



Certificate of Analysis

Productname: Jecoris aselli ol. (Typus A)

Inspection No: K05801/0923/536

Batchnumber: 23G12-T03-105622

Expiration date: 31.05.2025

Analysed according to: ČL 2017-Dopl.2022, Ph.Eur. 11.0

Original Manuf. Date: 31.5.2023

Sample Unit: 1 x 25 ml

Batch Size: 394 x 1 l

Identification of producer: V00236

Batch no. of vendor: 8010554001

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear, yellowish liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
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			Fagron CZ
Relative density	0,917 - 0,930	0,923			Fagron CZ
Refractive index	1,477 - 1,484	1,477			Fagron CZ
Acid value	<=2,0	0,16			Fagron CZ
Anisidine value	<=30,0	10,5			Fagron CZ
Iodine value	150 - 180	154			Fagron CZ
Peroxid value	<=10,0	4,29			Fagron CZ
Unsaponifiable matter	<=1,5	0,93	%		Fagron CZ
Stearine	Conform	Conform			Fagron CZ
Composition of fatty acids	Conform	Conform		GC	Contract Lab
Myristic acid	2,0 - 6,0	3,9	%		Contract Lab
Palmitic acid	7,0 - 14,0	10,3	%		Contract Lab
Stearic acid	1,0 - 4,0	2,2	%		Contract Lab
Palmitoleic acid	4,5 - 11,5	8,3	%		Contract Lab
cis-Vaccenic acid	2,0 - 7,0	4,9	%		Contract Lab
Oleic acid	12,0 - 21,0	18,3	%		Contract Lab
Gadoleic acid	1,0 - 5,5	1,9	%		Contract Lab
Gondoic acid	5,0 - 17,0	12,3	%		Contract Lab
Erucic acid	0 - 1,5	1,0	%		Contract Lab
Cetoleic acid	5,0 - 12,0	9,0	%		Contract Lab
Linoleic acid	0,5 - 3,0	1,4	%		Contract Lab
alfa-Linolenic acid	0 - 2,0	0,7	%		Contract Lab
Moroctic acid	0,5 - 4,5	1,8	%		Contract Lab
Timnodonic acid (EPA)	7,0 - 16,0	10,1	%		Contract Lab
Cervonic acid (DHA)	6,0 - 18,0	12,0	%		Contract Lab
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 103	<10	CFU/g		Contract Lab

Name Fagron a.s. (CZ)
Kontrolní laboratoř č. 536

Address Holická 1098/31m, Olomouc
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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	910	IU/g	Contract Lab
Vitamin D3	60 - 250	94	IU/g	Contract Lab

Quality: Excipient

Performed by: Ludmila Burianová

Responsible: Mgr. Zdeňka Šinclová, QC
MVDr. Zdenka Borská, QP

Date: 20.09.2023

Conclusion: **APPROVED**

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