



Certificate of Analysis

FARMADENT d.o.o.
Minarikova ul. 6
2000 Maribor
Prejel: FUJS DRAGO
ZA: 
Datum prejema: 26-5-14
Pregledal: MAROLT Robert, mag. farm., spec.
Datum pregleda: 28-5-2014

Productname: **Amygdalae oleum raffinatum**
Number of analysis/Inspection Code: 1 / KEUR-98214B
Batchnumber: **13G12-B07-283220**
Reference code / No.: 1166 / 128345
Analysed according to: **PH.EUR 7.8**

| Tests | Requirement | Result | Unit | Standard remark |
|----------------------------|--|---------|------|---|
| Appearance | Clear, pale yellow liquid | Conform | | Data producer |
| Relative density | About 0,916 | 0,916 | | TLC |
| Identification A | Conform | Conform | | Composition of fatty acids; data producer |
| Identification B | Conform | Conform | | Max. 270 nm; data producer |
| Specific absorbance | 0,2 - 6,0 | 2,0 | | Data producer |
| Acid value | <=0,5 | 0,1 | | Data producer |
| Peroxide value | <=5,0 | 2,9 | | Data producer |
| Unsaponifiable matter | <=0,9 | <=0,9 | %m/m | Data producer |
| Composition of fatty acids | Conform | Conform | | GC; data producer |
| Saturated fatty acids <C16 | <=0,1 | <0,05 | % | |
| Palmitic acid | 4,0 - 9,0 | 6,4 | % | |
| Palmitoleic acid | <=0,8 | 0,5 | % | |
| Margaric acid | <=0,2 | 0,1 | % | |
| Stearic acid | <=3,0 | 1,5 | % | |
| Oleic acid | 62,0 - 86,0 | 66,3 | % | |
| Linoleic acid | 20,0 - 30,0 | 24,8 | % | |
| Linolenic acid | <=0,4 | 0,1 | % | |
| Arachidic acid | <=0,2 | 0,1 | % | |
| Eicosenoic acid | <=0,3 | 0,1 | % | |
| Behenic acid | <=0,2 | <0,05 | % | |
| Erucic acid | <=0,1 | <0,05 | % | |
| Sterols | Conform | Conform | | Data producer |
| Water (Karl Fischer) | <=0,1 | 0,03 | % | |
| Residual solvents | CPMP/ICH/283/95 | Conform | | Data producer |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analyse performed by the authorized lab Synergy Health.

Release:
Drs. M.V. Garcia Alia
Pharmacist - QA Manager / QP

31-07-13

Expiration: 07-2015

Conclusion: APPROVED