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成品检验报告书

CERTIFICATE OF ANALYSIS

Code No.: RD-JB-Y327-10

品名 Product name	盐酸左旋咪唑 Levamisole hydrochloride		检验号 Identification No.	1B220602W		
产品批号 Batch No.	LV22630	生产日期 Mfg. date	2022-12-10	报告日期 Report date		
批量 Batch size	500kg	包装规格 Package size	25kg/drum	复验期 Retest date		
项目 Parameter	BP 标准 Specification of BP		检验结果 Results			
性状 Appearance	白色或几乎白色结晶性粉末。 A white or almost white crystalline powder.		白色结晶性粉末。 A white crystalline powder.			
溶解度 Solubility	水中易溶, 在乙醇中溶解, 微溶于二氯甲烷 freely soluble in water, soluble in ethanol (96 per cent), slightly soluble in methylene chloride		符合规定 Qualified			
鉴别 Identification	比旋 Specific Optical Rotation	~ 121° to ~ 128°		- 124°		
	红外 Infrared absorption spectrophotometry	红外图谱应与标准品图谱一致 IR spectrophotometry similar to which of Levamisole Hydrochloride CRS		符合规定 Qualified		
	氯化物反应 Chlorides	呈氯化物的特征反应 It gives reaction of chlorides		符合规定 Qualified		
溶液外观 Appearance of solution	S溶液是澄清的, 且颜色不深于参考溶液Y7 Solution S is clear and not more intensely coloured than reference solution Y7.		符合规定 Qualified			
酸度 pH	3.0 to 4.5		4.13			
有关物质 Related substance	杂质A、B、C、D、E均应≤0.2%。 Impurities A,B,C,D,E: For each impurity, not more than 0.2%.		A:0.02%,B:ND,C:<0.01%, D:0.01%, E:<0.01%			
	其他单个未知杂质应≤0.10%。 Other individual unspecified impurities: not more than 0.10%.		<0.05%			
	总杂质应≤0.3%。 Total of all impurities: not more than 0.3%.		0.03%			
干燥失重 Loss on drying	≤0.5%		0.07%			
硫酸盐灰分 Sulfated ash	≤0.1%		0.01%			
滴定含量(按干燥品计) Assay (calculated on the dried basis)	98.5% to 101.0%		99.6%			
项目 Parameter	内控标准 In-house Specifications		检验结果 Results			
微生物限度 Microbial limit	需氧菌总数应≤10 <sup>3</sup> cfu/g Total viable aerobic bacteria ≤ 10 <sup>3</sup> cfu/g		符合规定 Qualified			
	霉菌和酵母菌数应≤10 <sup>3</sup> cfu/g Yeasts fungus and mycetes ≤ 10 <sup>3</sup> cfu/g		符合规定 Qualified			
	大肠埃希菌应不得检出 Escherichia coli should be absent.		符合规定 Qualified			
结论 Conclusion:	本品符合英国药典。 The product complies to the standard of BP.					
包装和贮存 Packaging and storage	避光保存 protected from light.					

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