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CERTIFICATE OF ANALYSIS

Product 产品名称	Mepivacaine Hcl 盐酸甲哌卡因; N-(2, 6 二甲苯基)-1-甲基-2-哌啶甲酰胺盐酸盐 (C ₁₆ H ₂₂ N ₂ O • HCl)		
Batch No. 批号	22070102	MFG. DATE 生产日期	2022. 07. 01
Approval Date 批准日期	2022. 07. 11	EXP. DATE 有效期至	2024. 06. 30
Tests 项目	Results 结果	Specifications 标准	
Description 性状	White crystalline powder 白色结晶性粉末	White or almost white crystalline powder 白色或类白色结晶性粉末	
Solubility 溶解度	Complies 符合规定	Soluble in water and methanol, very slightly soluble in chloroform, practically insoluble in ether 在水和甲醇中易溶, 在氯仿中微溶, 在乙醚中几乎不溶。	
pH 值	4. 72	about 4. 5. 约 4. 5	
Identification 鉴别	Complies 符合规定	A: By IR, To match with working standard 红外吸收图谱应与对照品一致	
	符合规定	B: Melting point (熔点): 149° -153°	
	Complies 符合规定	C: A solution responds to the test for Chloride 氯化物鉴别应符合规定	
Loss on drying 干燥失重	0. 12%	≤1. 0%	
Organic impurities 有机杂质	Not detected 未检出	2, 6-dimethylaniline ≤20ppm 2, 6-二甲苯胺 ≤20ppm	
	0. 01%	Bupivacaine related substances B ≤0. 15% 布比卡因有关物质 B ≤0. 15%	
	Not detected 未检出	Picolinamide ≤0. 15% 吡啶酰胺 ≤0. 15%	
	0. 06%	任意非特定杂质 ≤0. 1%	
	0. 12%	Total impurities ≤0. 4% 总杂质 ≤0. 4%	
Residual solvents 残留溶剂	Not detected 未检出	Methanol ≤0. 3% 甲醇 ≤0. 3%	
	Not detected 未检出	Ethanol ≤0. 5% 乙醇 ≤0. 5%	
	Not detected 未检出	Glacial acetic acid ≤0. 5% 冰醋酸 ≤0. 5%	
	Not detected 未检出	N-methylpyrrolidone ≤0. 053% N-甲基吡咯烷酮 ≤0. 053%	
Assay 含量	99. 33%	98. 0%-102. 0% (calculated on the dried basis 以干品计)	
Conclusion 结论 :	Conforms to USP43 符合 USP43 标准		

