

执行标准	IHS	
Standard adopted		
分析项目 Items of analysis	质量标准 Specification	实测结果 Results
Description	a white or off white crystalline powder	a white crystalline powder
solubility	soluble in dimethyl sulfoxide & slightly soluble in ethanol and methanol	complies
identification,HP LC	the principal peak in the chromatogram obtained with test solution is corresponds to retention time the principal peak in the chromatogram obtained with RS in the assay	complies
melting point	132-165℃	163℃
heavy metals	not more than 10ppm	complies
loss on drying	not more than 0.5%	0.248%
specific optical rotation	-18.0 °to -26.0°	-25.06°
residual solvent		
methanol	NMT 3000ppm	complies
chloroform	NMT 60ppm	complies
sulphated ash	not more than 0.1%	0.05%
assay	98-102% on dry basis	99.811%
结论 Conclusion	合格 Qualified	