CERTIFICATE OF ANALYSIS

Product name:	**Paclitaxel**		
Ref. Standard	**Current USP Standard**		
Batch Number:	NF-20190220	Manu. Date:	Feb. 20, 2019
Batch Size:	3000g	Expiration Date:	Feb. 19, 2021
Net Weight:	3000g	Report Date;	Feb. 20, 201*
Molecular Formula:	$C_{47}H_{51}NO_{14}$	Molecular Weight:	853.9
Storage Condition:	Preserve in tight, light-resistant containers, and store at 20°C—25°C.		

TEST ITEM	SPECIFICATION	RESULTS
Appearance	White or almost white crystalline powder	White crystalline Powder
Identification	FT-IR	Conform
	HPLC	Conform
	NMR	Conform
	Mass	Conform
Solubility	Soluble in ethanol, methanol, Chloroform, hardly soluble in water	Conform
Specific Optical Rotation	-49.0º ~ -55.0º at 20°C	-49.6º
Melting Point	213°C—216°C	213.6°C
Water	≤1.0%	0.51%
Residual Solvent	Meets the requirements of ICH	Conform
Ethyl Acetate	≤5000ppm	300ppm
Acetone	≤5000ppm	300ppm
Methanol	≤3000ppm	58ppm
Acetic acid	≤5000ppm	22ppm
Residual of volatile Solvents	Meets the requirements of ICH	Conform
Chloroform	≤60ppm	Absence
Dichloromethane	≤600ppm	5ppm

Residue of ignition		≤0.2%	0.12%
Bacteria endotoxins		≤0.4 USP EU/mg	0.135 EU/mg
Microbial Limits			
Total aerobic microbial count		≤100 cfu/g	60 cfu/g
Staphylococcus aureus		Absence	Absence
Pseudomonas aeruginosa		Absence	Absence
Salmonella species		Absence	Absence
Escherichia Coli		Absence	Absence
Heavy Metals		≤20ppm	10ppm
IMPURITIES:			
Baccatin III		≤0.2%	0.00%
7-Xylosyl paclitaxel		≤0.2%	0.00%
10-Deacetyl Paclitaxel		≤0.5%	0.05%
cephalomannine	x_1	≤0.05%	0.12%
2",3"-Dihydrocephalomannine	x_2	≤0.00%	0.00%
	(x_1+x_2)	≤0.05%	0.12%
10-Deacetyl-7-epi-paclitaxel		≤0.5%	0.05%
Benzyl analog	y_1	≤0.02%	0.01%
3"-4"-Dehydropaclitaxel C	y_2	≤0.00%	0.04%
	(y_1+y_2)	≤0.02%	0.05%
7-epi-paclitaxel		≤0.5%	0.14%
7-epi-cephalomannine		≤0.3%	0.00%
Any other single impurity		≤0.1%	0.05%max
Total Impurities		≤1.5%	0.43%
Assay (HPLC)		98.5%-102%	100.50%
CONCLUSION		The lot meets the specifications.	
Tested by:	Mr. Yang Fangchao	Approved by:	Mr. Niu Jicheng

Xi'an Natural Field Bio-Technique Company Limited
Inspection

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