**Triglycerides, medium-chain**

**DEFINITION**

Mixture of triglycerides of saturated fatty acids, mainly of caprylic (octanoic) acid and of capric (decanoic) acid. Medium-chain triglycerides are obtained 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.

**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.

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**ASSAY**

Dissolve 0.200 g in 50 ml of ethanol R. Titrate with 0.1 M sodium hydroxide, determining the end-point potentiometrically (2.2.20).

1 ml of 0.1 M sodium hydroxide is equivalent to 24.82 mg of C_{16}H_{34}O_{16}.

**STORAGE**

In an airtight container, at a temperature not exceeding 25 °C.

**IMPURITIES**

Specified impurities: B.

Other detectable impurities (the following substances would, if present at a sufficient level, be detected by one or other of the tests in the monograph. They are limited by the general acceptance criterion for other/unspecified impurities and/or by the general monograph Substances for pharmaceutical use (2034). It is therefore not necessary to identify these impurities for demonstration of compliance. See also 5.10. Control of impurities in substances for pharmaceutical use): A, C, D.

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**TRIGLYCERIDES, MEDIUM-CHAIN**

**Triglycerida saturata media**
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 peroxide-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 (2.5.1) 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/l 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 bromphenol blue solution R. Not more than 0.15 ml of 0.01 M hydrochloric acid R 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></td>
<td></td>
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<tr>
<td>0 - 1</td>
<td>70</td>
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<tr>
<td>1 - 35</td>
<td>70 → 240</td>
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<tr>
<td>35 - 50</td>
<td>240</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:
– caprylic 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 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 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: 357.8 nm.

Atomic generator: graphite furnace.

Copper: 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 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.
Atomic absorption spectrometry (2.2.23, Method I).

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: 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.

01/2008:2032

TRIGLYCEROL DIISOSTEARATE

Triglyceroli diisostearas

DEFINITION
Mixture of polyglycerol diesters of mainly isostearic acid, obtained by esterification of polyglycerol and isostearic acid. The polyglycerol consists mainly of triglycerol.

CHARACTERS

Appearance: clear, yellowish, viscous liquid.

Solubility: practically insoluble in water, miscible with ethanol (96 per cent) and with fatty oils.

IDENTIFICATION

A. Infrared absorption spectrophotometry (2.2.24).

Preparation: film between 2 plates of sodium chloride R.

Comparison: triglycerol diisostearate CRS.

B. Composition of fatty acids (see Tests).

TESTS

Appearance of solution. The solution is not more intensely coloured than reference solution BY3 (2.2.2, Method I).

Mix 10 ml with 10 ml of ethanol (96 per cent) R.

Acid value (2.5.1): maximum 3.0, determined on 1.0 g.

Saponification value (2.5.6): 180 to 230, determined on 0.25 g.

Iodine value (2.5.4, Method B): maximum 3.0.

Peroxide value (2.5.5, Method B): maximum 6.0.

Composition of fatty acids (2.4.22, Method B). Use the mixture of calibrating substances in Table 2.4.22.-1.

Composition of the fatty-acid fraction of the substance:
- sum of the contents of the fatty acids eluting between palmitic acid and stearic acid: minimum 60.0 per cent;
- sum of the contents of myristic acid, palmitic acid and stearic acid: maximum 11.0 per cent.

Water (2.5.12): maximum 0.5 per cent, determined on 2.00 g.