

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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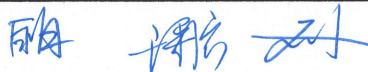
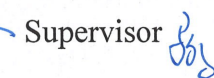
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5-FLUOROURACIL

Batch No.	FLU2021128	Manufacture Date	Dec.21,2021
Total Quantity	201.00KG	Report Date	Dec.30,2021
Commercial Quantity	200.00KG	Re-test Date	Dec.20,2024
Inspection No.	2105000276		

TEST	SPECIFICATIONS	RESULTS
	(USP)	
Characteristics	White to practically white Practically odorless, Crystalline powder.	Complies
Identification	A. IR B. UV($\leq 3.0\%$) C. Chemical test	Complies 0.21%
Loss on drying	$\leq 0.5\%$	0.09%
Residue on ignition	$\leq 0.1\%$	0.06%
Heavy metals	$\leq 0.002\%$	$< 0.002\%$
Fluorine Content	13.9~15.0%	14.19%
Assay(Calculated on the dried basis)	98.0~102.0%	99.88%

Conclusion The product meets the requirements of USP36

Analyst  Supervisor 

Chief of Laboratory 
QA Release Date 


S/SMP/QC-024

DEc. 30, 2021

Dec. 30, 2021