DEFINITION

Mixture of triglycerides of saturated fatty acids, mainly of caprylic acid (octanoic acid, C8H16O2) and of capric acid (decanoic acid, C10H20O2). Medium-chain triglycerides are obtained from the oil extracted from the hard, dried fraction of the endosperm of Elaeis guineensis Jacq. or from the dried endosperm of Cocos nucifera L. or from the dried endosperm of Elaeis guineensis Jacq.

Content: minimum 95.0 per cent of saturated fatty acids with 8 and 10 carbon atoms.

CHARACTERS

Appearance: colourless or slightly yellowish, oily liquid. Solubility: practically insoluble in water, miscible with alcohol, with methylene chloride, with light petroleum and with fatty oils.

IDENTIFICATION

First identification: B, C.

Second identification: A, D.

A. Heat 3.0 g under a reflux condenser for 30 min with 50 ml of a mixture of equal volumes of alcohol R and 2 M alcoholic potassium hydroxide R. Reserve 10 ml of the mixture for identification test D. To 40 ml of the mixture add 30 ml of water R, evaporate the alcohol and acidify the hot solution with 25 ml of dilute hydrochloric acid R. After cooling, shake with 50 ml of perchloric-free ether R. Wash the ether layer with 3 quantities, each of 10 ml, of sodium chloride solution R, dry over anhydrous sodium sulphate R and filter. Evaporate the ether and determine the acid value (2.5.7) of the residue, using 0.300 g. The acid value is 350 to 390.

B. It complies with the test for saponification value (see Tests).

C. It complies with the test for composition of fatty acids (see Tests).

D. Evaporate 10 ml of the alcoholic mixture obtained in identification test A to dryness on a water-bath. Transfer the residue into a test-tube, add 0.3 ml of sulphuric acid R and close the test-tube with a stopper through which a U-shaped glass tube is inserted. One end of the U-tube is dipped into 3 ml of a 10 g/1 solution of tryptophan R in a mixture of equal volumes of sulphuric acid R and water R. Heat the test-tube in a silicone-oil bath at 180 °C for 10 min and collect the liberated fumes in the tryptophan reagent. Heat the tryptophan reagent on a water-bath for 1 min. A violet colour develops.

TESTS

Appearance. The substance to be examined is clear (2.2.1) and not more intensely coloured than reference solution Y3 (2.2.2, Method I).

Alkaline impurities. Dissolve 2.00 g in a mixture of 1.5 ml of alcohol R and 3.0 ml of ether R. Add 0.05 ml of bromophenol blue solution R. Not more than 0.15 ml of 0.01 M hydrochloric acid is required to change the colour of the indicator to yellow.

Relative density (2.2.5): 0.93 to 0.96.

Refractive index (2.2.6): 1.440 to 1.452.

Viscosity (2.2.9): 25 mPas to 33 mPas.

Acid value (2.5.1): maximum 0.2.

Hydroxyl value (2.5.3, Method A): maximum 10.

Iodine value (2.5.4): maximum 1.0.

Peroxide value (2.5.5, Method A): maximum 1.0.

Saponification value (2.5.6): 310 to 360.

Unsaponifiable matter (2.5.7): maximum 0.5 per cent, determined on 5.0 g.

Composition of fatty acids. Gas chromatography (2.4.22, Method C).

Column:

- material: fused silica,
- size: l = 30 m, Ø = 0.32 mm,
- stationary phase: macrogol 20 000 R (film thickness 0.5 µm),

Carrier gas: helium for chromatography R.

Flow rate: 1.3 ml/min.

Temperature:

<table>
<thead>
<tr>
<th>Time (min)</th>
<th>Temperature (°C)</th>
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<tbody>
<tr>
<td>Column</td>
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<tr>
<td></td>
<td>1 - 35</td>
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<td>35 - 50</td>
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Injection port 250

Detector 250

Detection: flame ionisation.

Split ratio: 1:100.

Composition of the fatty acid fraction of the substance:

- caproic acid: maximum 2.0 per cent,
- caprylic acid: 50.0 per cent to 80.0 per cent,
- capric acid: 20.0 per cent to 50.0 per cent,
- lauric acid: maximum 3.0 per cent,
- myristic acid: maximum 1.0 per cent.

Chromium: maximum 0.05 ppm, if intended for use in parenteral nutrition.

Atomic absorption spectrometry (2.2.23, Method I).
**Triglycerides, medium-chain**

**Test solution.** Dissolve 2.0 g of the substance to be examined in methyl isobutyl ketone R3 and dilute to 10.0 ml with the same solvent.

**Solution A.** Dilute 0.100 ml of chromium liposoluble standard solution (1000 ppm Cr) R to 10.0 ml with methyl isobutyl ketone R3.

**Stock solution.** Dilute 0.100 ml of solution A to 10.0 ml with methyl isobutyl ketone R3.

**Reference solutions.** Prepare 3 reference solutions by dissolving for each 2.0 g of the substance to be examined in the minimum volume of methyl isobutyl ketone R3, adding 0.5 ml, 1.0 ml and 2.0 ml, respectively, of stock solution and diluting to 10.0 ml with methyl isobutyl ketone R3.

