



Taizhou Creating Bio-pharm Co., Ltd.

ADD: 715 Room, Unit A, Junyue Building, Taizhou, Zhejiang, China

TEL: 0086-576-88827176

FAX: 0086-576-88822496

分析证明书

CERTIFICATE OF ANALYSIS

Product name: Docetaxel trihydrate 三水多西他赛 CAS:148408-66-6	
Batch no. 批号: 20221001	Quantity 数量: 2.6kgs
Manuf. date 生产日期: 2022/10/09	Expiry date 有效期: 2024/10/09

ANALYSIS TEST 检验项目	SPECIFICATIONS 规格	RESULTS 结果
Description	White to off-white crystalline powder	Conforms
solubility	Insoluble in water, soluble in ethanol and acetone	Conforms
Specific optical rotation	-39.0° ~ 41.0°	-39.6°
Identification	IR: The IR spectrum of sample corresponds to that of reference standard	Conforms
	HPLC: The retention time of the major peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard, as obtained in the assay.	
Clarity and color of solution	Clear and colorless	Conforms
Related Compounds	10-Deacetyl baccatinIII ≤0.15%	ND
	2-Debenzoxy-2-pentenoyl docetaxel ≤0.5%	ND
	6-Oxodocetaxel ≤0.3%	0.0470%
	4-Epidocetaxel ≤0.15%	0.0535%
	4-Epi-6-oxodocetaxel ≤0.2%	ND
	Any unknown single impurity ≤0.10%	0.031%
	Total impurities ≤1.0%	0.16%
Residual Solvents	Acetone ≤0.5%	0.06%
	Methanol ≤0.5%	0.15%
	Dichloromethane ≤0.06%	0.04%
	N-Hexane ≤0.029%	0.002%
water	5.0%-7.0%	6.15%
heavy metals	≤20ppm	<20ppm
Residue on ignition	≤0.1%	0.03%
Assay	97.5%~102.0%	99.7%
Storage: stored at 2-8°C and in a hermetical, light-resistant area.		
CONCLUSION: THE PRODUCT CONFORMS TO THIS STANDARD		

复核人 Checker:

化验人 Analyst:

