



检验报告书

CERTIFICATE OF ANALYSIS

产品名称 Product Name	紫杉醇(半合成) Paclitaxel(Semi-synthetic)				
产品批号 Batch No.	M-P002-2003002	检验编号 Serial No.	P002-2003002	报告书编号 Certificate No.	BC-P002-2007002
包装规格 Package Size	1kg/袋 1kg/Piece	批量 Batch Size	4.36kg	生产日期 Mfg. Date	2020.03.21 Year Month Day
样品来源 Sample From	中试车间 Pilot Workshop	CAS No.	33069-62-4	复检日期 Retest Date	2021.09.20 Year Month Day
检验依据 Specification	BS-SMP2.01.P002.001(试)-1			报告书日期 Certificate Date	2020.07.15 Year Month Day
检验项目及结果 TEST ITEMS AND RESULTS					
检验项目 TEST ITEMS	质量标准 SPECIFICATIONS			检验结果 TEST RESULTS	
性状 Characteristics	白色或类白色粉末 White or off-white powder			白色粉末 White powder	
溶解性 Solubility	在甲醇、乙醇或三氯甲烷中溶解, 在乙醚中微溶, 在水中几乎不溶 Soluble in methanol, ethanol or trichloromethane, slightly soluble in ether and almost insoluble in water			符合规定 Conform	
鉴别 1 (HPLC) Identification (HPLC)	供试品溶液主峰保留时间(含量检测项下)应与对照品主峰保留时间一致。The retention time of the principal peak conforms to that of the reference standard, in the assay.			一致 Conform	
鉴别 2 (红外光谱) Identification (IR)	本品的红外吸收图谱应与对照品的图谱一致。 The IR spectrum of sample conforms to that of reference standard.			与对照的图谱一致 Conform	
比旋度 Specific optical rotation	-49.0°~-55.0°			-53.3°	
水分 Water	≤4.0%			1.0%	
干燥失重 Loss on drying	≤1.0%			0.7%	
炽灼残渣 Residue on ignition	≤0.2%			0.03%	
有关物质 Related substances	N-苯甲酰基-(2R,3S)-3-苯基异丝氨酸≤0.10%; N-benzoyl-(2R,3S)-3-phenylisoserine≤0.10%			未检出 Not detected	
	10-脱乙酰基巴卡亭 III≤0.10%;10-Deacetylbaaccatin III≤0.10%			未检出 Not detected	
	7-表-10-脱乙酰基巴卡亭 III≤0.10%; 7-Epi-10-deacetylbaaccatin III≤0.10%			未检出 Not detected	
	巴卡亭 III≤0.10%;Baaccatin III≤0.10%			0.002%	
	7-表-巴卡亭 III≤0.10%;7-Epi-baaccatin III≤0.10%			未检出 Not detected	
	紫杉醇光降解产物≤0.10%;Paclitaxelphotodegradant ≤0.10%			未检出 Not detected	
	10-脱乙酰基紫杉醇≤0.10%;10-Deacetylpaclitaxel≤0.10%			未检出 Not detected	
	三尖杉宁碱≤0.10%;Cephalomannine≤0.10%			0.02%	
2-脱苯甲酰基紫杉醇-2-戊烯酸酯≤0.10%; 2-Debenzoylpaclitaxel-2-pentenoate≤0.10%			未检出 Not detected		

生产场地 (MANUFACTURING SITE): 中国重庆市北碚区三圣镇 (Sansheng Town, Beibei District, Chongqing, China)
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重庆市碚圣医药科技股份有限公司
Chongqing Beisheng Pharmaceutical Co., Ltd.

	7-表-紫杉醇≤0.20%;7-Epipaclitaxel≤0.20%	0.009%
	10,13-侧链紫杉醇≤0.10%;10,13- Bissichainpaclitaxel≤0.10%	未检出 Not detected
	7-乙酰基紫杉醇≤0.10%; 7-Acetylpaclitaxel≤0.10%	未检出 Not detected
	(4S,5R)-3-苯甲酰基-2-(4-甲氧基苯基)-4-苯基-5-恶唑啉巴卡亭 III ≤0.10%; (4S,5R)-3-benzoyl-2-(4-methoxy phenyl)-4-phenyl-5-oxazoline bacatine III≤0.10%	未检出 Not detected
	7-三氯乙氧羰基紫杉醇≤0.10%; 7-Trichloroethoxycarbonyl paclitaxel≤0.10%	0.001%
	13-三乙基硅烷-巴卡亭 III≤0.10%;13-Tes-baccatin III≤0.10%	未检出 Not detected
	7-三乙基硅烷-紫杉醇≤0.10%;7-Tes-paclitaxel≤0.10%	0.005%
	氧杂环丁烷开环,乙酰基和苯甲酰基 迁移, X ₁ ;Oxetane ring opened,acetyl and benzoyl migrated,X ₁	X ₁ , X ₂ 和 X ₃ 总量≤0.3%; Sum of X ₁ , X ₂ and X ₃ ≤0.3%
	10-乙酰乙酰基紫杉醇, X ₂ ; 10-Acetoacetylpaclitaxel,X ₂	
	7-表-10脱乙酰基紫杉醇, X ₃ ; 10-Deacetyl-7-epipaclitaxel,X ₃	
	最大单个未知单杂≤0.10%;Max. single unknown impurity≤0.10%	0.03%
	杂质总量≤1.0 %;Total impurities≤1.0%	0.14%
含量 (以无水和无溶剂计) Assay(on the anhydrous, solvent-free basis)	98.0%~102.0%	100.1%
残留溶剂 Residual solvents	四氢呋喃≤500ppm; Tetrahydrofuran≤500ppm	未检出 Not detected
	异丙醇≤1000ppm; Isopropanol≤1000ppm	11ppm
	乙酸乙酯≤1000ppm; Ethyl acetate≤1000ppm	10ppm
	丙酮≤1000ppm; Acetone≤1000ppm	95ppm
	正己烷≤290ppm; n-Hexane≤290ppm	2ppm
	二氯甲烷 ≤500ppm; Dichloromethane≤500ppm	未检出 Not detected
	吡啶≤200ppm; Pyridine≤200ppm	13ppm
	乙酸≤1000ppm; Acetic acid≤1000ppm	未检出 Not detected
微生物限度 Microbial contamination	正庚烷≤2000ppm; n-Heptane≤2000ppm	860ppm
	需氧菌总数≤100cfu/g;The total aerobic microbial count≤100cfu/g	未检出 Not detected
	金黄色葡萄球菌不得检出; Staphylococcus aureus must not be detected.	未检出 Not detected
	铜绿假单胞菌不得检出; Pseudomonas aeruginosa must not be detected.	未检出 Not detected
细菌内毒素 Bacterial endotoxins	沙门氏菌不得检出;Salmonella species must not be detected.	未检出 Not detected
	大肠杆菌不得检出;Escherichia coli must not be detected.	未检出 Not detected
结论: Conclusion:	本品按 BS-SMP2.01.P002.001(试)-1 标准检验, 结果符合规定。 The product meets the requirement of BS-SMP2.01.P002.001(试)-1.	

报告人/日期: 朱光雷 2020.07.15 复核人/日期: 李晚梅 2020.07.15 QC 负责人/日期: 陈七芳 2020.07.15 质量受权人/日期: 王 2020.07.15

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