

Certificate of Analysis

Productname: Arachidis oleum raffinatum

Inspection No: L02789/0424/536

Batchnumber: 24C20-T01

Expiration date: 31.10.2025

Analysed according to: ČL 2023, Ph. Eur. 11.0

Customer: FAGRON a.s.

Sample Unit: 1 x 200 ml

Batch Size: 380 x kg

Batch no. of vendor: 8011469001

	Requirement	Result	Unit	Standard remark
CHARACTERS				
Appearance	Clear, yellowish, viscous liquid.	Conform		
Solubility	Conform	Conform		
Relative density	About 0,915	0,912		
Freezing point	About 2	Conform	°C	
IDENTIFICATION				
Identification B	Conform	Conform		Composition of fatty acids
TESTS				
Acid value	<=0,5	0,1		
Peroxide value	<=5,0	1,4		
Unsaponifiable matter	<=1,0	0,41	%	
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	6,8	%	
Stearic acid	1,3 - 6,5	1,9	%	
Oleic acid	35,0 - 76,0	68,8	%	
Linoleic acid	8,0 - 43,0	14,9	%	
Linolenic acid	<=0,6	0,2	%	
Arachidic acid	0,5 - 3,0	0,9	%	
Eicosenoic acid	0,5 - 3,0	2,2	%	
Behenic acid	1,0 - 5,0	2,5	%	
Erucic acid	<=0,5	0,3	%	
Lignoceric acid	0,5 - 3,0	1,5	%	
Water	<=0,1	0,01	%	
Microbiology	Conform	Conform		
TAMC	<=2 x 10 ³	<10	CFU/g	
TYMC	<=2 x 10 ²	<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: QC Fagron a.s. (CZ)
Responsible: PharmDr. Ivana Urbánková, QA/ QP
Mgr. Barbora Agatha Halouzková, QA/ QP
Date: 18.04.2024

Conclusion: **APPROVED**

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