

检验报告书

Certificate of Analysis

报告书号COA #:

C150514-03

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产品名称 Product	盐酸左旋咪唑 Levamisole Hydrochloride	批号 Batch #	90915005
生产日期 Manufacture Date	2015.05.02	有效日期 Expiry Date	2020.05.01
数量 Quantity	500KG		
储存条件 Storage Conditions	密闭、避光保存 Kept in closed container, protected from light		
检验依据 Specification	EUROPEAN PHARMACOPOEIA		
检验项目Test Items	检验标准Specifications	检验结果Results	
【性状 Description】			
外观 Appearance	白色或类白色结晶粉末 White or almost white crystalline powder.	白色结晶粉末 Almost white powders	
溶解性 Solubility	易溶于水和酒精，微溶于二氯甲烷 Freely soluble in water, soluble in alcohol, slightly soluble in methylene chloride	符合规定 Complies	
【鉴别 Identification】			
红外 IR	应与对照图谱一致 Complies with reference spectrum.	符合规定 Complies	
氯化物 Chloride	应呈正反应 Positive.	符合规定 Complies	
【有关物质(HPLC) Related Substances(HPLC)】			
总杂质 Total Impurities	≤0.3%	≤0.05%	
单个已知杂质 Individual Specified			
杂质A Impurity A	≤0.2%	≤0.05%	
杂质B Impurity B	≤0.2%	≤0.05%	
杂质C Impurity C	≤0.2%	≤0.05%	
杂质D Impurity D	≤0.2%	≤0.05%	

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杂质E Impurity E	≤0.2%	≤0.05%	
其它未知杂质 Individual unspecified impurities	≤0.1%	≤0.05%	
【溶液颜色和澄清度 Color and clarity of the solution】	清澈, 颜色应低于对照溶液Y ₇ Clear, not more intensely colored than reference solution Y ₇ .	符合规定 Complies	
【干燥失重 Loss on Drying】	≤0.5%	0.1%	
【硫酸灰份 Sulphated Ash】	≤0.1%	0.1%	
【重金属 Heavy metals】	≤20ppm	≤20ppm	
【旋光度 (以干品计) Specific optical rotation】	-121° ~ -128°	-123.2°	
【pH 值 pH value】	3.0 - 4.5	4.5	
【含量 (以干品计) Assay (Dried substance)】	98.5% ~ 101.0%	99.3%	
结论: 检验结果符合现行EP标准. Conclusion: The items tested meet the requirement of Current EP.			
审核人/日期: 陈国勇 2015.05.14 Reviewed by QA Manager/Date		批准人/日期: 何培生 2015.05.14 Approved By Quality Director/Date	