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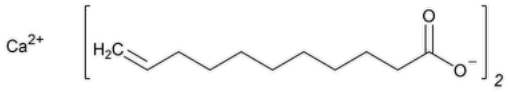
Calcium Undecylenate



$C_{22}H_{38}O_4Ca$ 406.62

10-Undecenoic acid, calcium (2+) salt;

Calcium 10-undecenoate CAS RN®: 1322-14-1; UNII: 77YW1RTU8V.

DEFINITION

Calcium Undecylenate contains NLT 98.0% and NMT 102.0% of calcium undecylenate ($C_{22}H_{38}O_4Ca$), calculated on the dried basis.

IDENTIFICATION

• **A.** **Identification Tests—General ⟨191⟩, *Chemical Identification Tests, Calcium***

Sample solution: 50 mg/mL of Calcium Undecylenate in 3 N hydrochloric acid. Pass through a suitable filter.

Acceptance criteria: Meets the requirements

• **B.** **Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197A

• **C.** The retention time of the undecylenic acid peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

Change to read:

• **Procedure**

Solution A: 0.15 N hydrochloric acid in water prepared as follows. Transfer 150 mL of ▲0.5 N hydrochloric acid VS▲ (ERR 1-Nov-2022) to a 500-mL volumetric flask, dilute with water to volume, and mix well.

Standard solution: 0.5 mg/mL of USP Undecylenic Acid RS in *n*-heptane, prepared as follows. Accurately weigh and transfer 25 mg of USP Undecylenic Acid RS to a suitable flask, add 20 mL of *Solution A*, and heat until the sample is liquified and transparent with two immiscible layers. Cool, upon which turbidity may be observed. Add 50 mL of *n*-heptane to the flask, and mix well. Transfer the *n*-heptane layer to a suitable container, and dry over anhydrous sodium sulfate. Centrifuge to clarify the mixture, and use the clear supernatant.

Sample solution: Nominally 0.5 mg/mL of undecylenic acid in *n*-heptane, prepared as follows. Accurately weigh and transfer 27.6 mg of Calcium Undecylenate, equivalent to 25 mg of undecylenic acid, to a suitable flask. Follow the preparation steps described in the *Standard solution*.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: GC

Detector: Flame ionization

Column: 0.25-mm × 30-m fused-silica capillary; coated with a 0.25-µm film of phase G35

Temperatures

Injection port: 280°

Detector: 350°

Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
100	—	100	5
100	10	220	13
220	30	240	15

Carrier gas: Helium

Flow rate: 0.7 mL/min

Injection volume: 1 µL

Injection type: Split, split ratio 25:1

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of calcium undecylenate ($C_{22}H_{38}O_4Ca$) in the portion of Calcium Undecylenate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times [M_{r1}/(2 \times M_{r2})] \times 100$$

r_U = peak response of undecylenic acid from the *Sample solution*

r_S = peak response of undecylenic acid from the *Standard solution*

C_S = concentration of USP Undecylenic Acid RS in the *Standard solution* (mg/mL)

C_U = concentration of Calcium Undecylenate in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of calcium undecylenate, 406.62

M_{r2} = molecular weight of undecylenic acid, 184.28

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

• **Limit of Free Undecylenic Acid**

Sensitivity solution: 0.005 mg/mL of USP Undecylenic Acid RS in *n*-heptane

Standard solution: 0.01 mg/mL of USP Undecylenic Acid RS in *n*-heptane

Sample solution: 10 mg/mL of Calcium Undecylenate in *n*-heptane prepared as follows. Accurately weigh and transfer 100 mg of Calcium Undecylenate into a suitable container, add 10 mL of *n*-heptane, and mix for 2 h by magnetic stirring. Centrifuge to clarify the mixture, and use the clear supernatant.

Chromatographic system: Proceed as directed in the *Assay* except for the *Injection type*.

Injection type: Split, split ratio 10:1

System suitability

Samples: *Sensitivity solution* and *Standard solution*

Suitability requirements

Relative standard deviation: NMT 5.0%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of undecylenic acid ($C_{11}H_{20}O_2$) in the portion of Calcium Undecylenate taken:

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

r_U = peak response of undecylenic acid from the *Sample solution*

r_S = peak response of undecylenic acid from the *Standard solution*

C_S = concentration of USP Undecylenic Acid RS in the *Standard solution* (mg/mL)

C_U = concentration of Calcium Undecylenate in the *Sample solution* (mg/mL)

Acceptance criteria: NMT 0.1%

SPECIFIC TESTS

• **Loss on Drying ⟨731⟩**

Analysis: Dry at 105° for 2 h.

Acceptance criteria: 2.0%–5.7%

• **Particle Size Distribution Estimation by Analytical Sieving ⟨786⟩**

Analysis: Test in accordance with this procedure, except use NMT 25 g and use a single No. 100 sieve that is to be shaken for NLT 30 min or until sifting is practically complete.

Acceptance criteria: NLT 99.0% of it passes through a No. 100 sieve

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.
- **USP Reference Standards** ⟨11⟩

USP Calcium Undecylenate RS

USP Undecylenic Acid RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
CALCIUM UNDECYLENATE	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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