

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≤0.5% Ethylacetate≤0.5%	0.02% Not detected
水分 Water		≤ 2.0 %	0.42%
有机杂质 Organic impurities		Aminobenzoic acid≤0.4% Tetracaine Related Compound B≤0.4% Tetracaine Related Compound C ≤0.4% Individual unspecific impurity≤0.4% Total impurities≤0.8%	Not detected 0.006% Not detected 0.2% 0.2%
灼烧残渣 Residue on ignition		≤ 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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