone≤5000ppm  | Not detected  |
|  | Methylbenzene≤890ppm   | Not detected  |
|  | Ethanol≤5000ppm  | Not detected  |
| Assay                                      | 98~101.0%(On anhydrous basis)  | 99.69%        |
| Conclusion : THE RESULTS CONFORM TO USP40. |  |               |

Analyst :lichao

Checker: shilijuan

Supervisor :maohongjun