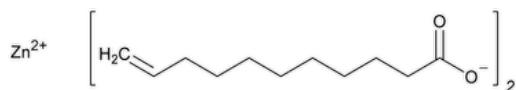


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Zinc Undecylenate



$C_{22}H_{38}O_4Zn$ 431.92

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

Zinc 10-undecenoate CAS RN[®]: 557-08-4; UNII: 388VZ25DUR.

DEFINITION

Zinc Undecylenate contains NLT 98.0% and NMT 102.0% of zinc undecylenate ($C_{22}H_{38}O_4Zn$), calculated on the dried basis.

IDENTIFICATION

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy](#): 197A
- **B.** The retention time of the undecylenic acid peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **C.**

Sample: 100 mg of Zinc Undecylenate

Analysis: Dissolve the *Sample* in a mixture of 10 mL of [water](#) and 1 mL of [ammonium hydroxide](#), and add a few drops of [sodium sulfide TS](#).

Acceptance criteria: A white, flocculent precipitate of zinc sulfide is formed.

ASSAY

Change to read:

• PROCEDURE

Solution A: 0.15 N hydrochloric acid in [water](#) prepared as follows. Transfer 150 mL of ▲0.5 N▲ (ERR 1-Dec-2022) [hydrochloric acid](#) 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 29.3 mg of Zinc 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 zinc undecylenate ($C_{22}H_{38}O_4Zn$) in the portion of Zinc 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 Zinc Undecylenate in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of zinc undecylenate, 431.92

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

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

IMPURITIES

• ALKALIES AND ALKALINE EARTHS

Sample solution: Boil 1.50 g of Zinc Undecylenate with a mixture of 50 mL of [water](#) and 10 mL of [hydrochloric acid](#), filter while hot, and wash the separated acid portion with 50 mL of hot [water](#). Render the combined filtrate and washings alkaline with 6 N ammonium hydroxide. Add [ammonium sulfide TS](#) to precipitate the zinc completely, dilute with [water](#) to 200 mL, and filter. Use the clear filtrate.

Analysis: To 100 mL of the *Sample solution*, add 0.5 mL of [sulfuric acid](#), evaporate to dryness, and ignite over a low flame to constant weight.

Acceptance criteria: The weight of the residue is NMT 7.5 mg (1.0%).

• 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 Zinc Undecylenate in [n-heptane](#) prepared as follows. Accurately weigh and transfer 100 mg of Zinc 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 (C₁₁H₂₀O₂) in the portion of Zinc 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 Zinc 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: NMT 1.25%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- **USP REFERENCE STANDARDS (11)**
[USP Zinc Undecylenate RS](#)
[USP Undecylenic Acid RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
ZINC UNDECYLENATE	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

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