Medium-Chain Triglycerides

Glycerides, mixed decanoyl and octanoyl;
Caprylic and capric triglycerides.

DEFINITION

Medium-Chain Triglycerides consist of a mixture of triglycerides of saturated fatty acids, mainly of caprylic acid ($C_8H_{16}O_2$) and capric acid ($C_{10}H_{20}O_2$). The fatty acids are derived from the oil extracted from the hard, dried fraction of the endosperm of *Cocos nucifera* L. or from the dried endosperm of *Elaeis guineensis* Jacq. They contain NLT 95% of saturated fatty acids with 8 and 10 carbon atoms.

IDENTIFICATION

- **A.** Meet the requirements in *Specific Tests* for *Fats and Fixed Oils* ⟨401⟩*, Procedures, Saponification Value*
- **B.** Meet the requirements in *Specific Tests* for *Fats and Fixed Oils* ⟨401⟩*, Procedures, Fatty Acid Composition*

IMPURITIES

Delete the following:

▲• LIMIT OF CHROMIUM

[NOTE—Use this test for Medium-Chain Triglycerides intended for use in parenteral nutrition.]

Sample stock solution: 500 mg/mL of Medium-Chain Triglycerides in diisobutyl ketone

Sample solution: 200 mg/mL of Medium-Chain Triglycerides in diisobutyl ketone, from *Sample stock solution*

Chromium standard stock solution: 0.283 mg/mL of potassium dichromate in water, using potassium dichromate previously dried at 105° for 4 h

Chromium standard solution: Immediately before use, prepare 0.283 µg/mL of potassium dichromate in water, from the *Chromium standard stock solution*. This solution contains the equivalent of 0.1 µg/mL of chromium.

Standard solutions: Into each of three 10-mL volumetric flasks, transfer 4.0 mL of *Sample stock solution*, add 0.5, 1.0, and 2.0 mL, respectively, of *Chromium standard solution*, and dilute with diisobutyl ketone to volume. These solutions contain 0.005, 0.01, and 0.02 µg/mL of chromium.

Instrumental conditions

(See *Atomic Absorption Spectroscopy* ⟨852⟩.)

Mode: Atomic absorption spectrophotometer equipped with a graphite furnace

Analytical wavelength: 357.8 nm

Lamp: Chromium hollow-cathode

Carrier gas: Argon

Analysis

Samples: *Standard solutions* and *Sample solution*

Determine the abosrbances of the *Standard solutions* and the *Sample solution* in triplicate, and determine the average of the steady readings for each. Plot the average absorbances of the *Standard solutions* and the *Sample solution* versus the concentration of added chromium. Draw the straight line best fitting the points, and extrapolate the line until it meets the concentration axis. The distance between this point and the intersection of the axes represents the concentration of chromium in the *Sample solution*.

Acceptance criteria: NMT 0.05 µg/g▲ (IRA 1-Mar-2019)

Delete the following:

▲• LIMIT OF COPPER

[NOTE—Use this test for Medium-Chain Triglycerides intended for use in parenteral nutrition.]

Sample stock solution and **Sample solution:** Proceed as directed in the test for *Limit of Chromium*.

Copper standard stock solution: 0.393 mg/mL of cupric sulfate in water

Copper standard solution: Immediately before use, prepare 0.393 µg/mL of cupric sulfate in water, from the *Copper standard stock solution*. This solution contains the equivalent of 0.1 µg/mL of copper.

Standard solutions: Into each of three 10-mL volumetric flasks, transfer 4.0 mL of *Sample stock solution*. Add 1.0, 2.0, and 4.0 mL, respectively, of *Copper standard solution*, and dilute with diisobutyl ketone to volume. These solutions contain 0.01, 0.02, and 0.04 µg/mL of copper.

Instrumental conditions

(See *Atomic Absorption Spectroscopy* ⟨852⟩.)

Mode: Atomic absorption spectrophotometer equipped with a graphite furnace

Analytical wavelength: 324.7 nm

Lamp: Copper hollow-cathode

Carrier gas: Argon

Analysis

Samples: *Standard solutions* and the *Sample solution*

Record the average of the steady readings for each of the *Standard solutions* and the *Sample solution* in triplicate. Plot the absorbances of the *Standard solutions* and the *Sample solution* versus the concentration of added copper. Draw the straight line best fitting the points, and extrapolate the line until it meets the concentration axis. The distance between this point and the intersection of the axes represents the concentration of copper in the *Sample solution*.

