



Taizhou Crene Biotechnology Co., Ltd.

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Certificate of analysis

Productname: Paclitaxel

Cas number: **33069-62-4**

Molecular Formula: $C_{47}H_{51}NO_{14}$

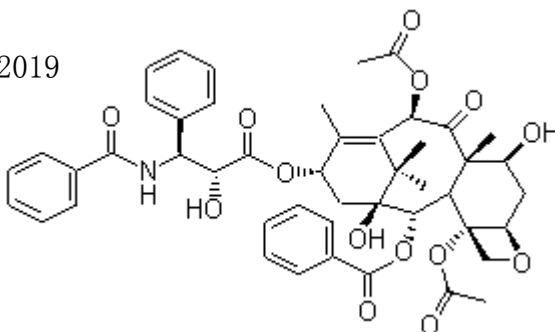
Molecular Weight: 853.92

Date of production: Nov. 08, 2019

Batch NO: 20191108

Exp Date: Nov. 07, 2021

Chemical structure:



Items	Specifications	Results
Appearance	White or almost white crystalline powder	Complies
Identification	IR, HPLC	Complies
Related substance	10-Deacetylbaccatin III $\leq 0.1\%$	No detected
	Baccatin III $\leq 0.2\%$	0.08%
	Photodegradant $\leq 0.1\%$	No detected
	10-Deacetylpaclitaxel $\leq 0.5\%$	No detected
	2-Debenzoylpaclitaxel-2-pentenoate $\leq 0.7\%$	No detected
	Oxetane ring opened, acetyl and benzoyl migrated $\leq 0.4\%$	$\leq 0.04\%$
	10-Acetoacetylpaclitaxel $\leq 0.4\%$	$\leq 0.04\%$
	10-Deacetyl-7-epipaclitaxel $\leq 0.4\%$	$\leq 0.04\%$
	7-Epipaclitaxel $\leq 0.4\%$	$\leq 0.03\%$
	10,13-Bissidechainpaclitaxel $\leq 0.5\%$	No detected
	7-Acetylpaclitaxel $\leq 0.6\%$	No detected
	13-Tes-baccatin III $\leq 0.1\%$	No detected
	7-Tes-paclitaxel $\leq 0.3\%$	No detected
	Others $\leq 0.1\%$	0.02%
	Total $\leq 2.0\%$	0.2%
Specific Rotation	$-49.0^{\circ} \sim -55.0^{\circ}$	-51.4°
Residual solvents	Ethanol $\leq 5000\text{ppm}$	No detected
	Dichloromethane $\leq 600\text{ppm}$	No detected
	Acetone $\leq 5000\text{ppm}$	649ppm
	N-heptane $\leq 5000\text{ppm}$	890ppm
Water	$\leq 4.0\%$	0.5%
Residue on ignition	$\leq 0.2\%$	0.03%
Heavy metals	20ppm	Complies
Bacteria endotoxins	$\leq 0.4\text{ EU / mg}$	Complies
Assay(HPLC)	97.0%~102.0%	99.8%

Conclusion: It complies with the USP38 Standard.

Analyst: Zhao

Checker: Liu

Q.C Director. Fang F