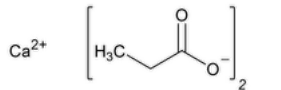


Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2023
Document Type: NF Monographs
DocId: GUID-337D7EAD-2B6A-45E1-874F-8895BF9AF78F_2_en-US
DOI: https://doi.org/10.31003/USPNF_M952_02_01
DOI Ref: f0iuw

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Calcium Propionate

Change to read:



C₆H₁₀CaO₄ 186.22

▲Propanoic acid, calcium salt;

Calcium propionate▲(NF 1-May-2023) CAS RN®: 4075-81-4.

Change to read:

DEFINITION

Calcium Propionate contains NLT ▲97.0%▲(NF 1-May-2023) and NMT ▲102.0%▲(NF 1-May-2023) of calcium propionate (C₆H₁₀CaO₄), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- A. ▲[SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197A▲(NF 1-May-2023)

Add the following:

▲• B. Chromatographic Identity

Analysis: Examine the chromatograms obtained in the Assay.

Acceptance criteria: The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*.▲(NF 1-May-2023)

ASSAY

Change to read:

• PROCEDURE

▲**Solution A:** 10 mM [potassium phosphate, monobasic](#), with the pH adjusted to 2.5 using [phosphoric acid](#)

Solution B: [Acetonitrile](#)

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
3.0	100	0
15.0	70	30
25.0	50	50
26.0	100	0
35.0	100	0

Diluent: 2% (v/v) [phosphoric acid](#) in water

System suitability solution: 2.5 mg/mL of [USP Calcium Propionate RS](#) and 0.008 mg/mL of acrylic acid in *Diluent*

Standard solution: 2.5 mg/mL of [USP Calcium Propionate RS](#) in *Diluent*

Sample solution: 2.5 mg/mL of Calcium Propionate in *Diluent*

Chromatographic system(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** LC**Detector:** UV 210 nm**Column:** 4.6-mm × 25-cm; 5-µm packing [L1](#)**Column temperature:** 45°**Flow rate:** 1.0 mL/min**Injection volume:** 20 µL**Run time:** 35 min**System suitability****Samples:** *System suitability solution* and *Standard solution*[NOTE—The approximate relative retention times for related substances are listed in [Table 2](#).]**Table 2**

Name	Relative Retention Time
Calcium acetate	0.5
Calcium acrylate	0.95
Calcium propionate	1.0

Suitability requirements**Resolution:** NLT 1.5 between the calcium propionate peak and the acrylic acid peak, *System suitability solution***Tailing factor:** NMT 2, determined from the calcium propionate peak, *Standard solution***Relative standard deviation:** NMT 1%, determined from the calcium propionate peak, *Standard solution***Analysis****Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of calcium propionate in the portion of sample taken:

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

 r_U = peak area of calcium propionate from the *Sample solution* r_S = peak area of calcium propionate from the *Standard solution* C_S = concentration of [USP Calcium Propionate RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Calcium Propionate in the *Sample solution* (mg/mL)**Acceptance criteria:** 97.0%–102.0% on the anhydrous basis ▲ (NF 1-May-2023)**IMPURITIES****Add the following:****▲ Organic Impurities****Mobile phase, Diluent, System suitability solution, and Chromatographic system:** Proceed as directed in the Assay.**Sensitivity solution:** 0.01 mg/mL of [USP Calcium Propionate RS](#) in *Diluent***Standard solution:** 0.02 mg/mL of [USP Calcium Propionate RS](#) in *Diluent***Sample solution:** 20 mg/mL of Calcium Propionate in *Diluent***System suitability****Samples:** *System suitability solution*, *Sensitivity solution*, and *Standard solution*[NOTE—The approximate relative retention times for related substances are listed in [Table 2](#).]**Suitability requirements****Resolution:** NLT 1.5 between the calcium propionate peak and the acrylic acid peak, *System suitability solution***Relative standard deviation:** NMT 5.0%, determined from the calcium propionate peak, *Standard solution***Signal-to-noise ratio:** NLT 10, determined from the calcium propionate peak, *Sensitivity solution***Analysis****Samples:** *Standard solution* and *Sample solution*

[NOTE—The peak eluting at RRT 0.3 is the calcium ion peak. This peak and the peaks eluting before it are excluded from integration. These peaks are not from organic impurities of Calcium Propionate.]

Calculate the percentage of each individual impurity in the portion of sample taken: