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Stearoyl Polyoxylglycerides

DEFINITION

Stearoyl 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 300 and 4000. It is produced by partial alcoholysis of saturated oils, mainly containing triglycerides of stearic 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 hydrogenated oils. The hydroxyl value is NLT 85% and NMT 115% of the labeled nominal value, and the saponification value is NLT 90% and NMT 110% of the labeled nominal value. Stearoyl Polyoxylglycerides may contain free polyethylene glycols.

IDENTIFICATION

- **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197K

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

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

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

  Chromatographic system

    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 ⟨401⟩, Procedures, Fatty Acid Composition*.

IMPURITIES

- **Articles of Botanical Origin ⟨561⟩, *Methods of Analysis, Total Ash*:** NMT 0.2%

- **Alkaline Impurities**

  Sample: 5.0 g

  Analysis: Heat the *Sample* slightly until the test substance melts, add 10 mL of alcohol and 0.05 mL of bromophenol blue TS, and mix well. While the solution is still warm, 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 VS 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

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

  Potassium iodide solution: 75 mg/mL of potassium iodide

  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 the *Periodic acetic acid solution*. Shake, and allow to stand for 30 min. Add 40 mL of the *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 (see *Titrimetry ⟨541⟩*). 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

- **Fats and Fixed Oils ⟨401⟩, *Procedures, Acid Value***
  Sample: 2.0 g
  Acceptance criteria: NMT 2.0

Change to read:

- **Fats and Fixed Oils ⟨401⟩, *Procedures, Fatty Acid Composition*:** Stearoyl Polyoxylglycerides exhibits the following composition profile of fatty acids, as determined in the chapter (see *Table 1*).

Table 1

Carbon-Chain Length	Number of Double Bonds	Percentage (%)
12	0	≤5.0
14	0	≤5.0
16	0	▲37.0▲ (NF 1-May-2022) –50.0
18	0	▲50.0–60.0▲ (NF 1-May-2022)
▲Sum of palmitic acid (C16:0) and stearic acid (C18:0)		NLT 90.0▲ (NF 1-May-2022)

- **Fats and Fixed Oils ⟨401⟩, *Procedures, Hydroxyl Value***
  Sample: 1.0 g
  Acceptance criteria: 25–56, 85%–115% of the labeled nominal value
- **Fats and Fixed Oils ⟨401⟩, *Procedures, Iodine Value*:** NMT 2.0
- **Fats and Fixed Oils ⟨401⟩, *Procedures, Peroxide Value***
  Sample: 2.0 g
  Acceptance criteria: NMT 6.0
- **Fats and Fixed Oils ⟨401⟩, *Procedures, Saponification Value***
  Sample: 2.0 g
  Acceptance criteria: 67–112, 90%–110% of the labeled nominal value
- **Water Determination ⟨921⟩, *Method I***
  Sample: 1.0 g
  Solvent: Anhydrous pyridine or a mixture of methylene chloride and anhydrous methanol (70:30)
  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 glycols used as part of the official title. The label also indicates the hydroxyl value and the saponification value.

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

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

Topic/Question	Contact	Expert Committee
STEAROYL 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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