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CERTIFICATE OF ANALYSIS

Product Name 产品名称	Clopidogrel Bisulfate 硫酸氢氯吡格雷		
Batch No. 批号	20120801	Expiry Date 有效期至	2014-07
Report Date 报告日期	2012-08-07	Quantity 数量	1Kg

Items	Standard	Results	
Appearance 性状	White or off-white powder 白色至类白色粉末	White powder 白色粉末	
Identification 鉴别	1) IR: The IR spectrum of sample recorded as KBr pellet is concordant with similarly recorded spectrum of working standard. 红外鉴别应与对照图谱一致	Comply 符合规定	
	2) The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay. HPLC 鉴别供试品主峰保留时间应与对照品一致	Comply 符合规定	
	3) It responds to the test for Sulfate. 硫酸盐反应	Comply 符合规定	
Solubility 溶解性	Freely Soluble in methanol; slightly soluble in acetone and chloroform; practically insoluble in ethyl ether 易溶于甲醇, 微溶于丙酮、氯仿, 几乎不溶于乙醚	Comply 符合规定	
Assay 含量	98.5%~101.5%	99.24%	
Related Substances 有关物质	Impurity A 杂质 A	≤0.2%	0.02%
	Impurity B 杂质 B	≤0.3%	0.10%
	Impurity C 杂质 C	≤1.0%	N/D 未检出
	Other single impurity 其它杂质	≤0.1%	0.01%
	Total impurities 总杂质	≤1.5%	0.18%
Loss on drying 干燥失重	≤0.5%	0.16%	
Heavy metals 重金属	≤10ppm	<10ppm	
Residue on ignition 炽灼残渣	≤0.1%	0.07%	
Storage 储存	Keep tightly closed in a dry place. Protected from light with original package. 密封, 避光, 置阴凉干燥处保存		
Determination 结论	Complies with USP34 符合 USP34 标准		

Analyst: shilijuan
测试者: 石丽娟

Checker: liuhuaying
复核者: 刘华英

Supervisor: wanghongfu
负责人: 王洪福

