

CERTIFICATE OF ANALYSIS

Product name: OLIVAE OLEUM RAFFINATUM

Batch number: 12119-T52 ✓

Supplier's batch number: 124816

Number of analysis: 0889/1012/536

Analysed according to: Ph. Eur. 7.2

FARMADENT d.o.o.
Minarikova ul. 6
2000 Maribor
Prejel: FUJS DRAGO

Datum pregleda: 5.6.2013
Pregledal: MAROLT Robert, mag. farm. spec.

Datum pregleda: 6.3.2013

	Requirement	Result	Unit	Standard remark
CHARACTERS				
Appearance	Clear, colourless or greenish-yellow transparent liquid.	Conform		
Solubility	Conform	Conform		
Relative density	About 0,913	0,914		
IDENTIFICATION				
Acid value	$\leq 0,3$	0,18		
Identification of fatty oils	conform	Conform		
TESTS				
Acid value	$\leq 0,3$	0,18		
Peroxide value	$\leq 10,0$	0,7		
Unsaponifiable matter	$\leq 1,5$	0,6	%	
Alkaline impurities	$\leq 0,1$	Conform	ml	0,01 mol/l HCL
Spec.absorption (270 nm)	$\leq 1,20$	0,36		
Composition of fatty acids	Conform	Conform		
Saturated fatty acids < C16	$\leq 0,1$	$< 0,05$	%	
Palmitic acid	7,5 - 20,0	11,5	%	
Palmitoleic acid	$\leq 3,5$	0,9	%	
Stearic acid	0,5 - 5,0	3,4	%	
Oleic acid	56 - 85	75,9	%	
Linoleic acid	3,5 - 20,0	6,6	%	
Linolenic acid	$\leq 1,2$	0,7	%	
Arachid acid	$\leq 0,7$	0,4	%	
Eicosenoic acid	$\leq 0,4$	0,3	%	
Behenic acid	$\leq 0,2$	0,1	%	
Lignoceric acid	$\leq 0,2$	0,1	%	
Sterols	Conform	Conform		
Sum of contents of sterols	≥ 93	98,0	%	
Cholesterolum	$\leq 0,5$	0,4	%	
Δ^7 -stigmasterolum	$\leq 0,5$	0,2	%	
Kampesterolum	$\leq 4,0$	1,2	%	
Stigmasterolum $\leq$ kampesterolum	Conform	Conform		
Sesame oil	Conform	Conform		
Water	$\leq 0,1$	$< 0,05$	%	
Microbiology		Conform		
TAMC	$\leq 2 \times 10^3$	Conform	CFU/g	
TYMC	$\leq 2 \times 10^2$	Conform	CFU/g	

The substance is suitable for use in the manufacture of parenteral preparations



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Release: Ing. Martina Zemanová, QC

RNDr. Jaromír Stodůlka, QP

Stodůlka



Date: 03.10.2012

Expiration: 30.09.2014 ✓

Conclusion: APPROVED