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

# Virgin Castor Oil

General Notices

Castor Oil

*(Ph. Eur. monograph 0051)*

**Action and use**

Stimulant laxative; emollient.

**Preparation**

Zinc and Castor Oil Ointment

Ph Eur

## DEFINITION

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

## PRODUCTION

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

## CHARACTERS

**Appearance**

Clear at 40 °C, 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.

## 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

**Optical rotation** (*2.2.7*)

+ 3.5° to + 6.0°.

**Specific absorbance** (*2.2.25*)

Maximum 0.7, 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 1.5.

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 10.0.

**Unsaponifiable matter** (*2.5.7*)

Maximum 0.8 per cent, determined on 5.0 g.

**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 mix vigorously for at least 5 min. Add 5 mL of *distilled water R* and mix 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:

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

$m_1$ = 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, determined on 1.00 g.

## STORAGE

In an airtight, well-filled container, protected from light.