

Status: Currently Official on 15-Feb-2025
Official Date: Official Prior to 2013
Document Type: NF Monographs
DocId: GUID-B60F2346-5660-41F4-97FE-7721AECF2902_2_en-US
DOI: https://doi.org/10.31003/USPNF_M35486_02_01
DOI Ref: 2zce6

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Glyceryl Monolinoleate

354.5 CAS RN®: 26545-74-4.

DEFINITION

Glyceryl Monolinoleate is a mixture of monoglycerides, mainly glyceryl monooleate and glyceryl monolinoleate, together with variable quantities of diglycerides and triglycerides. It is obtained by partial glycerolysis of vegetable oil that consists mainly of triglycerides of linoleic acid. It contains NLT 32.0% and NMT 52.0% of monoglycerides, NLT 40.0% and NMT 55.0% of diglycerides, and NLT 5.0% and NMT 20.0% of triglycerides. A suitable antioxidant may be added.

IDENTIFICATION

• **A. [THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST \(201\)](#).**

Standard solution: 50 mg/mL of [USP Glyceryl Monolinoleate 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 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 from 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)*.

• **C.** 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 Glyceryl Monolinoleate 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 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.]

Temperatures

Detector: 40°

Column: 40°

Flow rate: 1 mL/min

Injection volume: 40 μL

System suitability

Sample: *Sample solution*

[NOTE—The relative retention times for triglycerides, diglycerides, monoglycerides, and glycerin are about 0.76, 0.80, 0.86, and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.0 between the diglycerides and monoglycerides peaks

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 Glycerol Monolinoleate taken:

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

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

r_T = sum of the responses for all of the glyceride peaks

Acceptance criteria

Monoglycerides: 32.0%–52.0%

Diglycerides: 40.0%–55.0%

Triglycerides: 5.0%–20.0%

IMPURITIES

• LIMIT OF FREE GLYCERIN

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

Standard solutions: 0.4, 1.0, 2.0, and 4.0 mg/mL of glycerin in tetrahydrofuran

Analysis

Samples: *Sample solution* and *Standard solutions*

Plot the glycerin peak responses obtained versus the concentration of glycerin in the *Standard solutions*. From the standard curve so obtained, determine the glycerin concentration in the *Sample solution*.

Calculate the percentage of free glycerin in the portion of Glycerol Monolinoleate taken:

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

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

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

Acceptance criteria: NMT 6.0%

SPECIFIC TESTS

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

Sample: 1.0 g

Acceptance criteria: NMT 6.0

• [FATS AND FIXED OILS, Iodine Value \(401\)](#): 100–140

• [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: 160–180

• [FATS AND FIXED OILS, Fatty Acid Composition \(401\)](#): See [Table 1](#).

Table 1

Carbon-Chain Length	No. of Double Bonds	Percentage (%)
16	0	4.0–20.0
18	0	NMT 6.0
18	1	10.0–35.0

Carbon-Chain Length	No. of Double Bonds	Percentage (%)
18	2	NLT 50.0
18	3	NMT 2.0
20	0	NMT 1.0
20	1	NMT 1.0

- [WATER DETERMINATION, Method I \(921\)](#).

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 tight containers. No storage requirements specified.
- **LABELING:** The labeling indicates the name and the concentration of any added antioxidant.
- [USP REFERENCE STANDARDS \(11\)](#)
[USP Glycerol Monolinoleate RS](#)

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

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 30(3)

Current DocID: GUID-B60F2346-5660-41F4-97FE-7721AECF2902_2_en-US

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