



原理科技
YUANLI TECHNOLOGY

Zhengzhou Yuanli Biological Technology Co., Ltd.

郑州原理生物科技有限公司

Address: No. 52 Huangyang Street, Zhengzhou, 450000, Henan, China.

Phone: +86-371-63507389

Fax: +86-371-63507390

Certificate of Analysis

质量检验单

Product Name (产品名称): 10-Carboxymethyl-10H-acridine-9-one sodium salt (吡啶酮乙酸钠)	Batch No. (批号): ADS 2022010801J	
CAS No. (CAS 号): 58880-43-6	Quantity (批量): 62.6 kg	
Manufacturing Date (生产日期): 01/08/2022	Retest Date (复检日期): 01/07/2024	
Sampling Date (送检日期): 01/08/2022	Report Date (报告日期): 01/12/2022	
Test Items(检测项目)	Requirements (标准)	Results (结论)
Appearance (外观)	Greenish-yellow finely crystalline powder. (黄绿色结晶性粉末)	Complies (符合规定)
Identification(鉴别)	1、 IR spectrum of substance in tablet must conform to that of the reference standard. (物质的红外光谱符合参考标准。)	Complies (符合规定)
	2、 UV absorption spectrum 0.001% of solution of substance (solution pH 6.0) must have its max at (392±1)nm, (408±1)nm, min absorption at (328±1)nm, (400±1) nm. Optical density at (392±1) nm to that at (408±1) nm ratio must be 0.9 to 1.1. (0.001%的溶液, pH 6.0 的紫外吸收光谱在波长为(392±1)nm, (408±1)nm 有最大吸收, 在波长为(328±1)nm, (400±1) nm 有最小吸收。吸光度在波长(392±1) nm 和(408±1) nm 在 0.9-1.1 之间。)	Complies (符合规定)
Test(检查)	1、 Solubility: Freely soluble in water, slightly soluble in ethanol 96%, insoluble in chloroform. (溶解度: 易溶于水, 微溶于 96%乙醇, 不溶于氯仿。)	Complies (符合规定)



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	2、Clarity: A solution of 1.25 g substance in 10 ml of water should be clear (澄清度:取 1.25g 样品溶于 10ml 水中, 溶液应澄清。)	Complies (符合规定)
	3、pH value(pH 值): 9.0~11.0	10.96
Related substances(有关物质)	1、Acridone NMT 0.15%(吡啶酮不大于 0.15%)	0.014%
	2、N-Methyl acridone NMT 0.1%(N-甲基吡啶酮不大于 0.1%)	0.048%
	3、Unidentified impurities NMT 0.1%(未知杂质不大于 0.1%)	0.071%
	4、Sum of impurities NMT 0.5%(总杂质不大于 0.5%)	0.19%
Heavy metals(重金属)	NMT 0.001%(不大于 0.001%)	Complies (符合规定)
Loss on drying(干燥失重)	NMT 2.0%(不大于 2.0%)	1.03%
Residual organic solvents (有机溶剂残留)	2-propanol NMT 0.5%(异丙醇不大于 0.5%)	Complies (符合规定)
Assay (含量)	99.0~101.0 % calculated on dry basis(按干燥品计算: 99.0~101.0 %)	99.81%
Conclusion (结论)	The product complies with enterprise standard. (产品符合企业标准。)	
Checker (检验人): Yanjie Du	Rechecker (复核人): Jin Jin	Supervisor (主管): Minghui Yu

