

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.	FLU2020033	Manufacture Date	Mar.23,2020
Total Quantity	204.00KG	Report Date	Apr.7,2020
Commercial Quantity	200.00KG	Re-test Date	Mar.22,2025
Inspection No.	2005000151		

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 $\leq$ BY ₇ or Y ₇	Complies
pH	4.5~5.0	4.83
Related substances	Impurity F (2-ethoxy-5-fluorouracil) $\leq$ 0.25%	< 0.25%
(TLC)	Impurity G (Urea) $\leq$ 0.2%	< 0.2%
Related substances	Impurity A (Barbituric acid) $\leq$ 0.1%	< LOD, LOD=0.001%
	Impurity B (5-Hydroxyuracil) $\leq$ 0.1%	< LOD, LOD=0.01%
	Impurity C (Uracil) $\leq$ 0.1%	< LOD, LOD=0.01%
	Impurity D (5-Methoxyuracil) $\leq$ 0.1%	0.05%
	Impurity E (5-Chlorouracil) $\leq$ 0.1%	< LOD, LOD=0.01%
	Unspecified impurities $\leq$ 0.10%	< LOD, LOD=0.00025%
	Total $\leq$ 0.5%	0.05%
Loss on drying	$\leq$ 0.5%	0.10%
Sulphated ash	$\leq$ 0.1%	0.06%
Residual solvents	Dimethylformamide $\leq$ 0.088%	N.D.
Microbial Purity	Total aerobic count < 100CFU/g	< 10CFU/g
Assay	98.5~101.0%	99.79%

(Calculated on the dried basis).

Conclusion The product meets the requirements of Ph. Eur.10/CEP(R1-REV06)

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Chief of Laboratory

Apr. 7, 2020

QA Release Date

Apr. 7, 2020

