



Hangzhou Huarong Pharmaceutical Co., Ltd.

ADD: Room1101, Hakim International Building, Gongshu District,
Hangzhou, Zhejiang Province, China.

TEL: 0086-571-86758373

Website: www.huarongpharm.com

CERTIFICATE OF ANALYSIS

SOP-B-QA1108-02 appendix 2

Certificate No.:C220415

Product name:	Gemcitabine hydrochloride	Batch No.:	DA083-210702
Batch size:	28.58kg	Ref. standard:	USP standard
Manu. date:	Jul.28,2021	Retest date:	Jul.27,2024
ITEM	SPECIFICATION	RESULT	
Appearance	White to off-white solid	White solid	
Solubility	Soluble in water, slightly soluble in methanol, practically insoluble in alcohol.	Conform	
Specific rotation	+43° ~+50°	+47°	
Identification	A: IR	Conform	
	B: It gives reaction of chlorides.	Conform	
	C: HPLC(obtained in assay by HPLC)	Conform	
pH	2.0~3.0	2.62	
Residue on ignition	≤0.1%	0.03%	
Related substances	Cytosine≤0.1%	N.D.	
	α-anomer≤0.1%	<0.03%	
	Any individual unspecified impurity≤0.1%	0.02%	
	Total impurities≤0.2%	0.02%	
Assay	97.5%~101.5%	100.9%	
Residual solvents	Acetonitrile≤0.041%	N.D.	
	Acetone≤0.5%	0.03%	
	Isopropanol≤0.5%	N.D.	
	Anisole≤0.5%	N.D.	
Bacterial endotoxins	<0.05EU/mg	Conform	
Microbiological purity	Total number of aerobic bacteria≤10 ² cfu/g	<20cfu/g	
	Total number of mould and yeast≤10 ² cfu/g	<20cfu/g	
	Absence of Escherichia coli in 1g	Absent	
CONCLUSION: THIS BATCH COMPLIES WITH USP STANDARD.			
Remark: 1. N.D.=not detected. 2.Only for research use.			
PREPARED BY:	<i>[Signature]</i>	APPROVED	<i>[Signature]</i>



*Means the document is under process
Product under patent is for R&D purpose.