

Jiangxi Long Life Bio-Pharmaceutical Co., Ltd.
(A wholly owned subsidiary of Chiral Quest (Suzhou) Co., Ltd.)

Certificate of Analysis

产品检验报告

Product Name 产品名称:	(R)-3- (tert-butoxycarbonylamino) -4-(2,4,5-trifluorophenyl)butanoic acid
CAS No.:	486460-00-8
Batch No. 批号:	L018-7-160905
Batch Size 批数量:	139.3Kg
Date of Manufacturing 生产日期:	2016-09-25
Retest Date 复测日期:	2018-09-24
Specification 质量标准:	QAS-CP018-7-06

No.	Test Items 测试项目	Specification 质量标准	Results 结果
1	Appearance 外观	White to off-white powder 白色至类白色粉末	Off-white powder 类白色粉末
2	Identification by IR 红外鉴别	Conforms to spectrum of the standard 与对照品谱图一致	Conforms 一致
3	Identification by HPLC HPLC 鉴别	Conforms to retention time of the standard 与对照品保留时间一致	Conforms 一致
4	Water Content by KF (w/w%) 水份(KF,w/w%)	≤ 0.50%	0.12%
5	Specific rotation 比旋度	+13.0 ⁰ ~+18.0 ⁰	+13.6 ⁰
6	Stereochemical purity by HPLC 立体化学纯度 (HPLC) -S-isomer S 型异构体	≤ 0.10%	0.01%
7	Related substances by HPLC (A%) 相关物质 (HPLC, A%) -3-amino-4-(2,4,5-trifluorophenyl)butanoic acid 3-氨基-4-(2,4,5-三氟苯基)丁酸 -Largest unknown impurity 单个最大未知杂质 Total impurities 杂质总量	≤ 0.10% ≤ 0.30% ≤ 0.50%	0.06% 0.05% 0.11%
8	Solvent Residue by GC 溶剂残留 (GC) -Ethyl acetate 乙酸乙酯 -Heptane 正庚烷 -Methanol 甲醇 -Toluene 甲苯 -Acetonitrile 乙腈	≤ 500ppm ≤ 500ppm ≤ 300ppm ≤ 89ppm ≤ 41ppm	74ppm 78ppm 35ppm ND ND
9	Residue on ignition 灼烧残渣	≤ 0.5%	0.04%

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10	Metal Residue 金属残留 -Rh 铑	≤ 10 ppm	< 10ppm
11	Assay by HPLC 含量 (w/w%) (On anhydrous basis 按干燥品计算)	98.0~102.0%	100.0%

Conclusion: Batch released. The batch complies with the specification. I hereby certify that the above information is authentic and accurate.

结论: 批放行。本批产品符合规定的质量标准。特此证明以上信息真实准确。

Comment 备注 NA

Certificate prepared by/Date 起草人/日期:

Certificate reviewed by/Date 审核人/日期:

Quality Control 质量控制

Certificate approved by/Date 批准人/日期:

Quality Assurance 质量保证

