# 精华制药集团南通有限公司检验报告

## NANTONG JINGHUA PHARMACEUTICAL CO. LTD.
## CERTIFICATE OF ANALYSIS

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# 氟 尿 嘧 啶
# 5-FLUOROURACIL

| | | | |
|---|---|---|---|
| Batch No. | FLU2019070 | Manufacture Date | Jul. 9, 2019 |
| Total Quantity | 201. 00KG | Report Date | Jul. 20, 2019 |
| Commercial Quantity | 200. 00KG | Re-test Date | Jul. 8, 2024 |
| Inspection No. | 190500223 | | |

| TEST | SPECIFICATIONS | | RESULTS |
|---|---|---|---|
| Characteristics | White or almost white, crystalline powder | | Complies |
| Solubility | Sparingly soluble in water, slightly soluble in alcohol | | Complies |
| Identification | IR | | Complies |
| Appearance of solution | Clear ≤ $BY_7$ or $Y_7$ | | Complies |
| pH | 4.5～5.0 | | 4. 92 |
| Related substances (TLC) | Impurity F (2-ethoxy-5-fluorouracil) | ≤ 0.25% | < 0.25% |
| | Impurity G (Urea) | ≤ 0.2% | < 0.2% |
| Related substances | Impurity A (Barbituric acid) | ≤ 0.1% | <LOD, LOD=0. 001% |
| | Impurity B (5-Hydroxyuracil) | ≤ 0.1% | <LOD, LOD=0. 01% |
| | Impurity C (Uracil) | ≤ 0.1% | <LOD, LOD=0. 01% |
| | Impurity D (5-Methoxyuracil) | ≤ 0.1% | 0. 05% |
| | Impurity E (5-Chlorouracil) | ≤ 0.1% | <LOD, LOD=0. 01% |
| | Unspecified impurities | ≤ 0.10% | <LOD, LOD=0. 00025% |
| | Total | ≤ 0.5% | 0. 05% |
| Loss on drying | ≤ 0.5% | | 0. 07% |
| Sulphated ash | ≤ 0.1% | | 0. 05% |
| Residual solvents | Dimethylformamide ≤0.088% | | N. D. |
| Microbial Purity | Total aerobic count <100CFU/g | | <10CFU/g |
| Assay (Calculated on the dried basis) | 98.5~101.0% | | 99. 86% |

Conclusion: The product meets the requirements of Ph Eur9/CEP(R1-REV06)

Analyst 陈伟 Jul.20,2019

Supervisor Jul. 20, 2019

Chief of Laboratory Jul.20,2019

QA Release Date Jul. 21. 2019