

## Certificate of Analysis

**Productname:** Arachidis oleum raffinatum

**Inspection No:** J10843/1222/536

**Batchnumber:** 22K09-T15

**Expiration date:** 30.06.2024

**Analysed according to:** ČL 2017-Dopl.2019,Ph.Eur.10.0

**Customer:** FAGRON a.s.

**Sample Unit:** 1 x 200 ml

**Batch Size:** 380 x kg

**Batch no. of vendor:** 8010132001

	Requirement	Result	Unit	Standard remark
<b>CHARACTERS</b>				
Appearance	Clear, yellowish, viscous liquid.	Conform		
Solubility	Conform	Conform		
Relative density	About 0,915	0,911		
Freezing point	About 2	2	°C	
<b>IDENTIFICATION</b>				
Identification B	Conform	Conform		Composition of fatty acids
<b>TESTS</b>				
Acid value	<=0,5	0,1		
Peroxide value	<=5,0	0,58		
Unsaponifiable matter	<=1,0	0,23	%	
Alkaline impurities	Conform	Conform		
Composition of fatty acids	Conform	Conform		GC
Saturated fatty acids <C16	<=0,4	<0,05	%	
Palmitic acid	5,0 - 14,0	5,7	%	
Stearic acid	1,3 - 6,5	1,7	%	
Oleic acid	35,0 - 76,0	74,0	%	
Linoleic acid	8,0 - 43,0	9,2	%	
Linolenic acid	<=0,6	0,2	%	
Arachidic acid	0,5 - 3,0	0,9	%	
Eicosenoic acid	0,5 - 3,0	2,7	%	
Behenic acid	1,0 - 5,0	2,9	%	
Erucic acid	<=0,5	0,4	%	
Lignoceric acid	0,5 - 3,0	2,1	%	
Water	<=0,1	0,01	%	
Microbiology	Conform	Conform		
TAMC	<=2 x 10 <sup>3</sup>	<10	CFU/g	
TYMC	<=2 x 10 <sup>2</sup>	<10	CFU/g	
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform		
Residual solvents	ICH Q3C	Conform		
Metallic residues	ICH Q3D	Conform		

Quality: Excipient

**Performed by:** Ing. Petra Drábková  
**Responsible:** Mgr. Zdeňka Šinclová, QC  
Mgr. Barbora Agatha Halouzková, QP  
**Date:** 08.12.2022

**Conclusion:** **APPROVED**

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