

常州市天华制药有限公司

CHANGZHOU TIANHUA PHARMACEUTICAL CO., LTD

产 品 检 验 报 告 单 CP02-2001001

CERTIFICATE OF ANALYSIS

品 名：色甘酸钠		生产日期：20191023
Name：Cromolyn Sodium		Date Of Produce：
批 号：CP02-191102M		报告日期：20200109
Batch No.：		Date of Test：
检验依据：USP42		
Inspection basis：		
项 目 Items	标 准 Specifications	结 果 Results
性 状 Appearance	White,hygroscopic,crystalline powder, odorless	White,hygroscopic,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	(1) The infrared spectrum of the Sample solution is consistent with that of a similarly prepared (2) The retention time of the major peak of the Sample solution corresponds to that of the Standard solution (3) The general test <191> should be complied with	Complies
水分 Water	≤10.0%	6.3%
重金属 Heavy metals	≤0.002%	<0.002%
草酸盐 Limit of Oxalaet	Comply with the standard	Complies
有关物质(HPLC) Related Substances	Specified unidentified impurity≤0.15% 2-Acetylresorcinol≤0.10% Cromolyn related compound A≤0.10% Cromolyn related compound B≤0.10% Any other individual unspecified impurity≤0.10% Total impurities≤0.5%	0.11% Not detected Not detected Not detected 0.050% 0.2%
残留溶媒 Residual Solvents	Ethanol≤ 0.5 %	Not detected
含 量 Assay	98.0 ~ 101.0 %	99.8%
有效期 Date of Expiry	202209	
结 论 Conclusion	Pass USP42	



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