

# GUILIN HUANG BIOCHEMISTRY PHARMACEUTICAL CO.,LTD CERTIFICATE OF ANALYSIS

Code: QC-PA-2-100605

(SOR-ZL-001-00-03)

Product: <b>PACLITAXEL</b>	Manufacture Date: <b>Jun 9, 2010</b>
Batch No.: <b>JF20100601</b>	Sampling Date: <b>Jun 9, 2010</b>
Batch Size: <b>3 Kg</b>	Reporting Date: <b>Jun 12, 2010</b>
Analysis Basis: <b>USP</b>	Expiry Date: <b>Jun 8, 2013</b>

TEST	TEST METHOD	SPECIFICATION	RESULT	
<b>ASSAY(HPLC)</b> (Calculated on the anhydrous, solvent-free basis)	USP <621>	97.0%~102.0%	99.7%	
<b>IDENTIFICATION</b>	IR USP <197K>	The IR spectrum exhibits maximum only at the same wavelength as that of a similar preparation of the USP reference standard	Conform	
	HPLC USP <621>	The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the standard preparation as obtained in the Assay	Conform	
<b>SPECIFIC ROTATION <math>[\alpha]_D^{20}</math></b> (Calculated on the anhydrous, solvent-free basis)	USP <781S> Method 1c	-49° ~ -55°	-52°	
<b>RELATED COMPOUNDS (HPLC)</b>	10-Deacetylpaclitaxel	NMT 0.5%	Undetected	
	Cephalomannine ( Paclitaxel related compound A) and 2", 3"-Dihydro Cephalomannine	USP <621>	NMT 0.5% (sum of 2 peaks )	0.067%
	10-Deacetyl-7-epipaclitaxel ( Paclitaxel related compound B)	Test 1	NMT 0.4%	0.030%
	7-epipaclitaxel		NMT 0.4%	0.012%
	Others		NMT 0.1%(each)	Tr=28.11, 0.034% Tr=33.17, 0.051%
	Total		NMT 2.0%	0.19%
<b>ORGANIC VOLATILE IMPURITIES</b>	Methylene Chloride	USP <467>	NMT 0.06%	Undetected
	Ethyl acetate		NMT 0.5%	Undetected
	Acetonitrile		NMT 0.041%	Undetected
	Acetone		NMT 0.5%	0.004%
	Total		NMT 0.5%	0.004%
<b>WATER</b>	USP <921> Method 1c	NMT 4.0%	0.5%	
<b>RESIDUE ON IGNITION</b>	USP <281>	NMT 0.2%	0.03%	
<b>HEAVY METALS</b>	USP <231> Method II	NMT 0.002%	<0.0015%	
<b>BACTERIAL ENDOTOXINS</b>	USP <85>	NMT 0.4 IU/mg Paclitaxel	<0.2 IU/mg	
<b>MICROBIAL LIMITS</b>	USP <61>	Total aerobic microbial count NMT 100 cfu/g	<10 cfu/g	
		It meets the requirements of the tests for the absence of <i>Staphylococcus aureus</i> , <i>Pseudomonas aeruginosa</i> , <i>Salmonella species</i> , and <i>Escherichia coli</i> .	Undetected	

**CONCLUSION**      This Batch meets the USP

Tested by: <b>吴芳 邓剑英</b> 许科杰	Checked by: <b>刘海明</b>	Chief Quality Officer: <b>吴玉杰</b>	Authorized by: <b>江明</b>
Date: 2010.06.12	Date: 2010.06.12	Date: 2010.06.12	Date: 2010.06.12