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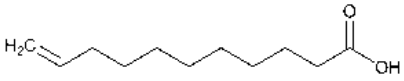
Undecylenic Acid



$C_{11}H_{20}O_2$ 184.28

10-Undecenoic acid;

Undec-10-enoic acid CAS RN®: 112-38-9; UNII: K3D86KJ24N.

Change to read:

DEFINITION

Undecylenic Acid contains NLT 97.0% and NMT ▲102.0%▲ (USP 1-Aug-2022) of undecylenic acid ($C_{11}H_{20}O_2$).

IDENTIFICATION

Delete the following:

▲• **A.**

Sample: 1 mL of Undecylenic Acid

Analysis: To the *Sample* add potassium permanganate TS dropwise.

Acceptance criteria: The permanganate color is discharged.▲ (USP 1-Aug-2022)

Add the following:

▲• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197A or 197F▲ (USP 1-Aug-2022)

Change to read:

• **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*.▲ (USP 1-Aug-2022)

ASSAY

Change to read:

• **Procedure**

▲**Standard solution:** 0.5 mg/mL of USP Undecylenic Acid RS in *n*-heptane

Sample solution: 0.5 mg/mL of Undecylenic Acid in *n*-heptane

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 undecylenic acid ($C_{11}H_{20}O_2$) in the portion of Undecylenic Acid 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 Undecylenic Acid in the *Sample solution* (mg/mL)▲ (USP 1-Aug-2022)

Acceptance criteria: 97.0%–▲102.0%▲ (USP 1-Aug-2022)

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.15%

• **Water-Soluble Acids**

Sample: 5 mL of Undecylenic Acid

Titrimetric system

Mode: Direct titration

Titrant: 0.01 N sodium hydroxide VS

Endpoint detection: Visual

Analysis: Shake the *Sample* with 5 mL of water and filter the water layer through a filter paper previously moistened with water. Add 1 drop of methyl orange TS, and titrate with *Titrant*.

Acceptance criteria: NMT 1.0 mL of *Titrant* is required to match the color produced by 1 drop of methyl orange TS in 5 mL of water.

SPECIFIC TESTS

• **Specific Gravity ⟨841⟩:** 0.910–0.913

Delete the following:

▲• **Congealing Temperature ⟨651⟩:** NLT 21°▲ (USP 1-Aug-2022)

Delete the following:

▲• **Refractive Index ⟨831⟩:** 1.447–1.448▲ (USP 1-Aug-2022)

• **Fats and Fixed Oils ⟨401⟩, *Procedures, Iodine Value*:** 131–138

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

Add the following:

▲• **USP REFERENCE STANDARDS** ⟨11⟩

USP Undecylenic Acid RS▲ (USP 1-Aug-2022)

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

Topic/Question	Contact	Expert Committee
UNDECYLENIC ACID	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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 46(2)

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