



## Certificate of Analysis

<b>Product Name</b>	Paclitaxel	<b>Manufacture Date</b>	Agu .10.2023
<b>Batch Number</b>	SW230810	<b>Analysis Date</b>	Agu .12.2023
<b>Batch Quantity</b>	5kg	<b>Expiry Date</b>	Agu .10.2025

ANALYSIS	SPECIFICATION	RESULT
Appearance	White crystalline powder	Conform
Origin	Yew Taxus plants dried roots, leaves and bark	Conform
Related substances	≤ 2.0% of total related substances	Conform
Organic volatile impurities	Complies with United States Pharmacopeia (USP) and the Chinese Pharmacopoeia (CP) Organic volatile impurities requirements	Conform
Specific rotation	$[\alpha]_{20 D} = -49.0 \sim 55.0$ °(10mg/mL solution in metha), anhydrous solvent dry product.	Conform
Moisture	≤ 4.0%	Conform
Residue on ignition	≤ 0.2%	Conform
Heavy metals	≤ 0.002%	Conform
Microbial limit	≤ 100cfu / g paclitaxel; Meet on Staphylococcus aureus, Pseudomonas aeruginosa, Salmonella, Enterobacter sterility test requirements of people.	Conform
Assay	99.0%	99.6%

<b>Packing description</b>	Sealed export grade drum & double of sealed plastic bag
<b>Storage</b>	Store in a cool and dry place, stay away from strong light and heat
<b>Shelf life</b>	2 years when properly stored

Quality Assurance Officer: 李强

Corrector: 佟丽华

Analyst: 方臻

