

CERTIFICATE OF ANALYSIS

Product: Drospirinone[CAS:67392-87-4]

Batch No: 20161020

Manufacturing Date: Oct., 2016

Expiry Date: Oct., 2018

Analysis Date: 2016-10-19

Quantity: 20 Kgs

检验项目和结果 Items And Results			
检验项目 Items	标准 Specifications	检测结果 Test results	
01 外观 Appearance	白色或类白色粉末 White or almost white powder	类白色粉末 almost white powder	
02 溶解度 Solubility	几乎不溶于水, 易溶于二氯甲烷, 溶于甲醇, 略溶于乙醇。 Practically insoluble in water, freely soluble in methylene chloride, soluble in methanol, sparingly soluble in ethanol (96 percent).	符合 Conforms	
03 鉴别 Identification	IR	符合 Conforms	
	Specific optical rotation	符合 Conforms	
04 比旋度 Specific rotation	-187.0°~-193.0°	-190.1°	
05 相关物质 Related substances	单一杂质≤0.10% Individual impurity≤0.10%	0.09%	
	总杂质≤0.3% Total impurities≤0.3%	0.25%	
06 干燥失重 Loss on drying	≤0.5%	0.1%	
07 含量 Assay	98.0%~102.0%	99.9%	
08 残留溶剂 Residual solvents	甲醇≤3000ppm Methanols≤3000ppm	未检出 Not Detected	
	二氯甲烷≤600ppm Methylene chlorides≤600ppm	未检出 Not Detected	
	异丙醚≤1000ppm Isopropyl ethers≤1000ppm	未检出 Not Detected	
	四氢呋喃≤720ppm Tetrahydrofurans≤720ppm	未检出 Not Detected	
	乙酸异丙酯≤5000ppm Isopropyl acetates≤5000ppm	32ppm	
	三乙胺≤320ppm Triethylamines≤320ppm	24ppm	
	吡啶≤200ppm Pyridine≤200ppm	未检出 Not Detected	
	2-甲基四氢呋喃(不得检出) 2 methyl tetrahydrofuran (No detected)	未检出 Not Detected	
	符合 EP7.0 标准 Meets the specification of EP7.0		
	结论 Conclusion		