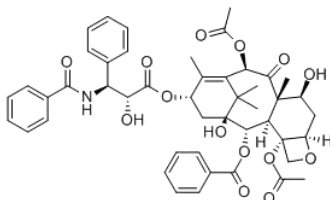


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Certificate of Analysis

Paclitaxel



Batch No: 20170307	Quantity: 3kg	
Manufacture Date: Mar.07, 2017	CAS: 33069-62-4	
Expiration date : Mar.06, 2019		
Items	Specifications	Results
Appearance	White or almost white powder	Almost white powder
Identification	H-NMR, MS	Complies
Solubility	Soluble in alcohol; insoluble in water	Complies
Water	≤4.0%	0.4%
Residue on ignition	≤0.2%	0.05%
Related (USP test substances)	10-Deacetylbaccatin III≤0.1%	<LOO
	Baccatin III≤0.2%	<LOO
	Photodegradant≤ 0.1 %	<LOO
	10-Deacetylpaclitaxel≤ 0.5%	<LOO
	2-Debenzoylpaclitaxel 2-pentenoate ≤ 0.7%	0.2%
	Oxetane ringopened,acetyl andbenzoylmigrated +10-acetoacetylpaclitaxel+7pi-10-aethyl paclitaxel≤0.4%	<LOD
	7-Epipaclitaxel≤ 0.4%	0.1%
	10,13-Bissidechainpaclitax≤ 0.5%	0.1%
	7-Acetylpaclitaxel≤ 0.6%	<LOD
	III 13-Tes-baccatin III≤ 0.1 %	<LOD
	7-Acetylpaclitaxel≤ 0.3%	0.08%

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Specific rotation (On anhydrous and solvent-free)	-49.0~-55.0°	-52.8°
Heavy metals	≤ 0.002%	<0.002%
Residual solvents	Tetrahydrofuran ≤ 720ppm	<LOD
	Ethyl acetate ≤ 5000ppm	9ppm
	n-Hexane ≤ 290ppm	2ppm
	Dichloromethane ≤ 600ppm	<LOD
	Pyridine ≤ 200ppm	153ppm
	Ethanol ≤ 5000ppm	<LOD
	Acetonitrile ≤ 410ppm	<LOD
	Acetone ≤ 5000ppm	7ppm
	N-heptane ≤ 5000ppm	1692ppm
Bacterial endotoxins	≤ 0.4EU/mg	<0.4EU/mg
Related Impurity by HPLC	Total impurity ≤ 1.0% Single impurity ≤ 0.5%	0.30% <LOD
Purity(HPLC)	≥ 99.5%	99.70%
Microbial limits	TAMC ≤ 100 CFU/g	≤ 10 CFU/g
	Staphylococcus aureus Absence	Absence
	Pseudomonas Absence	Absence
	Salmonella Absence	Absence
	Escherichia coli Absence	Absence
Assay (on anhydrous and solvent-free)	97.0%~102.0%	99.3%

Conclusion: The above substance has been tested according to In house Standards , and it meets requirements .

APIs provided by our company are only for scientific research and drug registration, not for any commercial purpose!