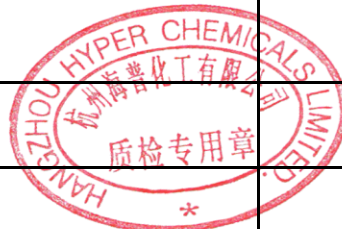


CERTIFICATE OF ANALYSIS

Product Name:	DOCETAXEL anhydrous		
Batch No.	240201		
Test Date	February 26, 2024	Report Date	March 5, 2024
Manufacturing Date	February 3, 2024	Expiry Date TO	February 2, 2027
CAS	114977-28-5	Analysis Basis	EP 10.0
Analytical results			
Items	Specifications		Results
Appearance	White or almost white crystalline powder		Conform
Identification	The IR spectrum of sample corresponds to that of reference standard		Conform
SOLUBILITY	Practically insoluble in water, freely soluble in anhydrous ethanol, soluble in methylene chloride.		Conform
SPECIFIC OPTICAL ROTATION	-41.5° ~ -38.5°		-39.8°
APPEARANCE OF SOLUTION	The solution is not more opalescent than reference suspension II(2.2.1) and not more intensely coloured than reference solution B5(2.2.2, Method I)		Conform
RELATED COMPOUNDS	Impurity A :NMT 0.2%		Not Detected
	Impurity B :NMT 0.3%		0.038%
	Impurity C :NMT 0.15%		0.037%
	Impurity E :NMT 0.15%		Not Detected
	Other Impurities:NMT 0.1%		0.079%
	Total Impurities:NMT 0.8%		0.250%
RESIDUAL SOLVENT	Acetone:NMT 5000ppm		400ppm
	Dichloromethane:NMT 600ppm		Not Detected



RESIDUAL SOLVENT	n-heptane:NMT 5000ppm	Not Detected
	Acetonitrile:NMT 410ppm	Not Detected
	Ethyl acetate:NMT 5000ppm	440ppm
	Ethanol:NMT 5000ppm	Not Detected
	Methanol:NMT 3000ppm	Not Detected
	THF:NMT 720ppm	Not Detected
	Pyridine:NMT 200ppm	Not Detected
	Acetic Acid:NMT 5000ppm	Not Detected
Microbial enumeration tests	The total aerobic bacteria:NMT 100cfu/g	Conform
	The total yeasts and molds:NMT 10cfu/g	Conform
	E.coli:Not Detected	Conform
	Staphylococcus aureus:Not Detected	Conform
	Salmonella:Not Detected	Conform
	Pseudomonas aeruginosa:Not Detected	Conform
	Enterobacteriaceae:Not Detected	Conform
Bacterial Endotoxins	NMT 0.3EU/mg	Conform
WATER	NMT1.5%	0.880%
SULFATED ASH	NMT 0.1% w/w	0.080%
HEAVY METALS	NMT 20ppm	<20ppm
Loss on Drying	NMT1.0%	0.660%
ASSAY	98.0%~102.0% (anhydrous substance)	99.880%
Conclusion	The product is in accordance with EP10.0 to test the above-mentioned items, The test results conform to the specification.	

Inspector: Carlifor Wu

Verifier: Jack He