



Certificate of analysis

Product name: Fludarabine Phosphate

Cas number: 75607-67-9

Molecular Formula: C₁₀H₁₃FN₅O₇P

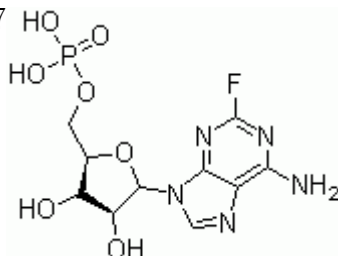
Molecular Weight: 365.21

Date of production: Aug. 26, 2017

Batch NO: 20170826

Exp Date: Aug. 25, 2019

Chemical structure:



Items	Specifications	Results
Appearance	White or off-white powder	Conforms
Identification	IR: The infrared absorption spectrum of the sample exhibits maxima only at the same wavelengths as that of the standard	Conforms
Water Content	≤ 1.0%	0.35%
Specific rotation (in 5mg/ml of water)	+10° - +14°	+12.8°
Limit of Free Phosphate	≤ 0.1%	0.05%
Heavy metals	≤ 0.002%	0.001%
Assay by HPLC	NLT 98.0% and NMT 102.0% on the anhydrous basic	99.6%
Microbial Limits Test (Total Microbial count)	NMT 1000CFU/g	15CFU/g
Limit of Sodium	≤ 0.2%	0.1%
Limit of chloride	≤ 0.2%	0.1%
Fludarabi bisphosphate Isoguanine Iso-ara-guanine Monophosphate 2-ethoxyphosphate analog 2-Fluoro-ara-adenine 2-Fluoroadenin Any other impurity in test A Any other impurity in test B Total of all other impurities Total Impurities	Chromatographic Purity (by HPLC)	
	≤ 0.4%	0.22%
	≤ 0.2%	ND
	≤ 0.8%	0.12%
	≤ 0.2%	ND
	≤ 0.2%	0.01%
	≤ 0.1%	0.03%
	≤ 0.1%	0.01%
	≤ 0.1%	0.05%
	≤ 0.5%	0.12%
≤ 1.5%	0.39%	
Residual solvents (by GC)	Methanol: NMT 2000ppm	35ppm
	Ethanol: NMT 3000ppm	60ppm
	Dichloromethane: NMT 600ppm	ND

Conclusion: It complies with the USP 32 Standard.

Analyst: Zhao

Checker: Liu

Q.C Director: Fang F