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

Olive Oil Ear Drops

General Notices

DEFINITION

Olive Oil Ear Drops are Virgin Olive Oil in a suitable container.

The ear drops comply with the requirements stated under Ear Preparations and with the following requirements.

IDENTIFICATION

Carry out the test for the *identification of fatty oils by thin-layer chromatography*, Appendix X N. The chromatogram obtained from the oil being examined shows spots corresponding to those in the *typical chromatogram* for olive oil. For certain types of olive oil the difference in the sizes of spots E and F is less pronounced than in the figure.

TESTS

Acid value

Not more than 2.0, Appendix X B. Use 5 g.

Light absorption

The *absorbance* of a 1% w/v solution in *cyclohexane* at the maximum at 270 nm is not more than 0.20, Appendix II B. The ratio of the *absorbance* at 232 nm to that at 270 nm is greater than 8.

Peroxide value

Not more than 20.0, Appendix X F.

Relative density

0.910 to 0.916, Appendix V G.

Unsaponifiable matter

Not more than 1.5% w/w when determined by the following method. To 5 g of the oil in a 150-mL flask add 50 mL of 2M *ethanolic potassium hydroxide* and heat under a reflux condenser on a water bath for 1 hour, shaking frequently. Add 50 mL of *water* through the condenser, shake, allow to cool and transfer the contents of the flask to a separating funnel, rinsing the flask with 50 mL of *petroleum spirit* (*boiling range, 40° to 60°*) in portions and adding the rinsings to the separating funnel. Shake vigorously for 1 minute, allow to separate and transfer the aqueous layer to a second separating funnel. If an emulsion forms add small quantities of *ethanol* (*96%*) or a concentrated solution of *potassium hydroxide*. Extract the aqueous layer with two 50-mL quantities of *petroleum spirit* (*boiling range, 40° to 60°*) and combine the organic layers in a third separating funnel. Wash with three 50-mL quantities of *ethanol* (*50%*), transfer the petroleum spirit layer to

a weighed 250-mL flask, rinse the separating funnel with small quantities of *petroleum spirit* (*boiling range, 40° to 60°*) and add the rinsings to the flask. Evaporate the solvent on a water bath, dry at 100° to 105° for 15 minutes with the flask in a horizontal position, allow to cool and weigh. Repeat the drying for successive 15-minute periods until the loss in weight between two successive weighings does not exceed 0.1%. Dissolve the residue in 20 mL of *ethanol* (*96%*) previously neutralised to 0.1 mL of *bromophenol blue solution* and, if necessary, titrate with *0.1M hydrochloric acid VS*. Calculate the percentage content of unsaponifiable matter from the expression:

$100(a-0.032b)/w$

where *a* is the weight, in g, of the residue, *b* is the volume, in mL, of *0.1M hydrochloric acid VS* required and *w* is the weight, in g, of oil taken. The test is not valid if $0.032b$ is greater than 5% of *a* and must be repeated.

Foreign fixed oils

Carry out the test for *composition of fatty acids by gas chromatography*, Appendix X N. The fatty-acid fraction of the oil has the following composition.

Saturated fatty acids of chain length less than C_{16}: Not more than 0.1%.

Palmitic acid: 7.5 to 20.0%.

Palmitoleic acid (equivalent chain length on polyethylene glycol adipate, 16.3): Not more than 3.5%.

Stearic acid: 0.5 to 5.0%.

Oleic acid (equivalent chain length on polyethylene glycol adipate, 18.3): 56.0 to 85.0%.

Linoleic acid (equivalent chain length on polyethylene glycol adipate, 18.9): 3.5 to 20.0%.

Linolenic acid (equivalent chain length on polyethylene glycol adipate, 19.7): Not more than 1.2%.

Arachidic acid: Not more than 0.7%.

Eicosenoic acid (equivalent chain length on polyethylene glycol adipate, 20.3): Not more than 0.4%.

Behenic acid: Not more than 0.2%.

Lignoceric acid: Not more than 0.2%.

Sterols

Carry out the test for the *determination of sterols*, Appendix X N. The sterol fraction of the oil has the following composition:

sum of contents of β-sitosterol, Δ5,23-stigmastadienol, clerosterol, sitostanol, Δ5-avenasterol and Δ5,24-stigmastadienol: not less than 93.0%.

cholesterol: not more than 0.5%.

Δ7-stigmasterol: not more than 0.5%.

campesterol: not more than 4.0%.

and the content of stigmasterol is not more than that of campesterol.

Sesame oil

Shake 10 mL for about 1 minute with a mixture of 0.5 mL of a 0.35% v/v solution of *furfuraldehyde* in *acetic anhydride* and 4.5 mL of *acetic anhydride* in a cylinder closed with a ground-glass stopper, filter through paper impregnated with *acetic anhydride* and add 0.2 mL of *sulfuric acid* to the filtrate. No bluish green colour develops.

STORAGE

Olive Oil Ear Drops should be kept in a well-filled container and protected from light.