湖南科伦制药有限公司

产品检验报告单

检验编号：Y-4R2403022

产品名称	注射用紫杉醇（白蛋白结合型）	批　　号	4R2403022
包装类型	中硼硅玻璃管制注射剂瓶	规　　格	100mg×1瓶/盒
请验单位	生产部	代 表 量	4747瓶
检验日期	2024-03-07	报告日期	2024-04-01
检验依据	《国家药品监督管理局标准》YBH03122020		

检验项目	标准规定	检验数据	检验结论
【性状】			
	本品为白色至淡黄色冻干块状物或粉末	本品为白色冻干块状物	符合规定
【鉴别】			
1．鉴别1	在紫杉醇含量测定项下记录的色谱图中，供试品溶液主峰的保留时间应与对照品溶液主峰的保留时间一致	在紫杉醇含量测定项下记录的色谱图中，供试品溶液主峰的保留时间与对照品溶液主峰的保留时间一致	符合规定
2．鉴别2	在人血白蛋白检查项下记录的色谱图中，供试品溶液主峰的保留时间应与对照品溶液主峰的保留时间一致	在人血白蛋白检查项下记录的色谱图中，供试品溶液主峰的保留时间与对照品溶液主峰的保留时间一致	符合规定
【检查】			
1．酸碱度	pH值应为6.0～7.5	6.8	符合规定
2．分散时间及复溶后溶液性状	应在15分钟内完全分散均匀，无未分散的固体物	在5分钟以内完全分散均匀，无未分散的固体物	符合规定
	溶液应为白色至淡黄色的乳状混悬液	白色的乳状混悬液	
3．粒径及粒径分布	平均粒径不得过200nm	105nm	符合规定
	粒径小于50nm微粒不得过5%	1%	
	粒径大于350nm微粒不得过5%	0.03%	
	D_{10}不得小于55nm	66nm	
	D_{50}应为80nm～150nm	97nm	
	D_{90}不得过300nm	157nm	
4．有关物质	杂质A不得过0.4%	未检出	符合规定
	杂质B不得过0.2%	未检出	
	杂质C不得过1.0%	0.13%	
	杂质D不得过0.2%	未检出	
	与巴卡停Ⅲ相对保留时间一致的杂质不得过0.2%	未检出	
	与C3～C11桥紫杉醇异构体相对保留时间一致的杂质不得过0.2%	未检出	
	其他单个杂质均不得过0.2%	未检出	
	杂质总量不得过1.5%	0.13%	
5．人血白蛋白多聚体	应不大于5.0%	2.4%	符合规定
6．人血白蛋白	每瓶含人血白蛋白应为720mg～1080mg	922mg	符合规定
7．残留溶剂	供试品中含乙醇不得过0.075%	0.036%	符合规定
8．紫杉醇结合率	应不得小于90%	96%	符合规定

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检验项目	标准规定	检验数据	检验结论
9．体外释放度	10μg/ml供试品溶液平均粒径不得过20nm	5.0nm	符合规定
	20μg/ml供试品溶液平均粒径不得过20nm	4.5nm	
	200μg/ml供试品溶液平均粒径不得过200nm	97nm	
10．含量均匀度	应符合规定	5.72	符合规定
11．水分	含水分不得过3.0%	0.41%	符合规定
12．不溶性微粒	含10μm及10μm以上的微粒不得过3000粒	51粒	符合规定
	含25μm及25μm以上的微粒不得过300粒	7粒	
13．渗透压摩尔浓度	应为300～360mOsmol/kg	348mOsmol/kg	符合规定
14．无菌	应符合规定	符合规定	符合规定
15．细菌内毒素	每1mg紫杉醇中含细菌内毒素的量应小于0.6EU	符合规定	符合规定
【含量】			
	按平均含量计算，含紫杉醇（$C_{47}H_{51}NO_{14}$）应为标示量的90.0%～110.0%	96.7%	符合规定

结论	本品按《国家药品监督管理局标准》YBH03122020标准检验 结论：符合规定

授权签字人：

2024.04.01

湖南科伦制药有限公司 检验专用章 (1)

Hunan Kelun Pharmaceutical Co., Ltd.

