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Propylene Glycol Monolaurate

Dodecanoic acid, monoester with 1,2-propanediol;
Lauric acid, monoester with propane-1,2-diol.

DEFINITION

Propylene Glycol Monolaurate is a mixture of the propylene glycol mono- and diesters of lauric acid. The requirements for monoester and diester content differ for the two types of Propylene Glycol Monolaurate, as set forth in the table below.

	Content of Monoesters (%)		Content of Diesters (%)	
	Min.	Max.	Min.	Max.
Type I	45.0	70.0	30.0	55.0
Type II	90.0	—	—	10.0

IDENTIFICATION

- A. [THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST \(201\).](#)**
Standard solution: 50 mg/mL of [USP Propylene Glycol Monolaurate Type I RS](#) (or [USP Propylene Glycol Monolaurate Type II RS](#)) in methylene chloride
Sample solution: 50 mg/mL in methylene chloride
Chromatographic system
(See [Chromatography \(621\), Thin-Layer Chromatography.](#))
Developing solvent system: Ether and hexane (70:30)
Spray reagent: 0.1 mg/mL of rhodamine 6G in alcohol
Analysis: Develop the chromatogram over a path of 15 cm, and dry the plate in a current of air. 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 from the *Sample solution* correspond to those from the *Standard solution*.
- B.** It meets the requirements in *Specific Tests* for [Fats and Fixed Oils, Fatty Acid Composition\(401\)](#).

ASSAY

- PROCEDURE**
Mobile phase: Tetrahydrofuran
Sample solution: 40 mg/mL of Propylene Glycol Monolaurate in tetrahydrofuran
Chromatographic system
(See [Chromatography \(621\), System Suitability.](#))
Mode: LC
Detector: Refractive index
Column: 7-mm × 60-cm; 5-μm packing L21 (100 Å)
[NOTE—Two 7-mm × 30-cm L21 columns may be used in place of one 60-cm column, provided *System suitability* requirements are met.]
Temperatures
Column: 40°
Detector: 40°
Flow rate: 1 mL/min
Injection volume: 40 μL

System suitability

Sample: *Sample solution*

Suitability requirements

[NOTE—The order of elution is diesters, monoesters, and propylene glycol.]

Relative standard deviation: NMT 1.0% for the monoester peak

Analysis

Sample: *Sample solution*

Calculate the percentage of monoesters or diesters in the portion of Propylene Glycol Monolaurate taken:

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

r_U = peak response for monoesters or diesters

r_T = sum of the peak responses of the monoesters and diesters

D = sum of the percentage content of propylene glycol and the percentage content of free fatty acids

Calculate the percentage content of free fatty acids in the portion taken:

$$\text{Result} = (A/561.1) \times 200$$

A = acid value

Acceptance criteria

Type I

Monoesters: 45.0%–70.0%

Diesters: 30.0%–55.0%

Type II

Monoesters: NLT 90.0%

Diesters: NMT 10.0%

IMPURITIES

• LIMIT OF PROPYLENE GLYCOL

Mobile phase, Sample solution, and Chromatographic system: Proceed as directed in the Assay.

Standard stock solution: 4 mg/mL of [USP Propylene Glycol RS](#) in tetrahydrofuran

Standard solutions: Into four 15-mL flasks introduce, respectively, 0.25, 0.5, 1.0, and 2.5 mL of *Standard stock solution*, and dilute with tetrahydrofuran to 5.0 mL. In a fifth 15-mL flask, introduce 5.0 mL of *Standard stock solution*.

Analysis

Samples: *Standard solutions* and *Sample solution*

Prepare a standard curve of peak area versus concentration, in mg/mL, of propylene glycol in the *Standard solutions*. Obtain the concentration of propylene glycol in the *Sample solution* from the standard curve.

Calculate the percentage of free propylene glycol in the portion of Propylene Glycol Monolaurate taken:

$$\text{Result} = (C/C_U) \times 100$$

C = concentration of propylene glycol in the *Sample solution* from the standard curve

C_U = concentration of the *Sample solution* (mg/mL)

Acceptance criteria

Propylene glycol monolaurate (Type I): NMT 5.0%

Propylene glycol monolaurate (Type II): NMT 1.0%

SPECIFIC TESTS

• [FATS AND FIXED OILS, Acid Value\(401\)](#): NMT 4

• [FATS AND FIXED OILS, Fatty Acid Composition\(401\)](#): Propylene Glycol Monolaurate exhibits the composition profile of fatty acids shown in [Table 1](#).

Table 1

Fatty Acids	Carbon-Chain Length	Percentage (%)
Caprylic acid	C8	NMT 0.5
Capric acid	C10	NMT 2.0
Lauric acid	C12	NLT 95.0
Myristic acid	C14	NMT 3.0
Palmitic acid	C16	NMT 1.0

• **FATS AND FIXED OILS, Iodine Value(401):** NMT 1

• **FATS AND FIXED OILS, Saponification Value(401):**

Propylene glycol monolaurate (Type I): 210–245

Propylene glycol monolaurate (Type II): 200–230

• **WATER DETERMINATION, Method Ia(921):**

Analysis: Use a mixture of methanol and methylene chloride (1:1) in place of methanol in the titration vessel.

Acceptance criteria: NMT 1.0%

• **ARTICLES OF BOTANICAL ORIGIN, Total Ash(561):** NMT 0.1%

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in well-closed containers, and protect from moisture. No storage requirements specified.

• **LABELING:** Label it to indicate the type (Type I or Type II).

• **USP REFERENCE STANDARDS (11):**

[USP Propylene Glycol RS](#)

[USP Propylene Glycol Monolaurate Type I RS](#)

[USP Propylene Glycol Monolaurate Type II RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
PROPYLENE GLYCOL MONOLAUATE	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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