



瑾 岚 医 药 技 术 开 发 有 限 公 司
JINLAN PHARM-DRUGS TECHNOLOGY CO., LIMITED
Hangzhou ROYAL Import & Export Co.,Ltd.

Certificate of Analysis

Name of Product	Paclitaxel (semi-synthetic)		
Batch No.	M-P002-2003003	Batch Size	5.03KG
Mfg. Date	2020/03/25	Retest date	2021/09/24
Analysis basis	BS-SMP2.01.P002.001		

Item	Specification	Results
Characteristics	White or off-white powder	White powder
Solubility	Soluble in methanol, ethanol or trichloromethane, slightly soluble in ether and almost insoluble in water	Conforms
Identification (HPLC)	The retention time of the principal peak conforms to that of the reference standard, in the assay.	Conforms
Identification (IR)	The IR spectrum of sample conforms to that of reference standard.	Conforms
Specific optical rotation	-49.0° ~ -55.0°	-53.0°
Water	NMT 4.0%	1.1%
Loss on drying	NMT 1.0%	0.5%
Residue on ignition	NMT 0.2%	0.04%
Related substances	N-benzoyl-(2R,3S)-3-phenylisoserine NMT 0.1%	Not detected
	10-Deacetylbaccatin III NMT 0.1%	Not detected
	7-Epi-10-deacetylbaccatin III NMT 0.1%	Not detected
	Baccatin III NMT 0.1%	0.002%
	7-Epibaccatin NMT 0.1%	Not detected
	Paclitaxel photodegradant NMT 0.1%	Not detected

	10-Deacetylpaclitaxel NMT 0.2%	Not detected
	Cephalomannine NMT 0.1%	0.02%
	2-Debenzoylpaclitaxel-2-pentenoate NMT 0.1%	Not detected
	7-Epipaclitaxel NMT 0.2%	0.01%
	10,13-bisichainpaclitaxel NMT 0.1%	Not detected
	7-Acetylpaclitaxel NMT 0.1%	0.01%
	(4S,5R)-3-benzene formyl-2-(4-methoxy phenyl)-4-phenyl-5-oxazoline baccatine III NMT 0.1%	Not detected
	7-Trichloroethoxycarbonyl paclitaxel NMT 0.1%	0.005%
	13-Tes-baccatin III NMT 0.1%	Not detected
	7-Tes-paclitaxel NMT 0.1%	0.005%
	X1: Oxetane ring opened, acetyl and benzoyl migrated	Sum of X1, X2 and X3 NMT 0.3%
	X2: 10-Acetoacetylpaclitaxel	
	X3: 10-Deacetyl-7-epipaclitaxel	
	Max single unknown impurity NMT 0.1%	0.03%
	Total impurities NMT 1.0%	0.14%
Assay (on the anhydrous, solvent-free basis)	98.0%~102.0%	99.3%
Residual solvents	Tetrahydrofuran NMT 500ppm	2ppm
	Isopropanol NMT 1000ppm	2ppm
	Ethyl acetate NMT 1000ppm	3ppm
	Acetone NMT 1000ppm	2ppm
	n-Hexane NMT 290ppm	0.1ppm
	Dichloromethane NMT 500ppm	Not detected
	Pyridine NMT 200ppm	8ppm

	Acetic acid NMT 1000ppm	Not detected
	1,2-Dichloroethane NMT 5ppm	3ppm
	n-Heptane NMT 2000ppm	225ppm
Microbial contamination	The total aerobic microbial count NMT 100cfu/g	Not detected
	Staphylococcus aureus must not be detected	Not detected
	Pseudomonas aeruginosa must not be detected	Not detected
	Salmonella species must not be detected	Not detected
	Escherichia coli must not be detected	Not detected
Bacterial endotoxins	NMT 0.40EU/mg	Conform
Conclusion	The product meets the requirement of BS-SMP2.01.P002.001	

Tested by: Jiang ling

Checked by: Liu Junying

Approved by: Li Chaochun

