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Mono- and Di-glycerides

DEFINITION

Mono- and Di-glycerides is a mixture of glycerol mono- and di-esters, with minor amounts of tri-esters, of fatty acids from edible oils. It contains NLT 40.0% of monoglycerides. The monoglyceride content is NLT 90.0% and NMT 110.0% of the value indicated in the labeling. It may contain suitable stabilizers.

ASSAY

• **MONOGLYCERIDES**

Mobile phase: Tetrahydrofuran

Sample solution: 40 mg/mL of Mono- and Di-glycerides 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 or three 7.5-mm × 30-cm L21 columns may be used in place of one 60-cm column provided that *System suitability* requirements are met.]

Temperatures

Column: 40°

Detector: 40°

Flow rate: 1 mL/min

Injection volume: 40 μL

System suitability

Sample: *Sample solution*

[NOTE—The order of elution is triglycerides, diglycerides, monoglycerides, and glycerin.]

Suitability requirements

Relative standard deviation: NMT 1.0%, determined from the monoglycerides peak

Analysis

Sample: *Sample solution*

Calculate the percentage of monoglycerides in the portion of Mono- and Di-glycerides taken:

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

r_U = peak response for monoglycerides

r_T = sum of the responses of all the peaks, except the solvent peak

Acceptance criteria: 90.0%–110.0% of the value indicated in the labeling

IMPURITIES

• **RESIDUE ON IGNITION (281):** NMT 0.1%

Change to read:

• **ARSENIC (211), [Procedures, Procedure 2](#)** (CN 1-Jun-2023) : NMT 3 μg/g

• **LIMIT OF FREE GLYCERIN**

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

Standard solutions: 0.5, 1.0, 2.0, and 4.0 mg/mL of [USP Glycerin RS](#) in tetrahydrofuran

Analysis

Samples: *Sample solution* and *Standard solutions*

Measure the responses for the glycerin peaks. Plot the concentration, in mg/mL, of [USP Glycerin RS](#) in the *Standard solutions* versus the glycerin peak responses obtained. From the standard curve so obtained, determine the glycerin concentration in the *Sample solution*.

Calculate the percentage of glycerin in the portion of Mono- and Di-glycerides taken:

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

Acceptance criteria: NMT 7.0%

SPECIFIC TESTS

- **FATS AND FIXED OILS, *Acid Value* (401):** NMT 4
- **FATS AND FIXED OILS, *Hydroxyl Value* (401):** 90.0%–110.0% of the value indicated in the labeling
- **FATS AND FIXED OILS, *Iodine Value* (401):** 90.0%–110.0% of the value indicated in the labeling. If the value stated in the labeling is less than 10, the iodine value is NMT 10.
- **FATS AND FIXED OILS, *Saponification Value* (401):** 90.0%–110.0% of the value indicated in the labeling

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.
- **LABELING:** The labeling indicates the monoglyceride content, hydroxyl value, iodine value, saponification value, and name and quantity of any stabilizers.
- **USP REFERENCE STANDARDS (11).**
[USP Glycerin RS](#)

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

Topic/Question	Contact	Expert Committee
MONO- AND DI-GLYCERIDES	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: [Chromatographic Database](#)

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