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Glyceryl Monostearate

Octadecanoic acid, monoester with 1,2,3-propanetriol;
Monostearin
CAS RN®: 31566-31-1.

DEFINITION

Glyceryl Monostearate contains NLT 90.0% of monoglycerides of saturated fatty acids, chiefly glyceryl monostearate ($C_{21}H_{42}O_4$) and glyceryl monopalmitate ($C_{19}H_{38}O_4$). It may contain a suitable antioxidant.

ASSAY

• **Procedure**

Mobile phase: Tetrahydrofuran

Sample solution: 8 mg/mL of Glyceryl Monostearate 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

Temperature: Column and detector temperatures are maintained at 40°.

[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.]

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 0.77, 0.81, 0.86, and 1.0, respectively.]

Suitability requirements

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

Analysis

Sample: *Sample solution*

Calculate the percentage of monoglycerides in the portion of Glyceryl Monostearate taken:

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

r_U = peak response of the monoglycerides

r_T = sum of all the glyceride peak responses

Acceptance criteria: NLT 90.0% of monoglycerides of saturated fatty acids, chiefly $C_{21}H_{42}O_4$ and $C_{19}H_{38}O_4$

IMPURITIES

Inorganic Impurities

• **Residue on Ignition ⟨281⟩:** NMT 0.5%

Organic Impurities

• **Procedure: Limit of Free Glycerin**

Propionating reagent: Pyridine and propionic anhydride (1:2)

Internal standard solution: 0.2 mg/mL of tributyrin in chloroform

Standard solution: Transfer 15 mg of glycerin and 50 mg of tributyrin to a glass-stoppered, 25-mL conical flask. Add 3 mL of *Propionating reagent*, and heat at 75° for 30 min. Volatilize the reagents with the aid of a stream of nitrogen at room temperature, and add 12 mL of chloroform. Dilute 1 mL of this mixture with chloroform to 20 mL.

Sample solution: Transfer 50 mg of Glyceryl Monostearate to a glass-stoppered, 25-mL conical flask. Add 5 mL of *Internal standard solution* by pipet, and mix to dissolve. Immerse the flask in a water bath, maintained at a temperature between 45° and 50°, and volatilize the chloroform with the aid of a stream of nitrogen. Add 3 mL of *Propionating reagent*, and heat at 75° for 30 min. Volatilize the reagents with the aid of a stream of nitrogen at room temperature, and add 5 mL of chloroform.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: GC

Detector: Flame ionization (under typical conditions)

Column: 4-mm × 2.4-m borosilicate glass, packed with 2% liquid phase G16, on 80- to 100-mesh support S1A

Temperature

Injector: 300°

Detector: 310°

Column: The column is maintained isothermally at a temperature between 190° and 200°.

Carrier gas: Helium

Flow rate: 70 mL/min

System suitability

Sample: *Standard solution* (6–10 injections)

Suitability requirements

Resolution: NLT 4.0 between derivatized glycerin and tributyrin

Relative standard deviation: NMT 2.0% of the ratio of their peak areas

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the response factor, F:

$$F = (A_D/A_S) \times (W_S/W_D)$$

A_D = peak area of tributyrin from the *Standard solution*

A_S = peak area of tripropionin from the *Standard solution*

W_S = weight of glycerin in the *Standard solution* (mg)

W_D = weight of tributyrin in the *Standard solution* (mg)

Calculate the percentage of glycerin in the portion of Glyceryl Monostearate taken:

$$\text{Result} = (A_U/A_S) \times (W_D/W_U) \times F \times 100$$

A_U = peak area of tripropionin in the *Sample solution*

A_S = peak area of tributyrin in the *Sample solution*

W_D = weight of tributyrin in 5 mL of *Internal standard solution* (mg)

W_U = weight of Glyceryl Monostearate in the *Sample solution* (mg)

Acceptance criteria: NMT 1.2%

SPECIFIC TESTS

• **Melting Range or Temperature,** *Class I* ⟨741⟩**:** Does not melt below 55°

• **Fats and Fixed Oils,** *Acid Value* ⟨401⟩**:** NMT 6

• **Fats and Fixed Oils,** *Hydroxyl Value* ⟨401⟩**:** 290–330

• **Fats and Fixed Oils,** *Iodine Value* ⟨401⟩**:** NMT 3

• **Fats and Fixed Oils,** *Saponification Value* ⟨401⟩**:** 150–165

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **Labeling:** Label it to indicate the name and quantity of any added antioxidant.

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

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

Chromatographic Database Information: Chromatographic Database

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