



Certificate of Analysis

Productname: **Cocois oleum raffinatum**

Inspection No: J02653/0422/536
Batchnumber: **22B18-T04-093753**
Expiration date: 30.04.2023
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 31.10.2021

Sample Unit: 1 x 10 g
Batch Size: 22 x 200 g

Identification of producer: V00225
Batch no. of vendor: 158766

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	(Almost) white or pearly white, unctuous mass.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
Refractive index	About 1,449	1,449		40°C	Fagron CZ
IDENTIFICATION					
Identification A	23 - 26	25	°C	Melting point-capillary method	Fagron CZ
Identification B	Conform	Conform		Composition of fatty acids	Contract Lab
TESTS					
Melting point	23 - 26	25	°C	Open capillary method	Fagron CZ
Acid value	<=0,5	0,1			Fagron CZ
Peroxide value	<=5,0	0,83			Fagron CZ
Unsaponifiable matter	<=1,0	0,48	%		Fagron CZ
Alkaline impurities	Conform	Conform			Fagron CZ
Composition of fatty acids	Conform	Conform		GC	Contract Lab
Caproic acid	<=1,5	0,8	%		Contract Lab
Caprylic acid	5,0- 11,0	8,7	%		Contract Lab
Capric acid	4,0 - 9,0	7,7	%		Contract Lab
Lauric acid	40,0 - 50,0	48,7	%		Contract Lab
Myristic acid	15,0 - 20,0	18,9	%		Contract Lab
Palmitic acid	7,0 - 12,0	9,5	%		Contract Lab
Stearic acid	1,5 - 5,0	3,0	%		Contract Lab
Oleic acid	4,0 - 10,0	6,8	%		Contract Lab
Linoleic acid	1,0 - 3,0	1,6	%		Contract Lab
Linolenic acid	<=0,2	<0,2	%		Contract Lab
Arachidic acid	<=0,2	0,1	%		Contract Lab
Eicosenoic acid	<=0,2	<0,2	%		Contract Lab
Water	<=0,1	0,02	%		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

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Performed by: Pavla Šlězarová

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

Date: 01.04.2022

Conclusion: **APPROVED**

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