

精华制药集团南通有限公司检验报告

NANTONG JINGHUA PHARMACEUTICAL CO. LTD.

CERTIFICATE OF ANALYSIS

No.20, 3 Haibin Road, Yanhai Economic Development Zone, Rudong,

Nantong Jiangsu China, 226407

Tel: 86-513-85609405/85609406

氟尿嘧啶

5-FLUOROURACIL

Batch No.	FLU2018028	Manufacture Date	Apr. 12, 2018
Total Quantity	201.00KG	Report Date	Apr. 23, 2018
Commercial Quantity	200.00KG	Re-test Date	Apr. 11, 2023
Inspection No.	180500042		

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		4.72
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)	$\leq 0.1\%$	$< \text{LOD}$, LOD=0.001%
	Impurity B (5-Hydroxyuracil)	$\leq 0.1\%$	$< \text{LOD}$, LOD=0.01%
	Impurity C (Uracil)	$\leq 0.1\%$	$< \text{LOD}$, LOD=0.01%
	Impurity D (5-Methoxyuracil)	$\leq 0.1\%$	0.07%
	Impurity E (5-Chlorouracil)	$\leq 0.1\%$	$< \text{LOD}$, LOD=0.01%
	Unspecified impurities	$\leq 0.10\%$	$< \text{LOD}$, LOD=0.00025%
	Total	$\leq 0.5\%$	0.07%
Loss on drying	$\leq 0.5\%$		0.07%
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%		99.88%
(Calculated on the dried basis)			

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

Analyst 王华林 Khat Supervisor 顾晓林 Chief of Laboratory 王华林
 Apr. 23, 2018 QA Release Date 王华林 2018
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