



检验报告单

Certificate of Analysis

产品名称 (Product Name) : 丁卡因 (Tetracaine)

批号 (Batch NO.) : 20160603

报告日期(Report Date) : 20160603

检验依据(Inspection basis): USP 36



分析项目 Item of Analysis	标准 Standard	分析结果 Result of Analysis
性状 Description	应为白色或浅黄色、苍白固体 White or light yellow, waxy solid	类白色固体 White solid
鉴别 Identification	A. Dissolve 100 mg in 10 mL of dilut hydrochloric acid(1 in 120),and add 1 mL of potassium thiocyanate solution (1 in 4): a crystalline precipitate is formed. Recrystallize the precipitate from water, and dry at 80 for 2 hours: it melts between 130 and 132 .	符合规定 Conforms
	B: By UV, To match with working standard	符合规定 Complies
色谱法纯度 Chromatographic purity	应符合规定 Conform to standard	符合规定 Complies
干燥失重 Loss on drying	≤0.50%	0.02%
灼烧残渣 Residue on ignition	≤0.10%	0.05%
熔点 Melting range	41℃~46℃	42.5℃~43.0℃
溶剂残留	Ethanol≤0.5%	Not detected
	Acetone≤0.5%	0.006%
	4-Methyl-2-pentanone≤0.5%	Not detected
	DCM≤0.06%	Not detected
	PETROLEUM ETHER≤0.5%	0.02%
	Isopropyl ether≤0.5%	0.03%
含量 Assay	99.0%~101.0%	99.53%

结论: 本品依照 USP 36 标准检测, 结果符合规定

Conclusion: The Sample Complies With Specification of USP 36

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