

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: (S)-3-methylamino-1-(thiophene-2-yl)propan-1-ol
 CAS No. : 116539-55-0 Date of Manufacturing 生产日期: 2017-05-26
 Batch No.批号: L014-2-170509 Retest Date 复测日期: 2019-05-25
 Batch Size 批数量: 284.5Kg

No.	Test Items 测试项目	Specification 质量标准	Results 结果
1	Appearance 外观	White to yellow solid 白色至黄色固体	Off-white solid 类白色固体
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	Related substances by HPLC (A%) 相关物质 (HPLC, A%) 3-(methylamino)-1-(thiophen-3-yl)propan-1-ol 3-(methylamino)-1-(thiophen-2-yl)propan-1-one Individual unknown impurity 单个未知杂质 Total impurities 杂质总量	 ≤ 0.1% ≤ 0.1% ≤ 0.10% ≤ 1.0%	 0.07% ND 0.04% 0.14%
5	e.e. by HPLC 对映体过量% (HPLC)	≥ 99.5%	99.9%
6	Water Content by KF (w/w%) 水份(w/w%)	≤ 0.3%	0.14%
7	Specific rotation 比旋度 [α] _D ²⁰ (C=3, Ethanol)	-14.5 ⁰ ~-19.5 ⁰	-17.4 ⁰
8	Solvent Residue by GC 溶剂残留 (GC) Toluene 甲苯 Methanol 甲醇 Benzen 苯	 ≤ 890 ppm ≤ 150 ppm ≤ 2 ppm	 363ppm 67ppm ND
9	Residue on ignition 灼烧残渣	≤ 0.1%	0.05%
10	Formaldehyde Residue by HPLC 甲醛残留	≤ 1000 ppm	<35.2ppm
11	Metal Residue 金属残留 Rh 铑	≤ 10 ppm	<10ppm
12	Assay by HPLC 含量 (w/w%) (on dried basis 按干燥品计算)	98.0%~102.0%	100.2%

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Batch Size 批数量:	284.5Kg		

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

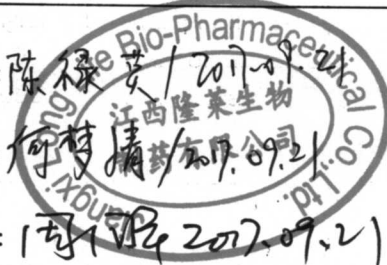
结论: 批放行。本批产品符合规定的质量标准。特此证明以上信息真实准确。

Comment 备注 NA

Certificate prepared by/Date 起草人/日期: 陈禄平 / 2017.09.21

Certificate reviewed by/Date 审核人/日期: 何梦清 / 2017.09.21

Certificate approved by/Date 批准人/日期: 何梦清 2017.09.21



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