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

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5-FLUOROURACIL

Batch No.	FLU2020070	Manufacture Date	Jun.9,2020
Total Quantity	201.00KG	Report Date	Jul.1,2020
Commercial Quantity	200.00KG	Re-test Date	Jun.8,2025
Inspection No.	2005000228		

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 ≤ BY_7 or Y_7		Complies
pH	4.5~5.0		4.80
Related substances (TLC)	Impurity F (2-ethoxy-5-fluorouracil)	≤ 0.25%	< 0.25%
	Impurity G (Urea)	≤ 0.2%	< 0.2%
Related substances	Impurity A (Barbituric acid)	≤ 0.1%	<LOD,LOD=0.001%
	Impurity B (5-Hydroxyuracil)	≤ 0.1%	<LOD,LOD=0.01%
	Impurity C (Uracil)	≤ 0.1%	<LOD,LOD=0.01%
	Impurity D (5-Methoxyuracil)	≤ 0.1%	0.06%
	Impurity E (5-Chlorouracil)	≤ 0.1%	<LOD,LOD=0.01%
	Unspecified impurities	≤ 0.10%	<LOD,LOD=0.00025%
	Total	≤ 0.5%	0.06%
Loss on drying	≤ 0.5%		0.08%
Sulphated ash	≤ 0.1%		0.06%
Residual solvents	Dimethylformamide ≤0.088%		N.D.
Microbial Purity	Total aerobic count <100CFU/g		<10CFU/g
Assay (Calculated on the dried basis)	98.5~101.0%		99.82%

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

Analyst: 陈芳 钱俊 [illegible] Supervisor: [illegible] Chief of Laboratory: [illegible] Jul. 1, 2020

[illegible] Jul. 1, 2020 QA Release Date: [illegible] Jul. 2, 2020

Jul. 1, 2020

Fecha Entrada: 04-05-2021
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