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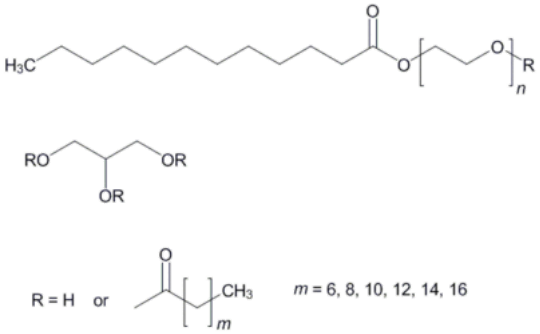
Lauroyl Polyoxylglycerides

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click https://www.uspnf.com/rb-lauroyl-polyoxylglycerides-notice-20210430.



Lauroyl Polyoxylglycerides 300 CAS RN®: 12737-91-6.
Lauroyl Polyoxylglycerides 600 CAS RN®: 137802-73-4.
Lauroyl Polyoxylglycerides 1500
CAS RN®: 121548-04-7.

DEFINITION

Lauroyl 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 1500. The article is produced by partial alcoholysis of saturated oils, mainly containing triglycerides of lauric acid with polyethylene glycols, by esterification of glycerol and polyethylene glycols with fatty acids, or as a mixture of glycerol esters and ethylene oxide condensate with the fatty acids of the hydrogenated oils. It may contain free polyethylene glycols.

IDENTIFICATION

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197A. This test only applies to Lauroyl Polyoxylglycerides 300 and Lauroyl Polyoxylglycerides 1500. Use USP Lauroyl Polyoxylglycerides 300 RS for the Lauroyl Polyoxylglycerides 300 sample. Use USP Lauroyl Polyoxylglycerides 1500 RS for the Lauroyl Polyoxylglycerides 1500 sample. For Lauroyl Polyoxylglycerides 300, 197F can also be used with the following standard/sample preparation details: the standard or sample is melted at 70° first and is suspended neat between suitable plates. For Lauroyl Polyoxylglycerides 1500, 197K can also be used.

Change to read:

• **B. Thin-Layer Chromatographic Identification Test ⟨201⟩:** For Lauroyl Polyoxylglycerides 300 and Lauroyl Polyoxylglycerides 1500 only

Standard solution: 50 mg/mL of USP Lauroyl Polyoxylglycerides 300 RS (for Lauroyl Polyoxylglycerides 300 sample) or ▲USP Lauroyl Polyoxylglycerides 1500 RS▲ (RB 1-May-2021) (for Lauroyl Polyoxylglycerides 1500 sample) in methylene chloride

Sample solution: 50 mg/mL of Lauroyl 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 ⟨401⟩, Procedures, Fatty Acid Composition*.

• **D.** It meets the requirements in *Specific Tests* for *Fats and Fixed Oils ⟨401⟩, Procedures, Saponification Value* for Lauroyl Polyoxylglycerides 600 only.

IMPURITIES

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

• **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 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, diluting to 100.0 mL with glacial acetic acid.

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

• **Fats and Fixed Oils ⟨401⟩, *Procedures, Acid Value***

Sample: 2.0 g

Acceptance criteria: NMT 2.0

• **Fats and Fixed Oils ⟨401⟩, *Procedures, Fatty Acid Composition*:** Lauroyl Polyoxylglycerides exhibits the composition profile of fatty acids shown in *Table 1*.

Table 1

Carbon-Chain Length	Number of Double Bonds	Percentage (%)
8	0	≤15.0
10	0	≤12.0
12	0	30.0–50.0
14	0	5.0–25.0

Carbon-Chain Length	Number of Double Bonds	Percentage (%)
16	0	4.0–25.0
18	0	5.0–35.0

- **Fats and Fixed Oils ⟨401⟩, *Procedures, Hydroxyl Value***
  Sample: 1.0 g
  Acceptance criteria: Within the range specified in *Table 2* for the labeled type

Table 2

Type of Polyethylene Glycols	Hydroxyl Value
300	65–85
600	50–70
1500	36–56

- **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: Within the range specified in *Table 3* for the labeled type

Table 3

Type of Polyethylene Glycols	Saponification Value
300	190–204
600	150–170
1500	79–93

- **Water Determination ⟨921⟩, *Method I***
  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 glycols used as part of the official title.
- **USP Reference Standards ⟨11⟩**
  USP Lauroyl Polyoxylglycerides 300 RS
  USP Lauroyl Polyoxylglycerides 1500 RS

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

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

Chromatographic Database Information: Chromatographic Database

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