Acceptance criteria: NMT 0.1 µg/g▲ (IRA 1-Mar-2019)

Delete the following:

▲• LIMIT OF LEAD

[NOTE—Use this test for Medium-Chain Triglycerides intended for use in parenteral nutrition.]

Sample stock solution and **Sample solution:** Proceed as directed in the test for *Limit of Chromium*.

Lead standard stock solution: Dissolve 160 mg of lead nitrate in 100 mL of water that contains 1 mL of lead-free nitric acid, and dilute with water to 1000 mL. Pipet 10 mL of this solution into a 100-mL volumetric flask, and dilute with water to volume.

Lead standard solution: Immediately before use, prepare 0.16 µg/mL of lead nitrate from the *Lead standard stock solution*. This solution contains the equivalent of 0.1 µg/mL of lead.

Standard solutions: Into each of three 10-mL volumetric flasks, transfer 4.0 mL of *Sample stock solution*. Add 1.0, 2.0, and 4.0 mL, respectively, of *Lead standard solution*, and dilute with diisobutyl ketone to volume. These solutions contain 0.01, 0.02, and 0.04 µg/mL of lead.

Instrumental conditions

(See *Atomic Absorption Spectroscopy* ⟨852⟩.)

Mode: Atomic absorption spectrophotometer equipped with a graphite furnace coated inside with palladium carbide

[NOTE—Calcination is carried out in the presence of oxygen at a temperature below 800°.]

Analytical wavelength: 283.3 nm

Lamp: Lead hollow-cathode
Carrier gas: Argon
Analysis
Samples: *Standard solutions* and the *Sample solution*
Record the average of the steady readings for each of the *Standard solutions* and the *Sample solution* in triplicate. Plot the absorbances of the *Standard solutions* and the *Sample solution* versus the concentration of added lead. Draw the straight line best fitting the points, and extrapolate the line until it meets the concentration axis. The distance between this point and the intersection of the axes represents the concentration of lead in the *Sample solution*.
Acceptance criteria: NMT 0.1 µg/g▲ (IRA 1-Mar-2019)

Delete the following:

▲• LIMIT OF NICKEL
[NOTE—Use this test for Medium-Chain Triglycerides intended for use in parenteral nutrition.]
Sample stock solution and **Sample solution:** Proceed as directed in the test for *Limit of Chromium*.
Nickel standard solution: Immediately before use, dilute 10 mL of nickel standard solution TS with water to 1000 mL. This solution contains the equivalent of 0.1 µg/g of nickel.
Standard solutions: Into each of three 10-mL volumetric flasks, transfer 4.0 mL of *Sample stock solution*. Add 1.0, 2.0, and 4.0 mL, respectively, of *Nickel standard solution*, and dilute with diisobutyl ketone to volume. These solutions contain 0.01, 0.02, and 0.04 µg/mL of nickel.
Instrumental conditions
(See *Atomic Absorption Spectroscopy* ⟨852⟩.)
Mode: Atomic absorption spectrophotometer equipped with a graphite furnace
Analytical wavelength: 232 nm
Lamp: Nickel hollow cathode
Carrier gas: Argon
Analysis
Samples: *Standard solutions* and the *Sample solution*
Record the average of the steady readings for each of the *Standard solutions* and the *Sample solution* in triplicate. Plot the absorbances of the *Standard solutions* and the *Sample solution* versus the concentration of added nickel. Draw the straight line best fitting the points, and extrapolate the line until it meets the concentration axis. The distance between this point and the intersection of the axes represents the concentration of nickel in the *Sample solution*.
Acceptance criteria: NMT 0.1 µg/g▲ (IRA 1-Mar-2019)

Delete the following:

