

Lot: 0080720



## CERTIFICATE OF ANALYSIS

### CROMOLYN SODIUM, USP

Batch/Lot Number : 165273  
 Manufacturing Date : 11/30/2018  
 Expiration Date : 10/31/2021  
 Retest Date : NOT APPLICABLE  
 CAS: 15826-37-6

† All dates in this document are in format mm/dd/yyyy unless otherwise specified

TESTS	SPECIFICATIONS	RESULTS
ASSAY ON ANHYDROUS BASIS	98.0 - 101.0 %	99.7 %
DESCRIPTION	White, odorless, crystalline powder. Is hygroscopic.	CONFORMS
IDENTIFICATION A: <197A>**	IR: Reference to standard spectrum.	POSITIVE
IDENTIFICATION B:*	UV: Reference to standard spectrum.	POSITIVE
ACIDITY OR ALKALINITY	<= 0.25 mL of 0.1 N NaOH or of 0.1 N HCl is required	<= 0.25 mL
WATER <921>I	<= 10.0 %	5.6 %
LIMIT OF OXALATE	<= 0.35 %	<= 0.35 %
RELATED COMPOUNDS	<= 0.5 % (Individual impurity)	<= 0.5 %
ELEMENTAL IMPURITIES <232>	Meets the requirements.	CONFORMS
RESIDUAL SOLVENTS <467>	Meets the requirements.	CONFORMS
SOLUBILITY	Soluble in water; insoluble in alcohol and in chloroform.	
**PACKAGING AND STORAGE**	Preserve in tight, light resistant containers.	
*TESTED ON 04/26/2019		
**TESTED ON 09/27/2019		
Lot number has been changed from CP02-181205 to 165273.		

The above mentioned product conforms to the specifications of USP.

The above test results are a direct transcription of information provided to MEDISCA from the Certificate of Analysis provided by the manufacturer / supplier. Additional testing conducted by MEDISCA is represented by an asterisk. This lot was manufactured by M: ZZ1182.

Dated : 04/26/2019

# 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	生产日期: 20181130✓	
Name: Sodium Cromoglicate ✓	Date Of Produce:	
批号: CP02-181205 ✓	报告日期: 20190222	
Batch No.:	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

电话: 0519-82891186

传真: 0519-82899734

网址: <http://www.tianhuachem.com>

