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Oleoyl Polyoxylglycerides

DEFINITION

Oleoyl Polyoxylglycerides is a mixture of monoesters, diesters, and triesters of glycerol and monoesters and diesters of polyethylene glycols. Polyethylene glycols used have a mean molecular weight between 300 and 400. The article is produced by partial alcoholysis of unsaturated oils, mainly containing triglycerides of oleic acid with polyethylene glycol, by esterification of glycerol and polyethylene glycol with fatty acids, or as a mixture of glycerol esters and ethylene oxide condensate with the fatty acids of the unsaturated oils. 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 Oleoyl Polyoxylglycerides RS in methylene chloride

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

Application volume: 10 µL

Developing solvent system: Ether and hexanes (70:30)

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 in *Specific Tests* (see *Table 1*) for *Fats and Fixed Oils, Fatty Acid Composition* ⟨401⟩.

IMPURITIES

• **Alkaline Impurities**

Sample: 5.0 g

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: 1.2 g

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

Blank: 25 mL of methylene chloride

Titrimetric system

(See *Titrimetry* ⟨541⟩.)

Mode: Residual titration

Titrant: 0.1 M sodium thiosulfate VS

Endpoint detection: Visual

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 0.1 M sodium thiosulfate VS. Perform a blank determination, and make any necessary correction.

Calculate the percentage of glycerol in the sample taken:

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

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)

F = equivalency factor, 23.0 mg/mEq

W = *Sample* weight (mg)

Acceptance criteria: NMT 5.0%

SPECIFIC TESTS

- **Articles of Botanical Origin,** *Total Ash* ⟨561⟩**:** NMT 0.1%
- **Fats and Fixed Oils,** *Acid Value* ⟨401⟩

  Sample: 2.0 g

  Acceptance criteria: NMT 2.0
- **Fats and Fixed Oils,** *Fatty Acid Composition* ⟨401⟩**:** Oleoyl Polyoxylglycerides exhibits the composition profile of fatty acids shown in *Table 1*.

Table 1

Carbon-Chain Length	Number of Double Bonds	Percentage (%)
16	0	4.0–9.0
18	0	≤6.0
18	1	58.0–80.0
18	2	15.0–35.0
18	3	≤2.0
20	0	≤2.0
20	1	≤2.0

- **Fats and Fixed Oils,** *Hydroxyl Value* ⟨401⟩

  Sample: 1.0 g

  Acceptance criteria: 45–65
- **Fats and Fixed Oils,** *Iodine Value* ⟨401⟩**:** 75–95
- **Fats and Fixed Oils,** *Peroxide Value* ⟨401⟩

  Sample: 2.0 g

  Acceptance criteria: NMT 12.0
- **Fats and Fixed Oils,** *Saponification Value* ⟨401⟩

  Sample: 2.0 g

  Acceptance criteria: 150–170
- **Water Determination,** *Method I* ⟨921⟩

Sample: 1.0 g

Analysis: Instead of using methanol as the solvent, one of two solvent systems can be used: a mixture of methylene chloride and anhydrous methanol (70:30 v/v), or anhydrous pyridine.

Acceptance criteria: NMT 1.0%

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 as part of the official title.
- **USP Reference Standards** ⟨11⟩
  USP Oleoyl Polyoxylglycerides RS

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

Topic/Question	Contact	Expert Committee
OLEOYL POLYOXYLGLYCERIDES	Documentary Standards Support	CE2020 Complex Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

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