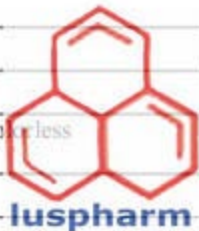


Product name	Gemcitabine HCl		
Batch No.	20170227	CAS NO	122111-03-9
Report Date	2017-03-07	Expiry date	2019-02

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	≤0.5%	0.1%
Heavy metals	≤10ppm	Conforms
Assay	97.5% ~ 101.5%	100.1%
CONCLUSION	The product complies with USP32.	
STORAGE	Preserve in well-sealed containers, protected from humidity and light,	



elaine@luspharm.com