

JINAN JIANFENG CHEMICAL CO.LTD.

TEL:0086-531-88110457, FAX: 0086-531-88110457 ADDR: NO.9 HUANENG ROAD JINAN CITY, CHINA

检验报告单

CERTIFICATE OF ANALYSIS

品名 (Product name) : 盐酸度洛西汀 (Duloxetine Hydrochloride)		
批号 (Batch No.) :10071402		
报告日期 (Report Date) : 2010/7/14		
分析项目 Item of analysis	标准 Standard	分析结果 Result of analysis
外观 Appearance	白色至类白色结晶性粉末 White to Almost White Crystalline Powder	白色结晶性粉末 White Crystalline Powder
鉴别 Identification	A. 红外吸收光谱 IR Spectrum	与对照图谱一致 The same as Std.Preparation
	B. 高效液相色谱 HPLC Retention Time	与对照品RT值一致 The same as Std.Preparation
	C. 氯化物 Test for Chloride	阳性 Positive
	D. 比旋度 Specific Rotation	+110~+130°
溶液外观 Appearance of Solution	溶液澄清度 Clarity of Solution	澄清 Clear(≡Ref.Susp.I)
	溶液色度 Color of Solution	不深于棕黄色5号, ≡BY5
重金属 Heavy Metals	≡0.001%(10ppm)	<0.001%(10ppm)
硫酸化灰粉 Sulphated Ash	≡0.1%	≡0.05%
干燥失重 Loss on drying	≡0.5%	≡0.05%
有关物质 HPLC Impurities	α-萘酚 1-Naphthol	≡0.15%
	异甲基度洛芬 Isomethylduloxetine	≡0.15%
	其他单个杂质 Individual Unspecified Impurity	≡0.10%
	总杂质 Total Impurities	≡1.0%
手性纯度 Enantiomeric Purity(HPLC):R-Duloxetine	≡0.15%	≡0.05%
残留溶液 Residual solvents	甲醇 Methanol	≡0.3%(3000ppm)
	异丙醇 2-Propanol	≡0.5%(5000ppm)
	丙酮 Acetone	≡0.5%(5000ppm)
	甲苯 Toluene	≡0.089%(890ppm)
含量测定 (折干) /HPLC Assay(on dried Basis)	98.0-102.0%	99.7%
粒径分布 Particle Size Distribution	d(0.9) ≡ 10um	7um
结论 Conclusion: 本品符合注册标准规定 Conform with specification		
审查者 (Exam)	化验者 (Analyst)	复核者 (Checker)

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