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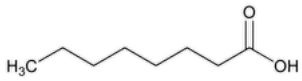
# Caprylic Acid



$C_8H_{16}O_2$ 144.21

Octanoic acid;

1-Heptanecarboxylic acid CAS RN®: 124-07-2.

## DEFINITION

Caprylic Acid contains NLT 99.0% of caprylic acid ($C_8H_{16}O_2$), calculated on the anhydrous basis.

## IDENTIFICATION

***Change to read:***

• **A.** ▲**Spectroscopic Identification Tests** ⟨197⟩**,** *Infrared Spectroscopy*: **197F**▲ (CN 1-May-2020)

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

## ASSAY

***Change to read:***

• **Procedure**

**Standard solution:** 10 mg/mL of USP Caprylic Acid RS in ethyl acetate

**Sample solution:** 10 mg/mL of Caprylic Acid in ethyl acetate

**System suitability solution:** 10 µg/mL of Caprylic Acid in ethyl acetate, prepared from the *Sample solution*

**Chromatographic system**

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

**Mode:** GC

**Detector:** Flame ionization

**Column:** 0.25-mm × 30-▲m▲ (ERR 1-May-2020) fused silica capillary column bonded with a 0.25-µm layer of phase G25

**Temperatures**

**Detector:** 250°

**Injection port:** 250°

**Column:** See *Table 1*.

**Table 1**

| Initial Temperature (°) | Temperature Ramp (°/min) | Final Temperature (°) | Hold Time at Final Temperature (min) |
|---|---|---|---|
| 100 | — | 100 | 1 |
| 100 | 5 | 220 | 10 |

**Carrier gas:** Helium

**Flow rate:** 1.5 mL/min

**Injection volume:** 1 µL

**Injection type:** Split injection. The split ratio is about 1:100.

**System suitability**

**Samples:** *Standard solution* and *System suitability solution*

**Suitability requirements**

**Relative standard deviation:** NMT 2.0%, *Standard solution*

**Signal-to-noise ratio:** NLT 5 for the major peak, *System suitability solution*

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of caprylic acid ($C_8H_{16}O_2$) in the portion of Caprylic Acid taken:

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

$r_U$ = peak response of caprylic acid from the *Sample solution*

$r_S$ = peak response of caprylic acid from the *Standard solution*

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

$C_U$ = concentration of Caprylic Acid in the *Sample solution* (mg/mL)

**Acceptance criteria:** NLT 99.0% on the anhydrous basis

## IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

• **Limit of Related Linear and Branched Alkyl Carboxylic Acids, Related Esters, Cyclic Esters and Ketone**

**Standard solution, System suitability solution, Sample solution, Chromatographic system,** and **System suitability:** Proceed as directed in the *Assay*.

**Analysis**

**Sample:** *Sample solution*

Calculate the percentage of each impurity in the portion of Caprylic Acid taken:

$$\text{Result} = (r_U/r_T) \times 100$$

$r_U$ = peak response of each individual impurity in the *Sample solution*

$r_T$ = sum of all the peaks except the peak due to solvent and peaks below the *Disregard limit* (see *Table 2*) in the *Sample solution*

**Acceptance criteria:** See *Table 2*.

Disregard any peak with an area less than 0.5 times the area of the major peak from the *System suitability solution*.

**Table 2**

| Impurity | Percentage (%) |
|---|---|
| Each individual | NMT 0.3 |
| Total | NMT 0.5 |

## SPECIFIC TESTS

• **Bacterial Endotoxins Test ⟨85⟩:** The level of bacterial endotoxins is such that the requirement in the relevant dosage form monograph(s) in which Caprylic Acid is used can be met. Where the label states that Caprylic Acid must be subjected to further processing during the preparation of injectable dosage forms, the level of bacterial endotoxins is such that the requirement in the relevant dosage form monograph(s) in which Caprylic Acid is used can be met.

• **Fats and Fixed Oils, *Peroxide Value* ⟨401⟩:** NMT 10.0

• **Water Determination, *Method Ia* ⟨921⟩:** NMT 0.7%

## ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, and store at room temperature.

• **Labeling:** Where Caprylic Acid must be subjected to further processing during the preparation of injectable dosage forms to ensure acceptable levels of bacterial endotoxins, it is so labeled.

• **USP Reference Standards ⟨11⟩**

USP Caprylic Acid RS

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| CAPRYLIC ACID | Documentary Standards Support | SE2020 Simple Excipients |

**Chromatographic Database Information:** Chromatographic Database

**Most Recently Appeared In:**
Pharmacopeial Forum: Volume No. PF 38(1)

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