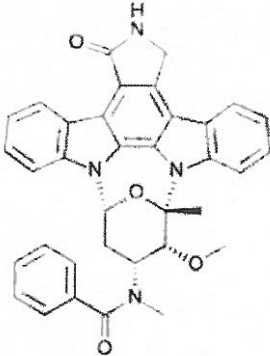


产品检验报告单

CERTIFICATE OF ANALYSIS

(Lab Sample)

Name 名称		Structure 结构			
Midostaurin 米哌妥林					
				CAS Number CAS 号	120685-11-2
				Quantity 数量	355.1g
Batch number 批号	QTH113-191202	Production date 生产日期	2019-12-11		
R&D MOA No 方法编号	QT-TM0-QTH113-09	Analytical Report 报告编号	QTH113-20-004		
Report date 报告日期	2020-01-10	Retest date 复检日期	2021-12-10		

Items 项目	Specifications 标准	Results 结果
Appearance 外观	White to light yellow or light green powder 白色至浅黄色或浅绿色粉末	Conforms 符合规定
Specific rotation 比旋度	+168° to +180° +168° ~ +180°	+171°
Identification (HPLC) 高效液相保留时间鉴别	The retention time of major peak of test solution should correspond to that of comparison solution. 供试品溶液主峰的保留时间与对照品溶液一致	Conforms 符合规定
Identification (IR) 红外光谱鉴别	The IR spectrum of the sample corresponds to the spectrum of reference standard. 供试品的红外光吸收图谱与对照品一致	Conforms 符合规定
Colour and clarity of solution (EP) 溶液的澄清度与颜色 (欧洲药典)	The solution is clear and not more intensely colored than reference solution GY ₃ 溶液应澄清无色; 如显色, 与 GY ₃ 标准比色液比较, 不得更深。	Conforms 符合规定
Related Substances 有关物质	Staurosporine NMT 0.10% 星孢菌素 ≤ 0.10%	0.09%
	Impurity A NMT 0.10% 杂质 A ≤ 0.10%	0.02%

	Impurity B NMT 0.10% 杂质 B ≤0.10%	0.02%
	Other individual impurity NMT 0.10% 其他单个杂质 ≤0.10%	0.02%
	Total impurities NMT 1.0% 总杂质 ≤1.0%	0.20%
<i>Residue solvents</i> 残留溶剂	Methanol NMT 0.3% 甲醇 ≤0.3%	0.001%
	Ethanol NMT 0.5% 乙醇 ≤0.5%	0.06%
	Dichloromethane NMT 0.06% 二氯甲烷 ≤0.06%	0.002%
	Ethyl acetate NMT 0.5% 乙酸乙酯 ≤0.5%	Not detected 未检出
	Tetrahydrofuran NMT 0.072% 四氢呋喃 ≤0.072%	Not detected 未检出
<i>Water</i> 水分	NMT 5.0% ≤5.0%	1.76%
<i>Residue on ignition</i> 炽灼残渣	NMT 0.1% ≤0.1%	0.01%
<i>Assay</i> 含量	98.0%~102.0% (on anhydrous and solvent free substance) 98.0%~102.0% (按无水、无溶剂物计)	99.4%
<i>Conclusion</i> 结论	The results conform to enterprise standard. 符合企业内控标准	
<i>Storage</i> 储存条件	Preserve in tightly closed container not above 30°C, protected from light. 遮光、密封, 在 30°C 以下保存	