

检验报告书

Certificate of Analysis

报告单号: CP-20141002

产品名称 Product Name	阿齐沙坦酯钾盐 Azilsartan kaMedoxoMil	CAS.No	863031-24-7
批号 Batch No.	AZ-K 20141017	数量 Quantity	50g
产品规格 Package	50g/包	检验依据 Test According to	企业标准 Enterprises Standard
生产日期 Date of Production.	2014.10.17	检验日期 Date of Analysis	2014.10.21
报告日期 Date of Report	2014.10.22	复测期 Retest Date	2016.10.16
检验项目 Test item	标准规定 Specification	检验结果 Test Result	
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	
溶解性 Solubility	溶于甲醇, 略溶于乙醇, 几乎不溶丙酮 Soluble in methanol, slightly soluble in ethanol, practically insoluble in acetone	符合规定 Conforms	
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	
	钾盐鉴别 Test of potassium	焰色反应呈紫色 Purple flame reaction	
残留溶剂 Residual Solvent	二氯甲烷 Dichloromethane	≤0.06%	Undetected
	丙酮 Acetone	≤0.5%	Undetected
	甲醇 methanol	≤0.5%	Undetected
	乙酸乙酯 Ethyl acetate	≤0.5%	0.26%
水分 water		≤0.5%	0.27%
澄清度 Appearance of solution	溶于应澄清无色 Clear and colourless	符合规定 Conforms	
PH		7.5~9.5	8.78
重金属 Heavy metals		≤10ppm	符合规定 Conforms
有关物质 Related substance	阿齐沙坦酸 ≤1.0%	Azilsartan ≤1.0%	0.32%
	未知杂质 ≤0.1%	Any unknown impurity ≤0.1%	未检出
	甲酯 ≤0.5%	Methyl ester ≤0.5%	未检出
	总杂质不大于 1.0%	Total Impurities ≤1.0%	0.32%
含量 外标法 By HPLC) Assay (on dry basis)		98.0%~102.0%	99.06%
检验结论: 本品按阿齐沙坦酯钾盐质量标准检验, 结果符合规定。 Conclusion: Complies with all requirements of the quality standards of Azilsartan kaMedoxoMil			
储藏 Storage	阴凉处干燥避光密封保存 Sealed Kept in cool (15-30°C), dry place, keep away from light.		

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