



Certificate of Analysis

Productname: Amygdalae oleum raffinatum

Inspection No: K05481/0923/536
Batchnumber: 23E16-T03-105620
Expiration date: 30.11.2024
Analysed according to: ČL 2017, Ph.Eur.11.0
Original Manuf. Date: 31.3.2023

Sample Unit: 1 x 25 ml
Batch Size: 465 x 100 ml

Identification of producer: V00225
Batch no. of vendor: 163389

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Pale yellow, clear liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
Relative density	About 0,916	0,918			Fagron CZ
Temperature of solidification	About -18	-18	°C		Fagron CZ
IDENTIFICATION					
Identification A	Conform	Conform		TLC	Fagron CZ
Identification B	Conform	Conform		Composition of fatty acids	Contract Lab
TESTS					
Specific absorbance	0,2 - 6,0	3,4			Fagron CZ
Acid value	<=0,5	0,4			Fagron CZ
Peroxide value	<=5,0	2,9			Fagron CZ
Unsaponifiable matter	<=0,9	0,5	%		Fagron CZ
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	67,1	%		Contract Lab
Linoleic acid	20,0 - 30,0	23,9	%		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	<0,05	%		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	3,2	%		Contract Lab
Stigmasterol	<=4,0	2,3	%		Contract Lab
Beta-sitosterol	73,0 - 87,0	75,2	%		Contract Lab
Delta 5-avenasterol	>=5,0	13,5	%		Contract Lab
Delta 7-avenasterol	<=3,0	1,4	%		Contract Lab
Delta 7-stigmasterol	<=3,0	0,2	%		Contract Lab
Brassicasterol	<=0,3	<0,3	%		Contract Lab

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

Water	<=0,1	0,01	%	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: Ludmila Burianová

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

Date: 15.09.2023

Conclusion: **APPROVED**

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