

CERTIFICATE OF ANALYSIS

PRODUCT	Gemcitabine HCl	CAS No.	122111-03-9
BATCH No.	20170404	EXP.DATE	2019.04.13
PROD.DATE	2017.04.14	QUANTITY	8.0 Kgs
TEST	STANDARD	RESULT	
Description	White or almost white powder	Complies	
Solubility	Soluble in water, slightly soluble in methanol, practically insoluble in acetone	Complies	
Identification			
A	Infrared absorption spectrophotometry (2.2.24) comparision Gemcitabine Hydrochloride CRS	Complies	
B	It gives reaction (a) of chloride (2.3.1)	Complies	
Tests			
Appearance of Solution	Solution S in clear(2.2.1) and not more intensely colored than reference solution BY ₇ (2.2.2,method II)	Complies	
PH	2.0~3.0 (2.2.3)	2.6	
Specific optical Rotation	+43 ~ +50° (2.2.7)	+49.0°	
Related substances (2.2.29)			
	Impurity A ≤ 0.1%	0.003%	
	Impurity B ≤ 0.1%	Not detected	
	Unspecified impurities ≤ 0.10%	0.03%	
	Total ≤ 0.2%	0.04%	
Heavy metals	≤ 10ppm (2.4.8)	Complies	
Sulphated ash	≤ 0.1% (2.4.14)	0.01%	
Residual solvents (2.4.24)			
	Toluene ≤ 0.01%	Not detected	
	Dichloromethane ≤ 0.01%	Not detected	
	Methanol ≤ 0.3%	Not detected	
	Acetone ≤ 0.5%	0.2%	
Bacterial endotoxins	< 0.05 eu/mg (2.6.14)	Complies	
Assay	97.5~101.5% (2.2.29)	99.3%	
Conclusion: The results comply with the requirements of Ph. Eur. EP8.0			