

Kalchem International

Chemicals & Compounding Supplies

样品名称 Product		辛伐他汀 Simvastatin		检验依据 The Standard		USP 34-03					
批号 Batch No.		101-002-160801		数量 Quantity		~Kg					
生产日期 Manufacture Date		2016-07-24		复验期 Retest Date		2019-07-23					
				报告日期 Report Date		2016-09-20					
检验项目 TEST ITEMS				标准规定 SPECIFICATIONS				检验结果 RESULTS			
性状 Characters				为白色或类白色粉末 White to off-white powder.				为白色粉末 A white powder			
溶解度 Solubility				几乎不溶于水, 易溶于氯仿、甲醇、乙醇, 略溶于丙二醇, 极微溶于正己烷。 Practically insoluble in water; freely soluble in chloroform, in methanol, and in alcohol; sparingly soluble in propyleneglycol; very slightly soluble in hexane.				符合规定 Conforms			
鉴别 Identification		A. IR 鉴别 By IR		A. 应符合规定 Conforms				符合规定 Conforms			
		B. HPLC 鉴别 By HPLC		B. 应符合规定 Conforms				符合规定 Conforms			
比旋度 Specific optical rotation (以干燥品计 On dry basis)				+285° ~ +298°				+291°			
重金属 Heavy metals				≤20ppm				<20ppm			
干燥失重 Loss on drying				≤0.5%				0.1%			
炽灼残渣 Residue on ignition				≤0.1%				<0.1%			
含量 (HPLC)(以干燥品计) Assay (By HPLC) (On dry basis)				98.0%~102.0%				98.5%			
色谱纯度 (HPLC) Chromatography Purity (By HPLC)											
辛伐他汀羧酸 simvastatin hydroxyacid				≤0.4%				0.06%			
洛伐他汀和表洛伐他汀 lovastatin and epilovastatin				≤1.0%				0.18%			
亚甲基辛伐他汀 methylene simvastatin				≤0.4%				0.06%			
辛伐他汀醋酸酯 acetyl simvastatin				≤0.4%				0.05%			
脱水辛伐他汀 anhydro simvastatin				≤0.4%				0.08%			
辛伐他汀二聚体 simvastatin dimer				≤0.4%				0.10%			
其它单个杂质 Any other individual impurity				≤0.10%				0.03%			
总杂质(除洛伐他汀、表洛伐他汀外) Total impurities (Except lovastatin and epilovastatin)				≤1.0%				0.38%			
残留溶剂 (GC) Residual organic solvents (By GC)											
甲醇 Methanol				≤3000ppm				ND			
乙醇 Ethanol				≤5000ppm				528ppm			
二氯甲烷 Methylene chloride				≤600ppm				ND			
颗粒度 Particle size				D(0.9) < 125µm				D(0.9): 29µm			
微生物限度 Microbial Limits											
总细菌 Total Plate Count				≤1000CFU/g				<10CFU/g			
酵母菌和霉菌 Total yeast and mold				≤100CFU/g				<10CFU/g			
大肠埃希菌 E.coli				Absence/g				ND			
结论 Conclusion				本品按最新的USP标准和客户标准检测, 结果符合规定。 It complies with all the requirements of current USP monograph & Customer Standard.							

储存条件 Storage: 密闭、充氮、15~30°C 或冷藏。Preserve in well-closed containers. Store under nitrogen, between 15°C and 30°C, or under refrigeration.

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