

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.	FLU2021012	Manufacture Date	Jan.19,2021
Total Quantity	201.00KG	Report Date	Feb.1,2021
Commercial Quantity	200.00KG	Re-test Date	Jan.18,2026
Inspection No.	2105000014		

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		4.79
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)	$\leq 0.1\%$	$< \text{LOD}, \text{LOD}=0.001\%$
	Impurity B (5-Hydroxyuracil)	$\leq 0.1\%$	$< \text{LOD}, \text{LOD}=0.01\%$
	Impurity C (Uracil)	$\leq 0.1\%$	$< \text{LOD}, \text{LOD}=0.01\%$
	Impurity D (5-Methoxyuracil)	$\leq 0.1\%$	0.06%
	Impurity E (5-Chlorouracil)	$\leq 0.1\%$	$< \text{LOD}, \text{LOD}=0.01\%$
	Unspecified impurities	$\leq 0.10\%$	$< \text{LOD}, \text{LOD}=0.00025\%$
	Total	$\leq 0.5\%$	0.06%
Loss on drying	$\leq 0.5\%$		0.10%
Sulphated ash	$\leq 0.1\%$		0.05%
Residual solvents	Dimethylformamide $\leq 0.088\%$		N.D.
Microbial Purity	Total aerobic count $< 100\text{CFU/g}$		$< 10\text{CFU/g}$
Assay	98.5~101.0%		99.84%

(Calculated on the dried basis)

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

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Feb. 1, 2021

Supervisor 孙伟
Feb. 1, 2021

Chief of Laboratory 孙伟 Feb. 1, 2021
QA Release Date 孙伟 Feb. 2, 2021
检验专用章