Fagron personalizing medicine

Certificate of Analysis

Productname: **Amygdalae oleum raffinatum**

Inspection No: I08173/1021/536
Batchnumber: **21I13-T08-088473**
Expiration date: 31.03.2023
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 31.8.2021

Sample Unit: 0 x
Batch Size: 116 x 1 l

Identification of producer: V00225
Batch no. of vendor: 158208

	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	0,917			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	2,1			Fagron CZ
Acid value	<=0,5	0,1			Fagron CZ
Peroxide value	<=5,0	0,70			Fagron CZ
Unsaponifiable matter	<=0,9	0,1	%		Fagron CZ
Composition of fatty acids	Conform	Conform		GC	Contract Lab
Saturated fatty acids <C16	<=0,1	<0,1	%		Contract Lab
Palmitic acid	4,0 - 9,0	5,6	%		Contract Lab
Palmitoleic acid	<=0,8	0,4	%		Contract Lab
Margaric acid	<=0,2	0,1	%		Contract Lab
Stearic acid	<=3,0	1,5	%		Contract Lab
Oleic acid	62,0 - 86,0	68,6	%		Contract Lab
Linoleic acid	20,0 - 30,0	23,5	%		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	<0,1	%		Contract Lab
Sterols	Conform	Conform			Contract Lab
Cholesterol	<=0,7	0,2	%		Contract Lab
Campesterol	<=5,0	3,5	%		Contract Lab
Stigmasterol	<=4,0	1,6	%		Contract Lab
Beta-sitosterol	73,0 - 87,0	74,6	%		Contract Lab
Delta 5-avenasterol	>=5,0	11,1	%		Contract Lab
Delta 7-avenasterol	<=3,0	1,9	%		Contract Lab
Delta 7-stigmastenol	<=3,0	2,3	%		Contract Lab
Brassicasterol	<=0,3	0,3	%		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

Water	<=0,1	<0,1	%	Contract Lab
Microbiology	Conform	Conform		Contract Lab
TAMC	<=2 x 103	<10	CFU/g	Contract Lab
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

The product conforms to ČL 2017, Ph.Eur.10.0.

Performed by: Lucie Kubáňová DiS.

Responsible: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QA

Date: 02.11.2021

Conclusion: **I certify that the above-mentioned batch of pharmaceutical raw material has been manufactured and tested in accordance with the requirements of Marketing Authorization (License) and requirements of Good Manufacturing Practice.**

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

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