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Certificate of analysis

品名	奥沙利铂 Oxaliplatin	CAS	61825-94-3
货号	D10465	批次	OK20260930H
生产日期	2026-09-30	复测日期	2028-09-29

执行标准:企业标准

分析项目 SPECIFICATION PROPERTIES	技术指标 STANDARD	实测结果 RESULTS
性状 Character	白色或类白色结晶性粉末；无臭 White or almost white crystalline powder; odourless	白色结晶性粉末；无臭 White crystalline powder; odourless
溶解度 Solubility	在水中微溶，在甲醇中极微溶，在无水乙醇中几乎不溶 Slightly soluble in water, very slightly soluble in methanol, practically insoluble in anhydrous ethanol	符合 Conforms
溶液澄清度与颜色 Appearance of solution	溶液应澄清无色 The solution is clear and colorless	符合 Conforms
酸度 Acidity	加入0.5ml酚酞指示液，溶液应为无色；消耗氢氧化钠滴定液体积≤0.60ml Add 0.5ml of phenolphthalein indicator; the solution is colorless. Not more than 0.60ml sodium hydroxide is required.	溶液无色；0.47ml The solution is colorless; 0.47ml
比旋度 Specific optical rotation	+74.5°~+78.0°（按干燥品计） Calculated on the dried basis	+76.8°
鉴别 Identification	化学鉴别呈正反应；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；本品红外光谱应与对照图谱一致 Chemical identification is positive; the retention time of the major peak of the sample solution corresponds to that of the standard solution; the IR spectrum	呈正反应； 符合 Positive; conforms; conforms

	of the sample is consistent with the reference spectrum.	
干燥失重 Loss on drying	≤0.5%	0.03%
有关物质 Related substances	草酸 ≤0.10% Oxalate ≤0.10% 杂质I ≤0.10% Impurity I ≤0.10% 杂质III ≤0.10% Impurity III ≤0.10% 其他单个杂质 ≤0.10% Any other impurity ≤0.10% 其他总杂质 ≤0.10% Total of other impurities ≤0.10% 总杂质 ≤0.30% Total impurities ≤0.30%	0.001% 0.01% 0.002% 0.02% 0.02% 0.03%
左旋异构体 Isomer	≤0.10%	未检出 N.D
细菌内毒素 Bacterial endotoxins	<1.0EU/mg	<1.0EU/mg
残留溶剂 Residual solvent	乙醇 ≤0.5% Ethanol ≤0.5%	未检出 N.D
银 Silver	≤0.0005%	0.00006%
含量 Assay	98.0%~102.0%（按干燥品计） Calculated on the dried basis	99.8%
微生物限度（内控） Microbial limits (Internal control)	需氧菌总数 ≤10^2cfu/g Total Aerobic Bacteria Count ≤10^2 cfu/g 霉菌和酵母菌总数 ≤10^2cfu/g Total Combined Yeasts and Molds Count ≤10^2cfu/g 大肠埃希菌不得检出 Escherichia coli should be absent 金黄色葡萄球菌不得检出 Staphylococcus aureus should be absent	1cfu/g <1cfu/g 未检出 N.D 未检出 N.D

注：此产品仅限用于科研，禁止直接用于临床，如有失误，后果自负。

QA：杜冰冰　　QC: 谢辉



沃凯生物