

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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氟胞嘧啶

FLUCYTOSINE(5-FLUORO CYTOSINE)

Batch No.	FLC2021002	Manufacture Date	Oct. 19, 2021
Total Quantity	503.00KG	Report Date	Mar. 9, 2022
Commercial Quantity	500.00KG	Re-test Date	Oct. 18, 2024
Inspection No.	2106000072		

TEST	SPECIFICATIONS	RESULTS
Description	A white or almost white crystalline powder	Complies
	A .UV($\leq 2.0\%$)	0.20%
	B.IR	Complies
Heavy metals	$\leq 0.002\%$	$< 0.002\%$
Loss on drying	$\leq 1.5\%$	0.10%
Residue on ignition	$\leq 0.1\%$	0.07%
Fluoride ions	$\leq 0.05\%$	0.001%
Related impurities by HPLC	5-Fluorouracil $\leq 0.1\%$	0.01%
	Single unspecified impurity $\leq 0.10\%$	0.01%
	Total impurities $\leq 0.4\%$	0.02%
Residual solvents(GC)	N,N-Dimethylaniline $\leq 5\text{ppm}$	N. D.
Assay (on dried basis)	98.5~101.0%	99.14%

Conclusion The product meets the requirements.

Analyst

[Handwritten signatures]
Mar. 9, 2022

Supervisor

[Handwritten signature]
Mar. 9, 2022

Chief of Laboratory

QA Release Date



S/SMP/QC-024