▲• LIMIT OF TIN
[NOTE—Use this test for Medium-Chain Triglycerides intended for use in parenteral nutrition.]
Sample stock solution and **Sample solution:** Proceed as directed in the test for *Limit of Chromium*.
Tin standard stock solution: Dissolve 500 mg of metallic tin (Sn) in a mixture of 5 mL of water and 25 mL of hydrochloric acid, and dilute with water to 1000 mL.
Tin standard solution: Immediately before use, dilute 10 mL of *Tin standard stock solution* with dilute hydrochloric acid (2.5 in 100) to 1000 mL, and then dilute 10 mL of the solution with water to 500 mL. This solution contains the equivalent of 0.1 µg/g of tin.
Standard solutions: Into each of three 10-mL volumetric flasks, transfer 4.0 mL of *Sample stock solution*. Add 1.0, 2.0, and 4.0 mL, respectively, of *Tin standard solution*, and dilute with diisobutyl ketone to volume. These solutions contain 0.01, 0.02, and 0.04 µg/mL of tin.
Instrumental conditions
(See *Atomic Absorption Spectroscopy* ⟨852⟩.)
Mode: Atomic absorption spectrophotometer equipped with a graphite furnace coated inside with palladium carbide
Analytical wavelength: 286.3 nm
Lamp: Tin hollow-cathode
Carrier gas: Argon
Analysis
Samples: *Standard solutions* and the *Sample solution*
Record the average of the steady readings for each of the *Standard solutions* and the *Sample solution* in triplicate. Plot the absorbances of the *Standard solutions* and the *Sample solution* versus the concentration of added tin. Draw the straight line best fitting the points, and extrapolate the line until it meets the concentration axis. The distance between this point and the intersection of the axes represents the concentration of tin in the *Sample solution*.
Acceptance criteria: NMT 0.1 µg/g▲ (IRA 1-Mar-2019)

Add the following:

▲• LIMIT OF CHROMIUM, COPPER, LEAD, AND NICKEL
[NOTE—Use this test for Medium-Chain Triglycerides intended for use in parenteral nutrition.]
Internal standard solution: [NOTE—Prepare this solution fresh every 6 months.] Transfer 2.0 mL of a solution containing 1000 mg/L of yttrium [NOTE—Yttrium ICP standard solutions are commercially available.[1]] and 2.0 mL of a solution containing 1000 mg/L of lutetium [NOTE—Lutetium ICP standard solutions are commercially available.[2]] to a 1000-mL volumetric flask, add 10 mL of 65% ultratrace nitric acid, dilute with water to volume, and mix.
Blank standard: Transfer 1.0 mL of the *Internal standard solution* to a 100-mL volumetric flask, add 10.0 mL of 65% ultratrace nitric acid, dilute with water to volume, and mix.
Standard stock solution: Transfer 1.0 mL each of the solutions containing 1000 mg/L of chromium, copper, lead, and nickel [NOTE—Single-element ICP standard solutions are commercially available.[3]] to a 100-mL volumetric flask, add 10.0 mL of 65% ultratrace nitric acid, dilute with water to volume, and mix. [NOTE—Prepare this solution fresh monthly.] Transfer 1.0 mL of this solution to a 100-mL volumetric flask, add 10 mL of 65% ultratrace nitric acid, dilute with water to volume, and mix. The concentration of each element in this solution is 100 µg/L. [NOTE—Prepare this solution fresh weekly.]
Standard solutions: [NOTE—Prepare these solutions fresh each time.] Into two separate 100-mL volumetric flasks, transfer 1.0 mL and 5.0 mL of the *Standard stock solution*, add 1.0 mL of the *Internal standard solution* and 10.0 mL of 65% ultratrace nitric acid, dilute with water to volume, and mix well. The concentration of each element in these solutions is 1 µg/L and 5 µg/L, respectively.

[1] A suitable yttrium ICP standard is available from LGC (www.lgcstandards.com) or Millipore Sigma (www.sigmaaldrich.com).
[2] A suitable lutenium ICP standard is available from LGC (www.lgcstandards.com) or Millipore Sigma (www.sigmaaldrich.com).
[3] Suitable single-element ICP standards are available from LGC (www.lgcstandards.com) or Millipore Sigma (www.sigmaaldrich.com).

