

Hunan Kelun Pharmaceutical Co., Ltd.

Certificate of Analysis

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
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 <i>Sample solution</i> should correspond to that of the <i>Standard solution</i> , as obtained in the <i>Assay of paclitaxel</i> .	The retention time of the major peak of the <i>Sample solution</i> corresponds to that of the <i>Standard solution</i> , as obtained in the <i>Assay of paclitaxel</i> .	Conforms
	B. The retention time of the major peak of the <i>Sample solution</i> should correspond to that of the <i>Standard solution</i> , as obtained in the <i>Human Albumin</i> .	The retention time of the major peak of the <i>Sample solution</i> corresponds to that of the <i>Standard solution</i> , as obtained in the <i>Human Albumin</i> .	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	122 nm	Conforms
	Particles size less than 50 nm: ≤ 5%	0.2%	
	Particles size larger than 350 nm: ≤ 5%	0.2%	
	D ₁₀ : ≥ 55 nm	74 nm	
	D ₅₀ : 80 nm - 150 nm	111 nm	
	D ₉₀ : ≤ 300 nm	187 nm	
Related substance	Impurity A: ≤ 0.4%	Not detected	Conforms
	Impurity B: ≤ 0.2%	Not detected	
	Impurity C: ≤ 1.0%	0.099%	
	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	



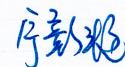
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Certificate of Analysis

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
	Total impurities: ≤1.5%	0.093%	
Human albumin polymers	≤ 5.0%	2.9%	Conforms
Human albumin	720 - 1080 mg per vial.	955 mg	Conforms
Residual solvents	Ethanol: ≤ 0.075%.	0.027%	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.	4.6 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.	112 nm	
Content uniformity	Should meet the requirements.	2.31	Conforms
Water content	≤ 3.0%	0.39%	Conforms
Particulate matters	≥ 10 µm: ≤ 3000 particles /vial.	46 particles /vial	Conforms
	≥ 25 µm: ≤ 300 particles /vial.	5 particles /vial	
Osmolality	300 - 360 mOsmol/kg	340 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.	99.8%	Conforms
Conclusion	It complies with the Specification YBH03122020 approved by NMPA.		

Authorized Signature:



Jun. 20, 2024