



Certificate of Analysis

Productname: Amygdalae oleum raffinatum

Inspection No: K02792/0523/536
Batchnumber: 23C15-T05-104046
Expiration date: 31.08.2024
Analysed according to: ČL 2017, Ph.Eur.11.0
Original Manuf. Date: 31.12.2022

Sample Unit: 1 x 25 ml
Batch Size: 648 x 1 l

Identification of producer: V00225
Batch no. of vendor: 162955

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Pale yellow, clear liquid.	Conform			Contract Lab
Solubility	Conform	Conform			Contract Lab
Relative density	About 0,916	0,918			Contract Lab
Temperature of solidification	About -18	-18	°C		Contract Lab
IDENTIFICATION					
Identification A	Conform	Conform		TLC	Contract Lab
Identification B	Conform	Conform		Composition of fatty acids	Contract Lab
TESTS					
Specific absorbance	0,2 - 6,0	2,8			Contract Lab
Acid value	<=0,5	0,4			Contract Lab
Peroxide value	<=5,0	1,2			Contract Lab
Unsaponifiable matter	<=0,9	0,4	%		Contract Lab
Composition of fatty acids	Conform	Conform		GC	Contract Lab
Saturated fatty acids <C16	<=0,1	<0,05	%		Contract Lab
Palmitic acid	4,0 - 9,0	6,4	%		Contract Lab
Palmitoleic acid	<=0,8	0,5	%		Contract Lab
Margaric acid	<=0,2	0,1	%		Contract Lab
Stearic acid	<=3,0	1,5	%		Contract Lab
Oleic acid	62,0 - 86,0	65,7	%		Contract Lab
Linoleic acid	20,0 - 30,0	25,3	%		Contract Lab
Linolenic acid	<=0,4	0,1	%		Contract Lab
Arachidic acid	<=0,2	0,1	%		Contract Lab
Eicosenoic acid	<=0,3	0,1	%		Contract Lab
Behenic acid	<=0,2	0,1	%		Contract Lab
Erucic acid	<=0,1	<0,05	%		Contract Lab
Sterols	Conform	Conform			Contract Lab
Cholesterol	<=0,7	0,5	%		Contract Lab
Campesterol	<=5,0	3,3	%		Contract Lab
Stigmasterol	<=4,0	2,1	%		Contract Lab
Beta-sitosterol	73,0 - 87,0	77,1	%		Contract Lab
Delta 5-avenasterol	>=5,0	12,5	%		Contract Lab
Delta 7-avenasterol	<=3,0	1,4	%		Contract Lab
Delta 7-stigmasterol	<=3,0	0,1	%		Contract Lab
Brassicasterol	<=0,3	<0,3	%		Contract Lab

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

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Water	<=0,1	0,009	%	Contract Lab
Microbiology	Conform	Conform		Contract Lab
TAMC	<=2 x 10 ³	<10	CFU/g	Contract Lab
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

Quality: Excipient

Performed by: Ekocentrum

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

Date: 16.05.2023

Conclusion: **APPROVED**

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