

常州市天华制药有限公司

CHANGZHOU TIANHUA PHARMACEUTICAL CO., LTD

产 品 检 验 报 告 单

CP1902001

CERTIFICATE OF ANALYSIS

品 名: 色甘酸钠 Name: Sodium Cromoglicate ✓	生产日期: 20181130 ✓ Date Of Produce:	
批 号: CP02-181205 ✓ Batch No.:	报告日期: 20190222 Date of Test:	
检验依据: USP41 Inspection basis :		
项 目 Items	标 准 Specifications	结 果 Results
性 状 Appearance	White slightly wettable crystalline powder, odorless	White slightly wettable crystalline powder, odorless
溶解性 Solubility	Soluble in water; insoluble in alcohol and in chloroform.	Soluble in water; insoluble in alcohol and in chloroform.
鉴 别 Identification	A、B In pass	complies
酸碱度 Acidity or Alkalinity	In pass	complies
相关物质 Related Substances	≤0.5 %	complies
草酸盐 Limit of Oxalacet	≤0.35 %	complies
水分 Water	≤10.0%	5.6%
残留溶剂 Residual Solvents	Ethanol ≤ 0.5 %	0.007%
重金属 Heavy metals	≤0.002%	complies
含 量 Assay	98.0 ~ 101.0 %	99.7%
有关物质(HPLC) Related Substances	Max: ≤ 0.4 % Total: ≤ 0.5 %	Max: ≤ 0.07 % Total: ≤ 0.2 %
有效期 Date of Expiry	20211129 ✓	
结 论 CONCLUSION	Pass USP41	

QA: 蒋爱华 蒋爱华

联系人: 李剑平

手机: 13906147316

E-mail: tianhuachem@gmail.com

Storage temperature: ≤30℃

Add: 3# Houyang chemical zone, Jintan Jiangsu China

QC: 周利民 周利民

电话: 0519-82891186

传真: 0519-82899734

网址: <http://www.tianhuachem.com>

