



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

Almond Oil Ear Drops

[General Notices](#)

DEFINITION

Almond Oil Ear Drops are Virgin Almond 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 almond oil.

TESTS

[Acid value](#)

Not more than 2.0, [Appendix X B](#). Use 5 g dissolved in 50 mL of the prescribed mixture of solvents.

[Peroxide value](#)

Not more than 10, [Appendix X F](#).

[Relative density](#)

0.911 to 0.920, [Appendix V G](#).

[Unsaponifiable matter](#)

Not more than 0.7% w/w, [Appendix X H, Method II](#). Use 5 g.

Apricot-kernel oil and peach-kernel oil

Shake 2 mL for 5 minutes with a mixture of 1 mL of [fuming nitric acid](#) and 1 mL of [water](#) and allow to separate. No pink or brown colour develops in either layer.

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 C₁₆ Not more than 0.1%.

[Palmitic acid](#) 4.0 to 9.0%.

[Palmitoleic acid](#) (equivalent chain length on [polyethylene glycol adipate](#), 16.3) Not more than 0.6%.

Margaric acid Not more than 0.2%.

[Stearic acid](#) Not more than 3.0%.

[Oleic acid](#) (equivalent chain length on [polyethylene glycol adipate](#), 18.3) 62.0 to 86.0%.

[Linoleic acid](#) (equivalent chain length on [polyethylene glycol adipate](#), 18.9) 20.0 to 30.0%.

[Linolenic acid](#) (equivalent chain length on [polyethylene glycol adipate](#), 19.7) Not more than 0.4%.

Arachidic acid Not more than 0.1%.

Gadoleic acid (equivalent chain length on [polyethylene glycol adipate](#), 20.3) Not more than 0.1%.

Behenic acid Not more than 0.1%.

Erucic acid (equivalent chain length on [polyethylene glycol adipate](#), 22.3) Not more than 0.1%.

Sterols

Carry out the test for [sterols in fatty oils](#), [Appendix X N](#). The sterol fraction of the oil has the following composition.

[Cholesterol](#) Not more than 0.7%.

Campesterol Not more than 4.0%.

[Stigmasterol](#) Not more than 3.0%.

β -*Sitosterol* 73.0% to 87.0%.

Δ^5 -*Avenasterol* At least 10.0%.

Δ^7 -*Avenasterol* Not more than 3.0%.

Δ^7 -*Stigmastenol* Not more than 3.0%.

Fucosterol Not more than 2.0%.

Brassicasterol Not more than 0.3%.

Sesame oil

Shake 10 mL with 5 mL of a mixture of 0.5 volume of a 0.35% v/v solution of [furfuraldehyde](#) in [acetic anhydride](#) and 4.5 volumes of [acetic anhydride](#) for 1 minute, filter through a filter paper impregnated with [acetic anhydride](#) and add 0.2 mL of [sulfuric acid](#). No bluish green colour develops.

STORAGE

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