



检验报告/Certificate of Analysis

检验报告单号Report No.: TNJ2012-0808S			
产品名称/Product Name	Hydrochlorothiazide	商品名/Trade Name	-
产品编号/Product Code	2P0092353	产品等级/Grade	USP grade
批 号/BatchNumber	TNJ250418-028	生产日期/Mfg Date	Apr.28,2025
批 量/Batch Size	1003.01Kg	复验日期/Retest Date	Apr.28,2029
依 据/According to	USP		
检验项目 Item	质量标准 Quality Standards	检验结果 Test Result	
Characters	White or practically white,practically odorless,crystalline powder (USP)	Practically white,practically odorless,crystalline powder	
Identification	A.IR spectrum conforms to Standard (USP<197K>) B.The retention time of the major peak of the Sample solution corresponds to that of the Standard solution,as obtained in the Assay (USP)	Complies	
Loss on drying	NMT 0.5% (USP<731>)	0.05%	
Residue on ignition	NMT 0.1% (USP<281>)	0.04%	
Chlorides	NMT 0.035% (USP<221>)	Complies	
☆Residual solvents	NMT 0.5% (USP<467>)	0.05%	
*Residual formaldehyde	NMT 15ppm (In-house)	3ppm	
Related compounds	Benzothiadiazine related compound A≤1.0% (USP Monograph HPLC)	0.09%	
	Hydrochlorothiazide dimer ≤0.5% (USP Monograph HPLC)	0.10%	
	5-chlorohydrochlorothiazide ≤0.5% (USP Monograph HPLC)	Not detected	
	Chlorothiazide ≤0.5% (USP Monograph HPLC)	Not detected	
	Total other inpurities excluding benzothiadiazine related compound A≤0.9% (USP Monograph HPLC)	0.10%	
	*Single unknown impurity ≤0.10% (USP Monograph HPLC)	Not detected	
	*Total unknown impurities ≤0.5% (USP Monograph HPLC)	Not detected	
Assay	Hydrochlorothiazide contains NLT 98.0% and NMT 102.0%of hydrochlorothiazide (CHCIN,DS),calculated on the dried basis. (USP Monograph HPLC)	99.5%	
备注	-The items marked with * are in-house specifications.		



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Remarks	- ☆ Ethanol is the only class 3 solvent used in the manufacturing and it is controlled by loss on drying as per ICH Q3C
检验结论: Conclusion:	本批产品符合 USP 标准。 Meets requirements under USP Hydrochlorothiazide Monograph.



安露

报告人Reporter / 日期 Date 04/29/2025

刘飞斌

QC经理 QC Manager / 日期Date