

检验结果 Analytical Results		
项目 Item	检验标准 Acceptance criteria	结果 Result
性状 Description	白色结晶或结晶性粉末 White, crystals or crystalline powder	白色结晶性粉末 White crystalline powder
溶解性 Solubility	极易溶于甲酸, 易溶于甲醇, 乙醇, 微溶于水 It is very soluble in methanoic acid, freely soluble in methanol and in ethanol(99.5), and slightly soluble in water.	符合规定 Conforms
熔点 Melting point	约 214℃ (熔融时同时分解) About 214℃ (with decomposition)	213.5℃
pH	3.0~4.0	3.2
鉴别 Identification	(1) 紫外吸收图谱与标准图谱比较, 在相同的波长处有相似的吸收强度。 Compare the Ultraviolet-visible absorption spectrum of sample with the Reference Spectrum, both spectra exhibit similar intensities of absorption at the same wavelengths. (2) 红外吸收图谱与标准图谱比较, 在相同的波数有相似的吸收强度。 Compare the infrared absorption spectrum of sample with the Reference Spectrum, both spectra exhibit similar intensities of absorption at the same wave numbers. (3) 本品的稀乙醇溶液显氯化物的鉴别反应 A solution of sample in dilute ethanol(1 in 200) responds to the qualitative tests for chloride.	符合规定 Conforms 符合规定 Conforms 符合规定 Conforms
有关物质 Related substances	相对保留时间 0.16 杂质 (impurity at RRT 0.16) ≤0.03% 未知单杂 (unspecifide impurity) ≤0.1%	未检出 N.D 0.03%
重金属 Heavy metals	≤10ppm	<10ppm
干燥失重 Loss on drying	≤0.1%	0.06%
炽灼残渣 Residue on ignition	≤0.1%	0.06%
残留溶剂 Residual solvents	异丙醇 (Isopropyl alcohol) ≤5000ppm 乙酸乙酯 (Ethyl acetate) ≤5000ppm 氯仿 (Chloroform) ≤60ppm	54ppm 13ppm 3ppm
含量 Assay	99.0%~101.0% (按干燥品计) (Calculated on the dried basis)	99.5%

结论: 合格  
Conclusion: