

# 检验报告单

## CERTIFICATE OF ANALYSIS

品名 /Product:	劳拉替尼 / Lorlatinib
CAS NO.: 1454846-35-5	生产日期/Mfg. Date: 20200817
批号/Batch No.: (L) CT0058-20200801	复检日期/Retest Date: 20210816
批量/Batch Size: 0.8kg	取样日期/Sampling Date: 20200818
包装/Packing Size: 1 kg/drum	报告日期/Report date: 20200818

检测项目 Analysis Item	检验标准 Specification		检测结果 Results
性状 Characteristics	白色至类白色粉末 White to off-white powder		类白色粉末 Off-white powder
鉴定 Identification	主峰保留时间与产品一致 The retention time of test sample major peak complies to reference standard		合格 Complies
水份 Water	< 0.5%		0.2%
干燥失重 Loss on drying	<1.0%		0.5%
灼烧残留 Residue on ignition	<1.0%		0.1%
相关杂质 Related substances by HPLC	最大单一杂质 Single impurity	< 0.20%	0.11%
	总杂质 Total impurity	<1.0%	0.20%
纯度 Purity	> 99.0%		99.80%
e.e 值 enantiomeric excess	> 99.5%		99.8%
含量 Assay	98.0^102.0%		99.51%
结论 Conclusion	本品符合企业标准 Complies to the enterprise specification		
储存条件 Storage condition	常温密闭保存 Preserve in tight, light-resistant containers, and store at room temperature		

分析：  
Analyzed by:

复核：  
Checked by:

审核：  
Approved by: