Hunan Kelun Pharmaceutical Co., Ltd.

Certificate of Analysis

Test No.: Y-4R2405112

Product Name	Paclitaxel For Injection (Albumin Bound)	**Batch No.**	4R2405112
Packaging	Injection Vials Made of Neutral Borosilicate Glass Tubing	**Strength**	100 mg × 1 vial/box
Test Requested by	Mfg. Dept.	**Batch Size**	4958 vials
Testing Date	02.06.2024	**Report Date**	19.06.2024
Mfg. Date	30.05.2024	**Exp. Date**	29.05.2027
Reference	Specification YBH03122020 approved by NMPA		

Test Items	Acceptance criteria	Test Results	Conclusions
Appearance	A white to pale yellow lyophilized cake or powder.	A white lyophilized cake.	Conforms
Identification	A. The retention time of the major peak of the *Sample solution* should correspond to that of the *Standard solution*, as obtained in the *Assay of paclitaxel*.	The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay of paclitaxel*.	Conforms
	B. The retention time of the major peak of the *Sample solution* should correspond to that of the *Standard solution*, as obtained in the *Human Albumin*.	The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Human Albumin*.	Conforms
pH	6.0 – 7.5	6.8	Conforms
Dissolution time and appearance of reconstituted solution	Should be completely dissolved uniformly and free from undispersed solids within 15 min. The reconstituted solution should be a white to pale yellow, milky suspension.	It is completely dissolved uniformly and free from undispersed solids within 5 min. The reconstituted solution is a white milky suspension.	Conforms
Particle size and particle size distribution	Average particle size: ≤ 200 nm	124 nm	Conforms
	Particles size less than 50 nm: ≤ 5%	Not detected	
	Particles size larger than 350 nm: ≤ 5%	0.03%	
	D_{10}: ≥55 nm	80 nm	
	D_{50}: 80 nm - 150 nm	115 nm	
	D_{90}: ≤300 nm	182 nm	
Related substance	Impurity A: ≤0.4%	Not detected	Conforms
	Impurity B: ≤0.2%	Not detected	
	Impurity C: ≤1.0%	0.093%	
	Impurity D: ≤0.2%	Not detected	
	Impurity corresponding to the relative retention time of Baccatine III: ≤ 0.2%	Not detected	
	Impurity corresponding to the relative retention time of C3-C11 bridge-bound paclitaxel isomer: ≤0.2%	Not detected	
	Any individual impurity: ≤0.2%	Not detected	

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Test No.: Y-4R2405123

Product Name	Paclitaxel For Injection (Albumin Bound)	**Batch No.**	4R2405123
Packaging	Injection Vials Made of Neutral Borosilicate Glass Tubing	**Strength**	100 mg × 1 vial/box
Test Requested by	Mfg. Dept.	**Batch Size**	10555 vials
Testing Date	04.06.2024	**Report Date**	21.06.2024
Mfg. Date	31.05.2024	**Exp. Date**	30.05.2027
Reference	Specification YBH03122020 approved by NMPA		

Test Items	Acceptance criteria	Test Results	Conclusions
	Total impurities: ≤1.5%	0.099%	
Human albumin polymers	≤ 5.0%	2.8%	Conforms
Human albumin	720 - 1080 mg per vial.	975 mg	Conforms
Residual solvents	Ethanol: ≤ 0.075%.	0.028%	Conforms
Paclitaxel binding rate	≥ 90%	97%	Conforms
In-vitro release rate	Average particle size of 10 μg/mL test solution should be NMT 20 nm.	4.4 nm	Conforms
	Average particle size of 20 μg/mL test solution should be NMT 20 nm.	4.6 nm	
	Average particle size of 200 μg/mL test solution should be NMT 200 nm.	108 nm	
Content uniformity	Should meet the requirements.	4.71	Conforms
Water content	≤ 3.0%	0.43%	Conforms
Particulate matters	≥ 10 μm: ≤ 3000 particles /vial.	42 particles /vial	Conforms
	≥ 25 μm: ≤ 300 particles /vial.	5 particles /vial	
Osmolality	300 - 360 mOsmol/kg	342 mOsmol/kg	Conforms
Sterility	Should meet the requirements.	Conforms	Conforms
Bacterial endotoxins	<0.6 EU/mg	Conforms	Conforms
Assay	It contains 90.0% - 110.0% of the labelled amount of Paclitaxel ($C_{47}H_{51}NO_{14}$), calculated on the average content.	96.3%	Conforms
Conclusion	It complies with the Specification YBH03122020 approved by NMPA.		

Authorized Signature:

Jun. 21, 2024