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Caprylocaproyl Polyoxylglycerides

Former Title: Caprylocaproyl Macrogolglycerides

DEFINITION

Caprylocaproyl Polyoxylglycerides is a mixture of monoesters, diesters, and triesters of glycerol and monoesters and diesters of polyethylene glycols. The polyethylene glycols used have a mean molecular weight between 200 and 400. It is produced by partial alcoholysis of medium-chain triglycerides with polyethylene glycol, by esterification of glycerol and polyethylene glycol with caprylic acid and capric acid, or as a mixture of glycerol esters and ethylene oxide condensate with caprylic acid and capric acid. It may contain free polyethylene glycols.

IDENTIFICATION

Change to read:

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

• **B.** Thin-Layer Chromatographic Identification Test ⟨201⟩

Standard solution: 50 mg/mL of USP Caprylocaproyl Polyoxylglycerides RS in methylene chloride

Sample solution: 50 mg/mL of Caprylocaproyl Polyoxylglycerides in methylene chloride

Application volume: 50 µL

Developing solvent system: Ether and hexanes (7:3)

Spray reagent: 0.1 mg/mL of rhodamine B in alcohol

Analysis

Samples: *Standard solution* and *Sample solution*

Proceed as directed in the chapter. Then spray the plate with *Spray reagent*, and locate the spots on the plate by examination under UV light at a wavelength of 365 nm.

Acceptance criteria: The R_F values of the principal spots of the *Sample solution* correspond to those of the *Standard solution*.

• **C.** It meets the requirements of the test for *Fats and Fixed Oils ⟨401⟩, Fatty Acid Composition*.

IMPURITIES

• **Articles of Botanical Origin,** *Total Ash* ⟨561⟩**:** NMT 0.1%

• **Alkaline Impurities**

Sample: 5.0 g of Caprylocaproyl Polyoxylglycerides

Analysis: To the *Sample* add 10 mL of alcohol and 0.05 mL of bromophenol blue TS, and mix well. Titrate with 0.01 N hydrochloric acid VS to change the color to yellow.

Acceptance criteria: NMT 1.0 mL of 0.01 N hydrochloric acid is required.

• **Limit of Free Ethylene Oxide and Dioxane**

Analysis: Proceed as directed in *Ethylene Oxide and Dioxane ⟨228⟩, Method I*.

Acceptance criteria

Ethylene oxide: NMT 1 µg/g

Dioxane: NMT 10 µg/g

• **Limit of Free Glycerol**

Sample: 1.20 g

Blank: 25 mL of methylene chloride

Periodic acetic acid solution: Dissolve 0.446 g of sodium periodate in 2.5 mL of a 25% (v/v) solution of sulfuric acid, and dilute with glacial acetic acid to 100.0 mL.

Potassium iodide solution: 75 mg/mL of potassium iodide

Titrimetric system

(See *Titrimetry ⟨541⟩*.)

Mode: Residual titration

Titrant: 0.1 M sodium thiosulfate

Analysis: Dissolve the *Sample* in 25 mL of methylene chloride, heating if necessary. Cool, and add 100 mL of water and 25.0 mL of *Periodic acetic acid solution*. Shake, and allow to stand for 30 min. Add 40 mL of *Potassium iodide solution*, and allow to stand for 1 min. Add 1 mL of

starch TS, and titrate the liberated iodine with *Titrant*. Perform a blank determination.

Calculate the percentage of free glycerol in the portion of Caprylocaproyl Polyoxylglycerides taken:

$$\text{Result} = [(V_B - V_S) \times N \times E \times F/W] \times 100$$

V_B = *Titrant* volume consumed by the *Blank* (mL)

V_S = *Titrant* volume consumed by the *Sample* (mL)

N = actual normality of the *Titrant* (mEq/mL)

E = equivalency factor for glycerol, 23 mg/mEq

F = unit conversion factor, 10^{-3} g/mg

W = *Sample* weight taken for the titration (g)

Acceptance criteria: NMT 5.0%

SPECIFIC TESTS

• **Fats and Fixed Oils,** *Acid Value* ⟨401⟩**:** NMT 2.0, determined on a 2.0-g specimen

• **Fats and Fixed Oils,** *Fatty Acid Composition* ⟨401⟩**:** Caprylocaproyl Polyoxylglycerides exhibit the composition profile of fatty acids shown in *Table 1*, as determined in the section *Fatty Acid Composition* under *Fats and Fixed Oils* ⟨401⟩.

Table 1

Carbon-Chain Length	Number of Double Bonds	Percentage (%)
6	0	≤2.0
8	0	50.0–80.0
10	0	20.0–50.0
12	0	≤3.0
14	0	≤1.0

• **Fats and Fixed Oils,** *Hydroxyl Value*⟨401⟩**:** The hydroxyl value is within the range specified in *Table 2* for the labeled type, when determined on a 1.0-g specimen.

Table 2

Ethylene Oxide Units per Molecule (Nominal Value)	Type of Polyethylene Glycol	Hydroxyl Value
4	200	80–120
6	300	140–180
8	400	170–205

• **Fats and Fixed Oils,** *Iodine Value* ⟨401⟩**:** NMT 2.0

• **Fats and Fixed Oils,** *Peroxide Value* ⟨401⟩**:** NMT 6.0, determined on a 2.0-g specimen

• **Fats and Fixed Oils,** *Saponification Value* ⟨401⟩**:** The saponification value is within the range specified in *Table 3* for the labeled type, determined on a 2.0-g specimen.

Table 3

Ethylene Oxide Units per Molecule (Nominal Value)	Type of Polyethylene Glycol	Saponification Value
4	200	265–285

Ethylene Oxide Units per Molecule (Nominal Value)	Type of Polyethylene Glycol	Saponification Value
6	300	170–190
8	400	85–105

• **Water Determination, *Method I*⟨921⟩:** NMT 1.0%, determined on a 1.0-g specimen. Use as the solvent anhydrous pyridine or a mixture of methylene chloride and anhydrous methanol (7:3).

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, protected from light and moisture. Store at controlled room temperature.

• **Labeling:** Label it to indicate the type and the average nominal molecular weight of polyethylene glycol used, or to indicate the number of ethylene oxide units per molecule (nominal value), as part of the official title.

• **USP Reference Standards ⟨11⟩**
USP Caprylocaproyl Polyoxylglycerides RS

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

Topic/Question	Contact	Expert Committee
CAPRYLOCAPROYL POLYOXYLGLYCERIDES	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

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