

Certificate of Analysis

Productname: Jecoris aselli ol. (Typus A)

Inspection No: 107285/0921/536
Batchnumber: 21H06-T04-088750
Expiration date: 31.07.2023
Analysed according to: ČL 2017-Dopl.2020,Ph.Eur.10.0
Original Manuf. Date: 23.7.2021

Sample Unit: 1 x 25 ml
Batch Size: 107 x 1 l

Identification of producer: V00236
Batch no. of vendor: 8008413001

	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	1,478			Fagron CZ
Acid value	<=2,0	0,2			Fagron CZ
Anisidine value	<=30,0	7,18			Fagron CZ
Iodine value	150 - 180	152			Fagron CZ
Peroxid value	<=10,0	3,66			Fagron CZ
Unsaponifiable matter	<=1,5	1,1	%		Fagron CZ
Stearine	Conform	Conform			Fagron CZ
Composition of fatty acids	Conform	Conform		GC	Contract Lab
Myristic acid	2,0 - 6,0	4,0	%		Contract Lab
Palmitic acid	7,0 - 14,0	11,5	%		Contract Lab
Stearic acid	1,0 - 4,0	2,1	%		Contract Lab
Palmitoleic acid	4,5 - 11,5	7,1	%		Contract Lab
cis-Vaccenic acid	2,0 - 7,0	4,9	%		Contract Lab
Oleic acid	12,0 - 21,0	17,6	%		Contract Lab
Gadoleic acid	1,0 - 5,5	1,8	%		Contract Lab
Gondoic acid	5,0 - 17,0	10,5	%		Contract Lab
Erucic acid	0 - 1,5	0,4	%		Contract Lab
Cetoleic acid	5,0 - 12,0	9,7	%		Contract Lab
Linoleic acid	0,5 - 3,0	1,4	%		Contract Lab
alfa-Linolenic acid	0 - 2,0	0,7	%		Contract Lab
Morocitic acid	0,5 - 4,5	1,9	%		Contract Lab
Timnodonic acid (EPA)	7,0 - 16,0	9,8	%		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)
 Kontrolní laboratoř č. 536

Address Holická 1098/31m, Olomouc
Post Code 779 00

Phone No. +420585222590
Fax No. +420 585 226 521

TYMC	<=2 x 102	<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	920	IU/g	Contract Lab
Vitamin D3	60 - 250	107	IU/g	Contract Lab

Selected parameters were additionally tested by FACZ Lab/ Contract Lab

Performed by: Lucie Kubáňová DiS.

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

Date: 22.09.2021

Conclusion: **APPROVED**

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Name	Fagron a.s. (CZ) Kontrolní laboratoř č. 536	Address	Holická 1098/31m, Olomouc	Phone No.	+420585222590
		Post Code	779 00	Fax No.	+420 585 226 521