

常州市天华制药有限公司

CHANGZHOU TIANHUA PHARMACEUTICAL Co., Ltd

产品检验报告单

CP2109001

CERTIFICATE OF ANALYSIS

品名: 盐酸丁卡因 Name: Tetracaine HCl	生产日期: 20210901 Date Of Produce:	
批号: CP01-210901 Batch No.:	报告日期: 20210915 Date Of Test:	
检验依据: USP 43 Inspection basis :		
项目 Items	标准 Specification	结果 Results
外观 Appearance	White or almost white, slightly hygroscopic, crystalline powder, odorless.	White, slightly hygroscopic, crystalline powder, odorless
溶解性 Solubility	Easy soluble in water, dissolved in ethanol, almost insoluble in benzene and ether	Easy soluble in water, dissolved in ethanol, almost insoluble in benzene and ether
鉴别 Identification	(A) IR	Conforms
	(B) Identification of Chloride	Conforms
	(C) The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay	Conforms
残留溶媒 Residual Solvents	Ethanol \leq 0.5% Ethylacetate \leq 0.5%	0.02% Not detected
水分 Water	\leq 2.0 %	0.42%
有机杂质 Organic impurities	Aminobenzoic acid \leq 0.4% Tetracaine Related Compound B \leq 0.4% Tetracaine Related Compound C \leq 0.4% Individual unspecific impurity \leq 0.4% Total impurities \leq 0.8%	Not detected 0.006% Not detected 0.2% 0.2%
灼烧残渣 Residue on ignition	\leq 0.1 %	0.02%
含量 Assay	98.0 ~ 102.0 %(on anhydrous basis)	99.8%
有效期 Exp. Date	202308	
结论 CONCLUSION	Conforms to USP 43	

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