**Source:** chromium hollow-cathode lamp.

**Wavelength:** 286.3 nm.

**Atomic generator:** graphite furnace.

**Carrier gas:** argon R.

**Copper:** maximum 0.1 ppm, if intended for use in parenteral nutrition.

**Test solution.** Dissolve 2.0 g of the substance to be examined in methyl isobutyl ketone R3 and dilute to 10.0 ml with the same solvent.

**Solution A.** Dilute 0.100 ml of copper liposoluble standard solution (1000 ppm Cu) R to 10.0 ml with methyl isobutyl ketone R3.

**Stock solution.** Dilute 0.100 ml of solution A to 10.0 ml with methyl isobutyl ketone R3.

**Reference solutions.** Prepare 3 reference solutions by dissolving for each 2.0 g of the substance to be examined in the minimum volume of methyl isobutyl ketone R3, adding 1.0 ml, 2.0 ml and 4.0 ml, respectively, of stock solution and diluting to 10.0 ml with methyl isobutyl ketone R3.

**Source:** copper hollow-cathode lamp.

**Wavelength:** 324.7 nm.

**Atomic generator:** graphite furnace.

**Carrier gas:** argon R.

**Lead:** maximum 0.1 ppm, if intended for use in parenteral nutrition.

**Test solution.** Dissolve 2.0 g of the substance to be examined in methyl isobutyl ketone R3 and dilute to 10.0 ml with the same solvent.

**Solution A.** Dilute 0.100 ml of lead liposoluble standard solution (1000 ppm Pb) R to 10.0 ml with methyl isobutyl ketone R3.

**Stock solution.** Dilute 0.100 ml of solution A to 10.0 ml with methyl isobutyl ketone R3.

**Reference solutions.** Prepare 3 reference solutions by dissolving for each 2.0 g of the substance to be examined in the minimum volume of methyl isobutyl ketone R3, adding 1.0 ml, 2.0 ml and 4.0 ml, respectively, of stock solution and diluting to 10.0 ml with methyl isobutyl ketone R3.

**Source:** lead hollow-cathode lamp.

**Wavelength:** 283.3 nm.

**Atomic generator:** graphite furnace coated inside with palladium carbide; calcination is carried out in the presence of oxygen at a temperature below 800 °C.

**Carrier gas:** argon R.

**Nickel:** maximum 0.2 ppm, if intended for use in parenteral nutrition.

**Atomic absorption spectrometry (2.2.23, Method II).**

**Test solution.** Dissolve 2.0 g of the substance to be examined in methyl isobutyl ketone R3 and dilute to 10.0 ml with the same solvent.

**Solution A.** Dilute 0.100 ml of nickel liposoluble standard solution (1000 ppm Ni) R to 10.0 ml with methyl isobutyl ketone R3.

**Stock solution.** Dilute 0.100 ml of solution A to 10.0 ml with methyl isobutyl ketone R3.

**Reference solutions.** Prepare 3 reference solutions by dissolving for each 2.0 g of the substance to be examined in the minimum volume of methyl isobutyl ketone R3, adding 1.0 ml, 2.0 ml and 4.0 ml, respectively, of stock solution and diluting to 10.0 ml with methyl isobutyl ketone R3.

**Source:** nickel hollow-cathode lamp.

**Wavelength:** 232 nm.

**Atomic generator:** graphite furnace.

**Carrier gas:** argon R.

**Tin:** maximum 0.1 ppm, if intended for use in parenteral nutrition.

**Atomic absorption spectrometry (2.2.23, Method II).**

**Test solution.** Dissolve 2.0 g of the substance to be examined in methyl isobutyl ketone R3 and dilute to 10.0 ml with the same solvent.

**Solution A.** Dilute 0.100 ml of tin liposoluble standard solution (1000 ppm Sn) R to 10.0 ml with methyl isobutyl ketone R3.

**Stock solution.** Dilute 0.100 ml of solution A to 10.0 ml with methyl isobutyl ketone R3.

**Reference solutions.** Prepare 3 reference solutions by dissolving for each 2.0 g of the substance to be examined in the minimum volume of methyl isobutyl ketone R3, adding 1.0 ml, 2.0 ml and 4.0 ml, respectively, of stock solution and diluting to 10.0 ml with methyl isobutyl ketone R3.

**Source:** tin hollow-cathode lamp.

**Wavelength:** 286.3 nm.

**Atomic generator:** graphite furnace coated inside with palladium carbide.

**Carrier gas:** argon R.

**Heavy metals (2.4.8):** maximum 10 ppm, if intended for use other than parenteral nutrition.

2.0 g complies with limit test D. Prepare the standard using 2 ml of lead standard solution (10 ppm Pb) R.

**Water (2.5.12):** maximum 0.2 per cent, determined on 10.00 g.

**Total ash (2.4.16):** maximum 0.1 per cent, determined on 2.0 g.

**STORAGE**

In a well-filled container, protected from light.

**LABELLING**

The label states, where applicable, that the substance is intended for use in parenteral nutrition.