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Glyceryl Monooleate

Oleic acid, 2,3-dihydroxypropyl ester, (±);
(RS)-1-Glyceryl oleate
356.54 CAS RN®: 25496-72-4.

DEFINITION

Glyceryl Monooleate is a mixture of monoglycerides, mainly glyceryl monooleate, together with variable quantities of diglycerides and triglycerides. It is obtained by partial glycerolysis of vegetable oil that consists mainly of triglycerides of oleic acid, or by esterification of glycerol with oleic acid of vegetable or animal origin. It is defined by the nominal content of monoglycerides. The assay requirements differ as set forth in the accompanying table. A suitable antioxidant may be added.

Nominal Content of Monoglycerides (%)			
	40	60	90
Monoglycerides	32.0–52.0	55.0–65.0	90.0–101.0
Diglycerides	30.0–50.0	15.0–35.0	<10.0
Triglycerides	5.0–20.0	2.0–10.0	<2.0

IDENTIFICATION

- A. [THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST \(201\)](#).**
Standard solution: 50 mg/mL of USP Glyceryl Monooleate 40% RS or USP Glyceryl Monooleate 90% RS in methylene chloride
Sample solution: 50 mg/mL of Glyceryl Monooleate in methylene chloride
Application volume: 10 µL
Developing solvent system: Ether and hexane (7:3)
Spray reagent: 0.1 mg/mL of rhodamine B in alcohol
Analysis: Proceed as directed in the chapter. Spray with the *Spray reagent*, and locate the spots on the plate by examination under UV light at a wavelength of 365 nm.
Acceptance criteria: The principal spot of the *Sample solution* corresponds in color, size, and *R_F* value to that of the *Standard solution*.
- B.** It meets the requirements in *Specific Tests* for [Fats and Fixed Oils, Iodine Value \(401\)](#).

ASSAY

- PROCEDURE**
Mobile phase: Tetrahydrofuran
Sample solution: 40 mg/mL of Glyceryl Monooleate in tetrahydrofuran
Chromatographic system
(See [Chromatography \(621\), System Suitability](#).)
Mode: LC
Detector: Refractive index
Column: 7.5-mm × 60-cm; 5-µm 100-Å packing L21
[NOTE—Two or three 7.5-mm × 30-cm L21 columns may be used in place of the one 60-cm column, provided that the system suitability requirements are met. The column temperature may be lowered to ambient temperature, although working at 40° provides stable separation conditions and ensures better sample solubility.]
Temperature

2/15/25/ 8:30 AM

Column: 40°

Detector: 40°

Flow rate: 1 mL/min

Injection size: 40 µL

System suitability

Sample: *Sample solution*

[NOTE—The relative retention times for triglycerides, diglycerides, monoglycerides, and glycerin are about 0.76, 0.79, 0.85, and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.0 between the diglycerides and monoglycerides

Relative standard deviation: NMT 2.0%, determined from the monoglycerides peak

Analysis

Sample: *Sample solution*

Calculate the percentage of monoglycerides, diglycerides, and triglycerides in the portion of Glyceryl Monooleate taken:

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

r_U = individual peak responses for the monoglycerides, diglycerides, and triglycerides, as appropriate

r_T = sum of all the glyceride peak responses

Acceptance criteria: See the table in the *Definition*.

IMPURITIES

• LIMIT OF FREE GLYCERIN

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

Standard solutions: Prepare four solutions by dissolving glycerin in tetrahydrofuran, and diluting each with tetrahydrofuran as necessary, to obtain solutions having known concentrations of 0.4, 1.0, 2.0, and 4.0 mg/mL.

Standard curve

Samples: *Standard solutions*

Plot: Record the chromatograms, and measure the responses for the glycerin peaks. Plot the glycerin peak responses obtained versus the concentration, in mg/mL, of glycerin in the *Standard solutions*.

Analysis

Sample: *Sample solution*

From the *Standard curve*, determine the glycerin concentration, in mg/mL, in the *Sample solution*.

Calculate the percentage of free glycerin in the portion of Glyceryl Monooleate taken:

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

C_S = concentration of glycerin in the *Sample solution* from the *Standard curve* (mg/mL)

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

Acceptance criteria: NMT 6.0%

SPECIFIC TESTS

- **FATS AND FIXED OILS, Acid Value (401):** NMT 6.0, determined on 1.0 g
- **FATS AND FIXED OILS, Iodine Value (401):** 65.0–95.0
- **FATS AND FIXED OILS, Peroxide Value (401):** NMT 12.0, determined on 2.0 g
- **FATS AND FIXED OILS, Saponification Value (401):** 150–175, determined on 2.0 g
- **FATS AND FIXED OILS, Fatty Acid Composition (401):** Glyceryl Monooleate exhibits the following composition profile of fatty acids (see [Table 1](#)), determined as directed in the chapter.

Table 1

Carbon-Chain Length	Number of Double Bonds	Percentage (%)
16	0	NMT 12.0
18	0	NMT 6.0
18	1	NLT 60.0
18	2	NMT 35.0
18	3	NMT 2.0
20	0	NMT 2.0
20	1	NMT 2.0

- **WATER DETERMINATION, *Method I* (921):** NMT 1.0%, using a mixture of methanol and methylene chloride (1:1) in place of methanol in the titration vessel
- **ARTICLES OF BOTANICAL ORIGIN, *Total Ash* (561):** NMT 0.1%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers. No storage requirements specified.
- **LABELING:** The labeling indicates the nominal content of monoglycerides and the name and the concentration of any added antioxidant.
- **USP REFERENCE STANDARDS (11).**
[USP Glyceryl Monooleate 40% RS](#)
[USP Glyceryl Monooleate 90% RS](#)

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

Topic/Question	Contact	Expert Committee
GLYCERYL MONOOLEATE	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: [Chromatographic Database](#)

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