Sesame oil, refined

EUROPEAN PHARMACOPOEIA 5.0

the chromatogram obtained with the reference solution (a) (0.5 per cent). Disregard any peak with an area less than 0.2 times the area of the principal peak in the chromatogram obtained with reference solution (a).

**Water (2.5.12).** Not more than 1.0 per cent, determined on 0.50 g by the semi-micro determination of water.

**Sulphated ash (2.4.14).** Not more than 0.1 per cent, determined on 1.0 g.

**ASSAY**

Dissolve 0.400 g in 50 ml of a mixture of equal volumes of anhydrous acetic acid R and methyl ethyl ketone R. Titrate with 0.1 M perchloric acid, determining the end-point potentiometrically (2.2.20). Carry out a blank titration. 1 ml of 0.1 M perchloric acid is equivalent to 50.08 mg of \( \text{C}_{20}\text{H}_{16}\text{Cl}_3\text{N}_3\text{O}_4\text{S} \).

**STORAGE**

Store protected from light.

**IMPURITIES**

A. (1RS)-1-(2,4-dichlorophenyl)-2-(1H-imidazol-1-yl)ethanol,

B. \( R = \text{Br} \): 3-(bromomethyl)-7-chloro-1-benzothiophen,

C. \( R = \text{OH} \): (7-chloro-1-benzothiophen-3-yl)methanol.

**SESAME OIL, REFINED**

**Sesami oleum raffinatum**

**DEFINITION**

Refined sesame oil is the fatty oil obtained from the ripe seeds of *Sesamum indicum* L. by expression or extraction, then refined. Improved colour and odour may be obtained by further refining. It may contain a suitable antioxidant.

**CHARACTERS**

A clear, light yellow liquid, almost colourless, practically insoluble in alcohol, miscible with light petroleum. It has a relative density of about 0.919. It solidifies to a soft mass at about \(-4^\circ\text{C}\).

**IDENTIFICATION**

*First identification: C.*

*Second identification: A, B.*

A. It complies with the test for refractive index (see Tests).

B. Carry out the identification of fatty oils by thin-layer chromatography (2.3.2). The chromatogram obtained is similar to the type chromatogram for sesame oil.

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

**TESTS**

**Refractive index (2.2.6):** 1.470 to 1.476.

**Acid value (2.5.1).** Not more than 0.6, determined on 10.0 g. If intended for use in the manufacture of parenteral dosage forms, not more than 0.3.

**Peroxide value (2.5.5).** Not more than 10.0. If intended for use in the manufacture of parenteral dosage forms, not more than 5.0.

![Figure 0433.1 - Chromatogram for the composition of triglycerides in sesame oil](image-url)

**Figure 0433.1. - Chromatogram for the composition of triglycerides in sesame oil**

See the information section on general monographs (cover pages)
Unsaponifiable matter (2.5.7). Not more than 2.0 per cent, determined on 5.0 g.

Alkaline impurities (2.4.19). It complies with the test for alkaline impurities in fatty oils.

Cottonseed oil. Mix 5 ml in a test-tube with 5 ml of a mixture of equal volumes of pentanol R and a 10 g/l solution of sulphur R in carbon disulphide R. Warm the mixture carefully until the carbon disulphide is expelled, and immerse the tube to one-third of its depth in boiling saturated sodium chloride solution R. No reddish colour develops within 15 min.

Composition of triglycerides. Examine by liquid chromatography (2.2.29).

Test solution. Into a 10 ml volumetric flask, weigh 200 g and dilute to 10.0 ml with the mobile phase.

The chromatographic procedure may be carried out using:
– two stainless steel columns 0.25 m long and 4.6 mm in internal diameter packed with octadecylsilyl silica gel for chromatography R (5 µm) in series,
– as mobile phase at a flow rate of 1.0 ml/min a mixture of 1 volume of methylene chloride R and 2 volumes of acetonitrile R,
– as detector a refractometer.

Inject 20 µl of the test solution. Identify the peaks from the type chromatogram (Figure 0433.-1). The fatty acid radicals are designated as linolenic (Ln), linoleic (L), oleic (O), palmitic (P) and stearic (S).

Calculate the percentage content of triglycerides from the areas of the peaks in the chromatogram obtained with the test solution by the normalisation procedure.

The composition of triglycerides is the following:
– LLL: 7.0 per cent to 19.0 per cent,
– OLL: 13.0 per cent to 30.0 per cent,
– PLL: 5.0 per cent to 9.0 per cent,
– OOL: 14.0 per cent to 25.0 per cent,
– POL: 8.0 per cent to 16.0 per cent,
– OPO: 5.0 per cent to 14.0 per cent,
– SOL: 2.0 per cent to 8.0 per cent,
– POP: 2.0 per cent to 10.0 per cent.

Water (2.5.12). If intended for use in the manufacture of parenteral dosage forms, not more than 0.05 per cent, determined on 5.0 g by the semi-micro determination of water.

STORAGE
Store in an airtight, well-filled container, protected from light.

Refined sesame oil intended for use in the manufacture of parenteral dosage forms is stored under an inert gas in an airtight container.

When the container has been opened, its contents are to be used as soon as possible. Any part of the contents not used at once is protected by an atmosphere of an inert gas.

LABELLING
The label states:
– whether the oil is obtained by expression or extraction,
– where applicable, the name and amount of any added antioxidant,
– where applicable, that the substance is suitable for use in the manufacture of parenteral dosage forms,
– where applicable, the name of the inert gas used.