Sample solution: Transfer 3.5 g of Medium-Chain Triglycerides into a suitable quartz flask. Add 5 mL of concentrated sulfuric acid[4] and heat slowly on a hot-plate in a fume hood. At the boiling heat, carefully add 5 mL of 30% hydrogen peroxide[5] in 1-mL increments. Continue heating until the solution is clear and colorless. Otherwise, add another 3 mL concentrated sulfuric acid and continue to add more 30% hydrogen peroxide. After cooling, cautiously add about 5 mL of water dropwise. Quantitatively transfer the flask's contents into a clean, dry, 20-mL volumetric flask, dilute with water to volume, and mix. Transfer 1.0 mL of digestion solution to a 20-mL volumetric flask, add 0.2 mL of the *Internal standard solution* and 2.0 mL of 65% ultratrace nitric acid, dilute with water to volume, and mix. Retain the remaining digestion solution for use in the test for *Limit of Tin*.

Blank solution: Prepare the blank digestion solution, following the preparation procedure for the *Sample solution*, but without using Medium-Chain Triglycerides.

Instrumental conditions

(See *Plasma Spectrochemistry* ⟨730⟩.)

Mode: ICP–MS

Spectrometer: Quadrupole mass spectrometer

Detector: Ion detector maintained under vacuum

System suitability

Samples: *Blank standard* and *Standard solutions*

Suitability requirements: Instrument performance must be verified to conform to the manufacturer's specifications for resolution and sensitivity. Before analyzing the *Sample solutions*, the instrument must pass a suitable performance check. The instrument should read all isotopes for the following elements shown in *Table 1* for the yttrium internal standard (89 amu) and the lutetium internal standard (175 amu), and should report the total element contents using the isotopes. Generate the calibration curve using the *Blank standard* and *Standard solutions* for each element. The linear regression coefficient is NLT 0.99.

Table 1

Element	Isotope (amu)
Chromium	52
Copper	63
Lead	206
Nickel	58
Tin	118

Analysis

Samples: *Blank solution* and *Sample solution*

Determine the concentration of each element in the *Blank solution* and in the *Sample solution* using the calibration curve.

Calculate the quantity, in µg/g, of each element in the portion of Medium-Chain Triglycerides taken:

$$\text{Result} = (C_U - C_B)/C_S$$

C_U = concentration of each element in the *Sample solution* (µg/L)

C_B = concentration of each element in the *Blank solution* (µg/L)

C_S = concentration of Medium-Chain Triglycerides in the *Sample solution* (g/L)

Acceptance criteria: See *Table 2*.

Table 2

Element	Acceptance Criteria, NMT (µg/g)
Chromium	0.05
Copper	0.1
Lead	0.1
Nickel	0.1 ▲ (IRA 1-Mar-2019)

Add the following:

▲• LIMIT OF TIN

[NOTE—Use this test for Medium-Chain Triglycerides intended for use in parenteral nutrition.]

Internal standard solution, Sample solution, Blank solution, Instrumental conditions, System suitability, and **Analysis:** Proceed as directed in the test for *Limit of Chromium, Copper, Lead, and Nickel*

Blank standard: Transfer 1.0 mL of the *Internal standard solution* to a 100-mL volumetric flask, add 10.0 mL of 30% hydrochloric acid,[6] dilute with water to volume, and mix.

Standard stock solution: Transfer 1.0 mL of a solution containing 1000 mg/L of tin [NOTE—Single-element ICP standard solutions are commercially available.[7]] to a 100-mL volumetric flask, add 25.0 mL of 30% hydrochloric acid, dilute with water to volume, and mix. [NOTE—Prepare this solution fresh monthly.] Transfer 1.0 mL of this solution to a 100-mL volumetric flask, add 25.0 mL of 30% hydrochloric acid, dilute with water to volume, and mix. The concentration of tin in this solution is 100 µg/L. [NOTE—Prepare this solution fresh each time.]

Standard solutions: [NOTE—Prepare these solutions fresh each time.] Into two separate 100-mL volumetric flasks, transfer 1.0 mL and 5.0 mL of the *Standard stock solution*, add 1.0 mL of the *Internal standard solution* and 25.0 mL of 30% hydrochloric acid, dilute with water to volume, and mix well. The concentration of tin in these solutions is 1 µg/L and 5 µg/L, respectively.

