

BENEPURE PHARMACEUTICAL CO., LTD.

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No.: BPAP-620-A-00/3.0

CERTIFICATE OF ANALYSIS

| Product Name | Tetracaine HCL | CAS No. | 136-47-0 |
|---------------|----------------|-------------|---------------|
| Batch No. | P011162019A | Mfg. Date | Nov. 09, 2019 |
| Quantity | 500kg | Retest Date | Nov. 08, 2021 |
| Packing | 25kg/Drum | Report Date | Nov. 14, 2019 |
| Specification | USP40 | | |

| ITEM | SPECIFICATION | RESULT | |
|--|--|-------------------------|--|
| Appearance | White crystalline power | White crystalline power | |
| Solubility | Easily soluble in water, soluble in ethanol, insoluble in ether and benzene. | Complies | |
| | A. By IR, should be corresponds to the standard solution. | Complies | |
| Identification | B. Should identify significant chloride reaction | Complies | |
| | C. The retention time of the major peak of the sample solution corresponds to that of the Standard solution, as obtained in tha Assay. | Complies | |
| Water | ≤2.0% | 0.09% | |
| Residue on Ignition | ≤0.1% | 0.08% | |
| Related Substances | Complies | Complies | |
| Heavy Metals | ≤10ppm | ≤10ppm | |
| Residual Solvents | | | |
| -Ethanol | ≤5000ppm | 400ppm | |
| -Acetone | ≤5000ppm | Not Detected | |
| -Toluene | ≤890ppm | Not Detected | |
| Assay (on Anhydrous basis) | 98.0~101.0% | 99.99% | |
| Conclusion | Comply with the specification. | | |
| Storage Preserve in tight containers, protected from strong light and high heat. | | ht and high heat. | |

Analyst: Reviewed by: Approved by:







