

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 \leq BY ₇ or Y ₇	Complies
pH	4.5~5.0	4.92
Related substances (TLC)	Impurity F (2-ethoxy-5-fluorouracil) \leq 0.25%	$<$ 0.25%
	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%	0.07%
Sulphated ash	\leq 0.1%	0.05%
Residual solvents	Dimethylformamide \leq 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* Supervisor *马强* Chief of Laboratory *陈伟* Jul. 20, 2019
于利强 Jul. 20, 2019 QA Release Date *陈伟* Jul. 21, 2019
 Jul. 20, 2019