Acceptance criteria: NMT 0.1 µg/g ▲ (IRA 1-Mar-2019)

• ALKALINE IMPURITIES

Sample solution: Dissolve 2.0 g of Medium-Chain Triglycerides in a mixture of alcohol and ethyl ether (1.5: 3.0).

Analysis: Add 0.05 mL of bromophenol blue TS to the *Sample solution*, and titrate with 0.01 N hydrochloric acid to a yellow endpoint.

Acceptance criteria: NMT 0.15 mL of 0.01 N hydrochloric acid is required.

[4] Suitable ultratrace concentrated sulfuric acid is available from Spectrum Chemicals (www.spectrumchemical.com) or Millipore Sigma (www.sigmaaldrich.com).

[5] Suitable ultratrace 30% hydrogen peroxide is available from Spectrum Chemicals (www.spectrumchemical.com) or Millipore Sigma (www.sigmaaldrich.com).

[6] Suitable ultratrace 30% hydrochloric acid is available from Spectrum Chemicals (www.spectrumchemical.com), Millipore Sigma (www.sigmaaldrich.com), WVR (us.vwr.com/store/) or other vendors.

[7] A suitable tin ICP standard is available from LGC (www.lgcstandards.com) or Millipore Sigma (www.sigmaaldrich.com).

SPECIFIC TESTS

- **FATS AND FIXED OILS** ⟨401⟩**,** *Procedures, Unsaponifiable Matter*
  Sample: 5.0 g
  Acceptance criteria: NMT 0.5%
- **SPECIFIC GRAVITY** ⟨841⟩**:** 0.93–0.96 at 20°
- **WATER DETERMINATION** ⟨921⟩**,** *Method I***:** NMT 0.2%
- **APPEARANCE**
  Diluent: Hydrochloric acid and water (2.75%: 97.25%)
  Sample: 10 mL
  Standard solution: Prepare immediately before use by mixing 2.4 mL of ferric chloride CS and 0.6 mL of cobaltous chloride CS with *Diluent* to make 10.0 mL, and diluting 5.0 mL of the solution with *Diluent* to make 10.0 mL.
  Analysis: Compare the *Sample* and the *Standard solution* by viewing them downward in matched color-comparison tubes against a white surface (see *Color and Achromicity* ⟨631⟩).
  Acceptance criteria: The *Sample* is clear and not more intensely colored than the *Standard solution*.
- **FATS AND FIXED OILS** ⟨401⟩**,** *Procedures, Acid Value***:** NMT 0.2
- **FATS AND FIXED OILS** ⟨401⟩**,** *Procedures, Fatty Acid Composition***:** The fatty acid fraction of Medium-Chain Triglycerides exhibits the following composition as seen in *Table 3*. Disregard any peak with an area less than 0.05% of the total area.

Table 3

Carbon-Chain Length	Number of Double Bonds	Percentage (%)
6	0	≤2.0
8	0	50.0–80.0
10	0	20.0–50.0
12	0	≤3.0
14	0	≤1.0

- **FATS AND FIXED OILS** ⟨401⟩**,** *Procedures, Hydroxyl Value***:** NMT 10
- **FATS AND FIXED OILS** ⟨401⟩**,** *Procedures, Iodine Value***:** NMT 1.0
- **FATS AND FIXED OILS** ⟨401⟩**,** *Procedures, Peroxide Value***:** NMT 1.0
- **FATS AND FIXED OILS** ⟨401⟩**,** *Procedures, Saponification Value*
  Sample: 1.0 g
  Acceptance criteria: 310–360
- **VISCOSITY—CAPILLARY METHODS** ⟨911⟩
  Analysis: Determine at 20 ± 0.1° with a capillary viscometer.
  Acceptance criteria: 25–33 centipoises
- **REFRACTIVE INDEX** ⟨831⟩**:** 1.440–1.452 at 20°
- **ARTICLES OF BOTANICAL ORIGIN** ⟨561⟩**,** *Methods of Analysis, Total Ash*
  Sample: 2.0 g
  Acceptance criteria: NMT 0.1%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, protected from light. Store at temperatures not exceeding 25°.
- **LABELING:** Where it is intended for use in parenteral nutrition, it is so labeled.