

Status: Currently Official on 17-Feb-2025

Official Date: Official as of 01-Dec-2023

Document Type: USP Monographs

DocId: GUID-DC2E68D2-CAB8-4B95-A009-C833FD02795B_8_en-US

DOI: https://doi.org/10.31003/USPNF_M20530_08_01

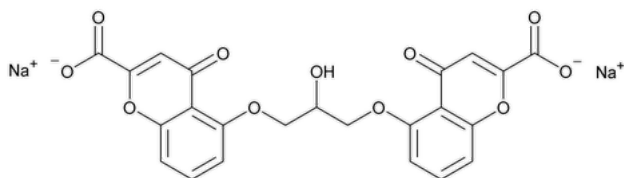
DOI Ref: ppr5x

© 2025 USPC

Do not distribute

Cromolyn Sodium

Change to read:



$C_{23}H_{14}Na_2O_{11}$ 512.33

4H-1-Benzopyran-2-carboxylic acid, 5,5'-[(2-hydroxy-1,3-propanediyl)bis(oxy)] $\blacktriangle$ (USP 1-Dec-2023) bis[4-oxo-, disodium salt];

Sodium 5,5'-[(2-hydroxypropane-1,3-diyl)bis(oxy)]bis(4-oxo-4H-chromene-2-carboxylate) CAS RN $^{\circ}$: 15826-37-6; $\blacktriangle$ UNII: Q2WXR110PK. $\blacktriangle$ (USP 1-Dec-2023)

DEFINITION

Cromolyn Sodium contains NLT 98.0% and NMT 101.0% of cromolyn sodium ($C_{23}H_{14}Na_2O_{11}$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197A or 197K

Analysis: Dry at 105° to constant weight.

Acceptance criteria: $\blacktriangle$ Meets the requirements $\blacktriangle$ (USP 1-Dec-2023)

- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **C. IDENTIFICATION TESTS—GENERAL (191), Chemical Identification Tests, Sodium:** Meets the requirements

ASSAY

PROCEDURE

Buffer: 2.1 g/L of [sodium acetate](#) in [water](#). Adjust with [glacial acetic acid](#) to a pH of 5.5.

Mobile phase: [Methanol](#) and *Buffer* (20:80)

Standard solution: 0.1 mg/mL of [USP Cromolyn Sodium RS](#) in [water](#)

Sample solution: 0.1 mg/mL of Cromolyn Sodium in [water](#)

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm $\times$ 25-cm; 5- μ m packing [L1](#)

Column temperature: 35°

Flow rate: 1.7 mL/min

Injection volume: 20 μ L

Run time: NLT 2 times the retention time of cromolyn

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of cromolyn sodium ($C_{23}H_{14}Na_2O_{11}$) in the portion of Cromolyn Sodium taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of cromolyn from the *Sample solution*

r_s = peak response of cromolyn from the *Standard solution*

C_s = concentration of [USP Cromolyn Sodium RS](#) in the *Standard solution* (mg/mL)

C_u = concentration of Cromolyn Sodium in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–101.0% on the anhydrous basis

IMPURITIES

Change to read:

• ORGANIC IMPURITIES

[NOTE—The *Sample solution* and *Standard solutions* are stable for 6 h at 4°.]

Diluent A: [Acetonitrile](#) and [water](#) (20:80)

Diluent B: [Methanol](#) and [water](#) (30:70)

Buffer: 2.1 g/L of [sodium acetate](#) in [water](#). Adjust with [glacial acetic acid](#) to a pH of 5.5.

Solution A: [Methanol](#) and *Buffer* (20:80)

Solution B: [Methanol](#)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
5	100	0
20	43	57
30	43	57
32	100	0
35	100	0

Standard stock solution: 0.15 mg/mL of [USP Cromolyn Related Compound A RS](#) and 0.06 mg/mL of [USP Cromolyn Related Compound B RS](#) in [acetonitrile](#)

Standard solution A: 0.0075 mg/mL of [USP Cromolyn Related Compound A RS](#) and 0.003 mg/mL of [USP Cromolyn Related Compound B RS](#) from the *Standard stock solution* in *Diluent A*

Standard solution B: 0.0015 mg/mL of [USP Cromolyn Sodium RS](#) in *Diluent B*

Sensitivity solution: 0.75 µg/mL of [USP Cromolyn Sodium RS](#) from *Standard solution B* in *Diluent B*

Sample solution: 1.5 mg/mL of Cromolyn Sodium in *Diluent B*

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; 5-µm packing [L1](#)

Temperatures

Autosampler: 4°

Column: 35°

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Samples: *Standard solution A*, *Standard solution B*, and *Sensitivity solution*

▲[NOTE— The relative retention times in [Table 2](#) are provided as information that could aid in peak assignment.]

Table 2

Name	Relative Retention Time
Cromolyn	1.0

