



CERTIFICATE OF ANALYSIS

FLUDARABINE PHOSPHATE

TEST	SPECIFICATIONS	RESULTS
Description	White Or Almost White Powder, Odorless	Complies
Specific Optical Rotation	+10°~+14°	+ 10.16°
Identification	(1) The Retention Time Should Be Concordant To That Of Standard Fludarabine Phosphate	Complies
	(2) IR Spectra Of Sample Should Be Concordant To That Of Standard Fludarabine Phosphate	Complies
Microbial Limits	The Total Aerobic Microbial Count Shall Not Exceed 1000cfu/Gm	Complies
Water	Less Than 3.0%	2.43%
Chloride	Not More Than 0.2%	Complies
Ethanol	Not More Than 0.5%	Not Detected
Free Phosphate	Not More Than 0.1%	Complies
Limit Of Sodium	Not More Than 0.2%	Complies
Related Substances (%)	C1 NMT0.8%	0.288%
	C2 NMT 0.2%	0.030%
	3', 5' -Diphosphate Analog NMT 0.4%	0.110%
	Other Individual Impurity Maximum NMT 0.1%	0.026%
	2-F-Adenine NMT 0.1%	0.000%
	2-F-Ara-Ad NMT 0.2%	0.010%
	2-Ethoxyphosphate Analog NMT 0.2%	0.000%
	Other Individual Impurity Maximum NMT 0.1%	0.085%
	Total Impurities NMT 1.5%	0.487%+0.217%
Heavy Metals	Less Than 20ppm	Complies
Assay	98.0%~102.0%(By Dried Substance)	99.31%