Certificate of Analysis

Test No.: Y-4R2403022

Product Name	Paclitaxel For Injection (Albumin Bound)	**Batch No.**	4R2403022
Packaging Form	Injection Vials Made of Middle Borosilicate Glass Tubing	**Strength**	100 mg / vial
Test Requested by	Mfg. Dept.	**Batch Size**	4747 vials
Testing Date	March 7th, 2024	**Report Date**	April. 1st, 2024
Mfg. Date	March 3rd, 2024	**Exp. Date**	March 2nd, 2027
Reference	*National Specification for Paclitaxel For Injection (Albumin Bound) YBH03122020*		
Test Items	**Specifications**	**Test Results**	**Conclusions**
Appearance	White to pale yellow, lyophilized cake or powder.	White lyophilized cake.	Complies
Identification (1)	The retention time of the principal peak in the chromatogram of the test solution should correspond to that of the standard solution as obtained in the Assay of Paclitaxel.	The retention time of the principal peak in the chromatogram of the test solution should correspond to that of the standard solution as obtained in the Assay of Paclitaxel.	Complies
Identification (2)	The retention time of the principal peak in the chromatogram of the test solution should correspond to that of the standard solution as obtained in the test for Human Albumin.	The retention time of the principal peak in the chromatogram of the test solution should correspond to that of the standard solution as obtained in the test for Human Albumin.	Complies
pH	6.0～7.5	6.8	Complies
Dissolution time and appearance of reconstituted suspension	Should be completely uniformly dissolved and free from undispersed solids within 15 minutes. The reconstituted suspension is white to pale yellow, milky and homogenous.	Should be completely uniformly dissolved and free from undispersed solids within 15 minutes. The reconstituted suspension is white to pale yellow, milky and homogenous.	Complies
Particle size and particle size distribution	Average particle size: ≤ 200 nm	105 nm	Complies
	Particles size less than 50 nm: ≤ 5%	1%	
	Particles size larger than 350 nm: ≤ 5%	0.03%	
	D10: ≥55 nm	66 nm	
	D50: 80 nm ~ 150 nm	97 nm	
	D90: ≤300 nm	157 nm	
Related substance	Impurity A ≤0.4%	Not detected	Complies
	Impurity B ≤0.2%	Not detected	
	Impurity C ≤1.0%	0.13%	
	Impurity D ≤0.2%	Not detected	
	Impurities corresponding to the relative retention time of Baccatine III: ≤ 0.2%	Not detected	
	Impurity corresponding to the relative retention time of C3~C11 bridged paclitaxel isomer: ≤0.2%	Not detected	
	Any individual impurity: ≤0.2%	Not detected	
	Total impurities: ≤1.5%	0.13%	

检验专用章 (1)

Human albumin polymers	≤ 5.0%	2.4%	Complies
Human albumin	720~1080 mg per vial.	922 mg	Complies
Residual solvents	Ethanol NMT 0.075%.	0.036%	Complies
Paclitaxel binding rate	≥ 90%	96%	Complies
In-vitro release rate	Average particle size of 10 μg/ml test solution should be NMT 20 nm.	5.0 nm	Complies
	Average particle size of 20 μg/ml test solution should be NMT 20 nm.	4.5 nm	
	Average particle size of 200 μg/ml test solution should be NMT 200 nm.	97 nm	
Content uniformity	Should comply.	5.72	Complies
Water content	≤ 3.0%	0.41%	Complies
Subvisible Particulate Matter	≥ 10 μm: ≤ 3000 particles /container.	51 particles /container	Complies
	≥ 25 μm: ≤ 300 particles /container.	7 particles /container	
Osmolality	300~360 mOsmol/kg	348 mOsmol/kg	Complies
Sterility	Should comply.	Complies	Complies
Bacterial endotoxin	＜0.6 EU/mg	Complies	Complies
Assay	It contains not less than 90.0%~110.0% of the labelled amount of Paclitaxel ($C_{47}H_{51}NO_{14}$), calculated with reference to the average content.	96.7%	Complies
Conclusion	It complies with the *National Specification for Paclitaxel For Injection (Albumin Bound) YBH03122020*.		

Authorized Signature:
Mo Jing
April. 1st, 2024