



GMP 管理文件

REC-QC-01-007-B

Certification of Analysis

File Code(文件编码): REC-QC-01-007-B

Analysis ID (检验编号): FP201402010

Name(检品名称)	Artemisinin(青蒿素)		
Batch Number(批号)	F2014022304	Genre(类别)	APIs
Quantity(数量)	500.00kg	Origin(来源)	Hunan Vigor Bio-Tech Co., Ltd. (湖南威嘉生物科技有限公司)
Manufacturing Date (生产日期)	Feb. 17, 2014	Expiry Date (有效期至)	Feb 16, 2016
Test Date (检验日期)	Feb. 23, 2014	Report Date (报告日期)	Feb. 25, 2014
Test Methods(检验依据)	TSD-ZL-02-001-B, SOP-QC-06-001-B		
Analysis Items(检验项目)	Specifications(标准规定)	Results(检验结果)	
Appearance(性状)	A colourless or white crystalline 白色或类白色结晶性粉末	White crystalline 白色结晶性粉末	
Clarity of the Solution(澄清度)	Clear or corresponds to slightly opalescent 不大于 1 级	Clear to slightly opalescent 小于 1 级	
Identity by IR(鉴别)	Corresponds to the reference 光谱图应与对照光谱图一致	Corresponds to the reference 与对照光谱图一致	
Specific Optical Rotation(比旋度)	+75°~+78°	+77°	
Loss on Drying(干燥失重)	NMT 0.5%	0.09%	
Impurities by HPLC(有关物质)			
(1) Artemisinin (脱氢青蒿素)	NMT 0.5%	0.06%	
(2) Any Unspecified Impurities (单一不明杂质)	NMT 0.5%	0.15%	
(3) Total Unspecified Impurities (总不明杂质)	NMT 1.0%	0.15%	
Assay by HPLC(含量)	97.0%~102.0%	99.3%	
Result(结论)	Conforms(符合规定)		



Analyst(检验人): 王美

Reviewed By(复核人): 贺颖东

QC Manager(负责人): 罗良