

Certificate of Analysis

Product Name:	Paclitaxel	Manufacture Date:	Aug.10, 2013
Batch Number:	DXZS130811	Analysis Date:	Aug. 11, 2013
Batch Quantity:	8kg	Certificate Date:	Aug. 11, 2013
Shelf life:	4 years when properly stored		
Storage:	Hygrosopic, protect from moisture & light , store under desiccant below 25°C		

Test/Observation	Specifications	Result
Identification	1) By IR Sample and Standard IR spectra in mineral oil dispersion 2) By UV The light absorption spectrum of sample solution exhibits Max.282,275 and 230nm	Complies
Assay Content % by HPLC (on anhydrous basis)	98.0%--102.1%	99.56%
Chromatographic impurities		
A. Highest individual impurity	≤ 0.5%	0.2% max
B. Unknown impurity	≤ 0.10%	0.05%
C. Total impurities	NMT1.0%	0.43%
Appearance	White to off-white crystal powder	Complies
Solubility in Polysorbate-80	45.0mg/ml Min	Complies
Specific Optical Rotation	-49.0° ~ -55.0°	Complies
Bacterial endotoxins	≤ 0.4EU/mg	0.15EU/mg
Heavy metals PPM	≤ 20 PPM	3PPM
Moisture	≤3.0%	0.96%
Residue on ignition	≤0.2%	0.05%
Microbiology		
Total Plate Count	<100cfu/g	12cfu/g
Yeast & Mold	<100cfu/g	docetaxel
E.Coli	Negative	10cfu/g
S. Aureus	Negative	docetaxel
Salmonella	Negative	Complies