Edition: BP 2025 (Ph. Eur. 11.6 update)

Refined Castor Oil

General Notices

(Ph. Eur. monograph 2367)

Ph Eur

DEFINITION

Fatty oil obtained from the seeds of *Ricinus communis* L. by cold expression. It is then refined. A suitable antioxidant may be added.

PRODUCTION

During the expression step, the temperature of the oil must not exceed 50 °C.

CHARACTERS

Appearance

Clear, almost colourless or slightly yellow, viscous, hygroscopic liquid.

Solubility

Slightly soluble in light petroleum, miscible with ethanol (96 per cent) and with glacial acetic acid.

Relative density

About 0.958.

Refractive index

About 1.479.

Viscosity

About 1000 mPa·s.

IDENTIFICATION

First identification: B, C.

Second identification: A, B.

A. A mixture of 2 mL of the substance to be examined and 8 mL of *ethanol (96 per cent) R* is clear (*2.2.1*).
B. Specific absorbance (see Tests).
C. Composition of fatty acids (see Tests).

TESTS

Appearance

The substance to be examined is clear (*2.2.1*) and not more intensely coloured than reference solution BY_3 or Y_3 (*2.2.2, Method I*).

Optical rotation (*2.2.7*)

+ 3.5° to + 6.0°.

Specific absorbance (*2.2.25*)

0.7 to 1.5, determined at the absorption maximum at 270 nm.

To 1.00 g add *ethanol (96 per cent) R* and dilute to 100.0 mL with the same solvent.

Acid value (*2.5.1*)

Maximum 0.8.

Dissolve 5.00 g in 25 mL of the prescribed mixture of solvents.

Hydroxyl value (*2.5.3, Method A*)

Minimum 160.

Peroxide value (*2.5.5, Method A*)

Maximum 5.0.

Unsaponifiable matter (*2.5.7*)

Maximum 0.8 per cent, determined on 5.0 g.

Oil obtained by extraction and adulteration

In a ground-glass-stoppered tube about 125 mm long and 18 mm in internal diameter, thoroughly mix 3 mL of the substance to be examined with 3 mL of *carbon disulfide R*. Shake for 3 min with 1 mL of *sulfuric acid R*. The mixture is less intensely coloured than a freshly prepared mixture of 3.2 mL of *ferric chloride solution R1*, 2.3 mL of *water R* and 0.5 mL of *dilute ammonia R1*.

Composition of fatty acids

Gas chromatography (*2.4.22*) with the following modifications.

Use the mixture of calibrating substances in Table 2.4.22.-3.

Test solution Introduce 75 mg of the substance to be examined into a 10 mL centrifuge tube with a screw cap. Dissolve in 2 mL of *1,1-dimethylethyl methyl ether R1* with shaking and heat gently (50-60 °C). Add, while still warm, 1 mL of a 12 g/L solution of *sodium R* in *anhydrous methanol R*, prepared with the necessary precautions, and shake vigorously for at least

5 min. Add 5 mL of *distilled water R* and shake vigorously for about 30 s. Centrifuge for 15 min at 1500 *g*. Use the upper layer.

Reference solution Dissolve 50 mg of *methyl ricinoleate CRS* and 50 mg of *methyl stearate CRS* in 10.0 mL of *1,1-dimethylethyl methyl ether R1*.

Column:

— *material*: fused silica;

— *size*: *l* = 30 m, Ø = 0.25 mm;

— *stationary phase*: *macrogol 20 000 R* (film thickness 0.25 µm).

Carrier gas *helium for chromatography R*.

Flow rate 0.9 mL/min.

Split ratio 1:100.

Temperature:

	Time (min)	Temperature (°C)
Column	0 - 55	215
Injection port		250
Detector		250

Detection Flame ionisation.

Injection 1 µL.

System suitability:

— *symmetry factor*: 0.7 to 1.5 for the peak due to methyl stearate in the chromatogram obtained with the test solution.

Calculate the percentage content of each fatty acid by the normalisation procedure.

Correct the area of the peak due to methyl ricinoleate, by multiplying by a factor *R* calculated using the following expression:

$$\frac{m_1}{m_2} \times \frac{A_2}{A_1}$$

m_1 = mass of methyl ricinoleate in the reference solution;

m_2 = mass of methyl stearate in the reference solution;

A_1 = area of the peak due to methyl ricinoleate in the chromatogram obtained with the reference solution;

A_2 = area of the peak due to methyl stearate in the chromatogram obtained with the reference solution.

Composition of the fatty-acid fraction of the oil:

— *palmitic acid*: maximum 2.0 per cent;

— *stearic acid*: maximum 2.5 per cent;

— *oleic acid and isomer*: 2.5 per cent to 6.0 per cent;

— *linoleic acid*: 2.5 per cent to 7.0 per cent;

— *linolenic acid*: maximum 1.0 per cent;

— *eicosenoic acid*: maximum 1.0 per cent;

— *ricinoleic acid*: 85.0 per cent to 92.0 per cent;

— *any other fatty acid*: for each fatty acid, maximum 1.0 per cent.

Water (*2.5.32*)

Maximum 0.3 per cent, or maximum 0.2 per cent if intended for use in the manufacture of parenteral preparations, determined on 1.00 g.

STORAGE

In an airtight, well-filled container, protected from light. If intended for use in the manufacture of parenteral preparations, store under an inert gas.

LABELLING

The label states, where applicable, that the substance is suitable for use in the manufacture of parenteral preparations and the name of the inert gas.

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