



湖北朗昕生化药业有限公司

Hubei Lansun Pharmaceutical Company

## 检验报告书

## Certificate of Analysis

报告单号: CP-20140906

产品名称 Product Name	阿齐沙坦酯 Azilsartan medoxomil	CAS No	863031-21-4
批号 Batch No.	AZ-20140901	数量 Quantity	5kg
产品规格 Package	5kg/包	检验依据 Test According to	企业标准 Enterprises Standard
生产日期 Date of Production.	2014.09.07	检验日期 Date of Analysis	2014.09.08
报告日期 Date of Report	2014.09.08	储藏 Storage	避光密封保存 Sealed, keep away from light.
<b>检验项目</b> <b>Test item</b>	<b>标准规定</b> <b>Specification</b>	<b>检验结果</b> <b>Test Result</b>	
外观 Appearance	白色或类白色结晶性粉末 White to off- white crystalline powder	白色结晶性粉末 White crystalline powder	
鉴别 I.D.	保留时间鉴别 Retention time	液相含量项下保留时间应与对照品一致 HPLC Retention time comply with reference	
水分 water	≤0.5%	0.16%	
灼烧残渣 ROI	≤0.1%	0.04%	
重金属 Heavy metals	≤10ppm	符合规定 Conforms	
残留溶剂 Residual Solvent	二氯甲烷 Dichloromethane ≤0.06%	Undetected	
	丙酮 Acetone ≤0.5%	0.014%	
	甲醇 methanol ≤0.5%	Undetected	
	乙酸乙酯 Ethyl acetate ≤0.5%	0.37%	
有关物质 Related substance	最大单个杂质≤0.50% largest Single Impurity ≤0.50%	0.12%	
	总杂质不大于 1.0% Total Impurities ≤1.0%	0.28%	
纯度 (By HPLC) Purity	不小于 99.0% Not Less than 99.0%	99.72%	
检验结论: 本品按阿齐沙坦酯质量标准检验, 结果符合规定。 Conclusion: Complies with all requirements of the quality standards of Azilsartan medoxomil			

检验人:

Analysis By:

复核:

Checked By:

质量经理:

Approved By: