



CERTIFICATE OF ANALYSIS

Product name	Gemcitabine HCl		
Batch No.	20190109	CAS NO	122111-03-9
Report Date	2019.01.18	Expiry date	2021.01.08
Inspection Items	Accepted Standard		Results
Description	White crystalline powder, odorless		Conforms
Solubility	Freely soluble in water, sparingly soluble in ethanol. Slightly soluble in acetone or chloroform		Conforms
Identification	IR		Conforms
	Chloride		Conforms
Specific rotation	+43 ~ +50°		+49°
Appearance of solution	Clear and colorless		Conforms
PH	2.0-3.0		2.4
Cytosine	≤0.1%		0.0009%
α-anomer	≤0.1%		Conforms
Any other impurity	≤0.1%		Conforms
Total impurities	≤0.2%		0.009%
Loss on drying	≤1.0%		0.09%
Residue on ignition	≤0.2%		0.1%
Heavy metals	≤10ppm		Conforms
Assay	97.5% ~ 101.5%		99.85%
CONCLUSION	The product complies with USP39.		
STORAGE	Preserve in well-sealed containers, protected from humidity and light		

Analyst :liyuling

Checker: wuhao

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