



Certificate of Analysis

Productname: Jecoris aselli ol. (Typus A)

Inspection No: J07323/0822/536

Batchnumber: 22F24-T01-097061

Expiration date: 31.05.2024

Analysed according to: Ph.Eur.10.8

Original Manuf. Date: 31.5.2022

Sample Unit: 1 x 25 ml

Batch Size: 614 x 1 l

Identification of producer: V00236

Batch no. of vendor: 8009600001

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear, yellowish liquid.	Conform			Contract Lab
Solubility	Conform	Conform			Contract Lab
IDENTIFICATION					
Identification A	Conform	Conform		Vitamin A, UV-spectrum	Contract Lab
Identification B	Conform	Conform		Vitamin D3, HPLC	Contract Lab
Identification C	Conform	Conform		Composition of fatty acids, GC	Contract Lab
TESTS					
Appearance	Conform	Conform			Contract Lab
Relative density	0,917 - 0,930	0,923			Contract Lab
Refractive index	1,477 - 1,484	1,479			Contract Lab
Acid value	<=2,0	0,2			Contract Lab
Anisidine value	<=30,0	1,9			Contract Lab
Iodine value	150 - 180	154			Contract Lab
Peroxid value	<=10,0	5,6			Contract Lab
Unsaponifiable matter	<=1,5	0,3	%		Contract Lab
Stearine	Conform	Conform			Contract Lab
Composition of fatty acids	Conform	Conform		GC	Contract Lab
Myristic acid	2,0 - 6,0	4,2	%		Contract Lab
Palmitic acid	7,0 - 14,0	11,4	%		Contract Lab
Stearic acid	1,0 - 4,0	1,9	%		Contract Lab
Palmitoleic acid	4,5 - 11,5	7,3	%		Contract Lab
cis-Vaccenic acid	2,0 - 7,0	4,3	%		Contract Lab
Oleic acid	12,0 - 21,0	16,0	%		Contract Lab
Gadoleic acid	1,0 - 5,5	1,7	%		Contract Lab
Gondoic acid	5,0 - 17,0	11,1	%		Contract Lab
Erucic acid	0 - 1,5	1,0	%		Contract Lab
Cetoleic acid	5,0 - 12,0	11,5	%		Contract Lab
Linoleic acid	0,5 - 3,0	1,3	%		Contract Lab
alfa-Linolenic acid	0 - 2,0	0,8	%		Contract Lab
Moroctic acid	0,5 - 4,5	2,4	%		Contract Lab
Timnodonic acid (EPA)	7,0 - 16,0	10,7	%		Contract Lab
Cervonic acid (DHA)	6,0 - 18,0	11,9	%		Contract Lab
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 103	<10	CFU/g		Contract Lab

Name Fagron a.s. (CZ)
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TYMC	<=2 x 10 ²	<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
ASSAY				
Vitamin A	600 - 2500	991	IU/g	Contract Lab
Vitamin D3	60 - 250	75	IU/g	Contract Lab

Quality: Excipient

Performed by: Ekocentrum + SVÚ

Responsible: Ing. Pavel Mišák, QC
PharmDr. Ivana Urbánková, QP

Date: 24.08.2022

Conclusion: **APPROVED**

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

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