

检验报告书

Certificate of Analysis

报告单号: CP201408003

产品名称 Product Name	卡巴拉汀重酒石酸盐 Rivastigmine tartrate	CAS No	129101-54-8
批号 Batch No.	KBJS-201408001	数量 Quantity	1KG
产品规格 Package	1KG/包	检验依据 Test According to	美国药典 37 版 USP 37
生产日期 Date of Production.	2014.08.05	检验日期 Date of Analysis	2014.08.07
报告日期 Date of Report	2014.08.07	储藏 Storage	密封避光保存 Sealed keep away from Light
检验项目 Test item	标准规定 Specification	检验结果 Test Result	
外观 Appearance	白色或类白色结晶粉末 White or almost white crystalline powder	类白色结晶粉末 almost white crystalline powder	
溶解度 Solubility	易溶于水和甲醇, 极微溶于乙酸乙酯 Very soluble in water and in methanol; very slightly soluble in ethyl acetate	符合规定 Conforms	
鉴别 I.D	红外 IR IR spectrum should conforms with Reference	符合规定 Conforms	
	保留时间鉴别 Retention time Retention time under purity comply with reference	符合规定 Conforms	
水分 Water	≤0.5%	0.32%	
灼烧残渣 Residue on Ignition	≤0.1%	0.08%	
重金属 Heavy metals	≤10ppm	符合规定 Conforms	
有关物质 Related substance	杂质 A ≤0.30% Impurity A ≤0.30%	0.10%	
	其它未知最大单个杂质 ≤0.10% Other unknown largest Single Impurity ≤0.10%	符合规定 Conforms	
	总杂质不大于 0.5% Total Impurities ≤0.5%	0.14%	
对映异构体 Enantiomer	≤0.30%	0.16%	
纯度 (By HPLC) Purity	不小于 99.5% Not Less than 99.5%	99.86%	
检验结论: 本品按卡巴拉汀重酒石酸盐质量标准检验, 结果符合规定。 Conclusion: Complies with all requirements of the quality standards of Rivastigmine tartrate			

检验人 Analysis By:

复核 Checked By:

质量经理 QM: