

Certificate of Analysis

Productname: Amygdalae oleum raffinatum

Inspection No: L02792/0524/536
Batchnumber: 23L06-T02-110751
Expiration date: 30.06.2025
Analysed according to: ČL 2023, Ph. Eur. 11.0
Original Manuf. Date: 30.10.2023

Sample Unit: 1 x 25 ml
Batch Size: 359 x 100 ml

Identification of producer: V00225
Batch no. of vendor: 164885

| | Requirement | Result | Unit | Standard remark | Insp. Site |
|-------------------------------|----------------------------|---------|------|----------------------------|--------------|
| CHARACTERS | | | | | |
| Appearance | Pale yellow, clear liquid. | Conform | | | Fagron CZ |
| Solubility | Conform | Conform | | | Fagron CZ |
| Relative density | About 0,916 | 0,918 | | | Fagron CZ |
| Temperature of solidification | About -18 | Conform | °C | | Fagron CZ |
| IDENTIFICATION | | | | | |
| Identification A | Conform | Conform | | TLC | Fagron CZ |
| Identification B | Conform | Conform | | Composition of fatty acids | Contract Lab |
| TESTS | | | | | |
| Specific absorbance | 0,2 - 6,0 | 4,4 | | | Fagron CZ |
| Acid value | <=0,5 | 0,4 | | | Fagron CZ |
| Peroxide value | <=5,0 | 2,0 | | | Fagron CZ |
| Unsaponifiable matter | <=0,9 | 0,6 | % | | Fagron CZ |
| Composition of fatty acids | Conform | Conform | | GC | Contract Lab |
| Saturated fatty acids <C16 | <=0,1 | <0,05 | % | | Contract Lab |
| Palmitic acid | 4,0 - 9,0 | 6,4 | % | | Contract Lab |
| Palmitoleic acid | <=0,8 | 0,4 | % | | Contract Lab |
| Margaric acid | <=0,2 | <0,05 | % | | Contract Lab |
| Stearic acid | <=3,0 | 1,5 | % | | Contract Lab |
| Oleic acid | 62,0 - 86,0 | 66,7 | % | | Contract Lab |
| Linoleic acid | 20,0 - 30,0 | 24,5 | % | | Contract Lab |
| Linolenic acid | <=0,4 | 0,1 | % | | Contract Lab |
| Arachidic acid | <=0,2 | 0,1 | % | | Contract Lab |
| Eicosenoic acid | <=0,3 | 0,1 | % | | Contract Lab |
| Behenic acid | <=0,2 | <0,05 | % | | Contract Lab |
| Erucic acid | <=0,1 | <0,05 | % | | Contract Lab |
| Sterols | Conform | Conform | | | Contract Lab |
| Cholesterol | <=0,7 | 0,4 | % | | Contract Lab |
| Campesterol | <=5,0 | 3,2 | % | | Contract Lab |
| Stigmasterol | <=4,0 | 2,3 | % | | Contract Lab |
| Beta-sitosterol | 73,0 - 87,0 | 76,6 | % | | Contract Lab |
| Delta 5-avenasterol | >=5,0 | 12,3 | % | | Contract Lab |
| Delta 7-avenasterol | <=3,0 | 1,1 | % | | Contract Lab |
| Delta 7-stigmasterol | <=3,0 | 0,5 | % | | Contract Lab |
| Brassicasterol | <=0,3 | <0,3 | % | | Contract Lab |

| | | | | | |
|-------------|----------------------------|------------------|---------------------------|------------------|------------------|
| Name | Fagron a.s. (CZ) | Address | Holická 1098/31m, Olomouc | Phone No. | +420585222590 |
| | Kontrolní laboratoř č. 536 | Post Code | 779 00 | Fax No. | +420 585 226 521 |

| | | | | |
|-------------------|---|---------|-------|---------------|
| Water | <=0,1 | 0,01 | % | Contract Lab |
| Microbiology | Conform | Conform | | Contract Lab |
| TAMC | <=2 x 103 | <10 | CFU/g | Contract Lab |
| TYMC | <=2 x 102 | <10 | CFU/g | Contract Lab |
| TSE/BSE | No contamination with TSE/BSE-risk materials. | Conform | | Data Producer |
| Residual solvents | CPMP/ICH/82 260/2006 | Conform | | Data Producer |
| Metallic residues | ICH Q3D on elemental impurities | Conform | | Data Producer |

Quality: Excipient

Performed by: QC Fagron a.s. (CZ)

Responsible: Mgr. Zdeňka Šinclová, QC
MVDr. Zdenka Borská, QA/ QP

Date: 26.04.2024

Conclusion: **APPROVED**

This document has been produced electronically from our quality system and is valid without signature.