

CERTIFICATE OF ANALYSIS

| 品 名: 丁卡因 Name: Tetracaine | | 生产日期: | 20230909 |
|------------------------------|---|------------------|--|
| | | Date Of Produce: | |
| 批 号: CP06-230901 | | 报告日期: | 20230914 |
| Ratch No · | | Date Of Test: | |
| 检验依据: | USI | P NF 2021 | |
| Inspection basis: | | | / / 田 |
| 项目 | 标 准 | | 结 果 |
| Items | Specifications | | Results |
| 外观 Appearance | White or light yellow, waxy solid. | | White waxy solid |
| | Soluble in alcohol, in ether, in benzene, and in chloroform; very slightly soluble in water. | | Complies |
| | (A) IR | | Complies |
| 鉴别 Identification | (B) The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay | | Complies |
| 干燥失重 Loss on drying | ≤0.5 % | | 0.2% |
| 灼烧残渣 Residue on ignition | ≤ 0.1 % | | 0.03% |
| 有机杂质 Organic impurities | Aminobenzoic acid≤0.4% Tetracaine Related Compound B≤0.4% Tetracaine Related Compound C ≤0.4% Individual unspecifie impurity≤0.4% Total impurities≤0.8% | | Not detected 0.01% Not detected 0.02% 0.3% |
| 残留溶剂 Residual solvent | Ethanol≤0.5% Ethyl acetate≤0.5% | | 0.0001% 0.004% |
| 含量 Assay | 98.0 ~ 102.0 %(on the dried basis) | | 99.8% |
| 有效期 Date of Expiry | 202608 | | DE PHARMACEUS |
| 结 论 CONCLUSION | USP NF 202 | | 021 海绵岛岛南瓜 |