

产品检验报告单

CERTIFICATE OF ANALYSIS

品名: 盐酸西替利嗪 Name: Cetirizine HCL	生产日期: Date Of Produce: 20220215	
批号: Batch No.: CP28-220201	报告日期: Date of Test: 20220222	
检验依据: Inspection basis : USP 40		
项 目 Items	标 准 Specifications	结 果 Results
外观 Appearance	A white or almost white crystalline	A white powder
美国药典对照标准品 USP Reference standards	USP Cetirizine Hydrochloride RS USP Cetirizine Related Compound A RS	Comforming
鉴别 Identification	A、B in Pass	Comforming
炽灼残渣 Residue on ignition	≤0.2%	0.09%
重金属 Heavy Metals	≤10ppm	Comforming
总杂质 Total impurity	≤0.3%	0.13%
酸度 (PH) Acidity	1.2 – 1.8	1.5
干燥失重 Loss on drying	≤0.5%	0.21%
残留溶剂 Residual Solvents	Acetone ≤75ppm Toluene ≤10ppm	Not detected Not detected
含量 Assay	98.0 – 102.0 %	99.6%
有效期 Date of Expiry	2025/01	
结 论 CONCLUSION	Pass USP 40	