

Certificate of Analysis

FARMADENT d.o.o. Minarikova ul. b 2000 Maribor Prejel: FUJS PRAGO

Datum predema: 7.1.2013
Pregledal: MAROLT Robert, mag. farm., spec.

June 2 1 - 201

Productname:

Amygdalae oleum raffinatum

Number of analysis/Inspection Code:

1 / KEUR-85843B

Batchnumber:

12E10-B02-271992

Reference code / No.:

1166 / 124015

Analysed according to:

PH.EUR 7.4

Tests	Requirement	Result	Unit	Standard remark
Appearance	Clear, pale yellow liquid	Conform		
Relative density	About 0,916	0,918		Data producer
Identification A	Conform	Conform		TLC
Identification B	Conform	Conform		Composition of fatty acids; data produc
Specific absorbance	0,2 - 6,0	1,29		Max. 270 nm; data producer
Acid value	<=0,5	0,12		Data producer
Peroxide value	<=5,0	1,7		
Unsaponifiable matter	<=0,9	<=0,9	%m/m	Data producer
Composition of fatty acids	Conform	Conform		GC; data producer
Saturated fatty acids <c16< td=""><td><=0,1</td><td><0,05</td><td>%</td><td>Data producer</td></c16<>	<=0,1	<0,05	%	Data producer
Palmitic acid	4,0 - 9,0	6,4	%	Data producer
Palmitoleic acid	<=0,8	0,5	%	Data producer
Margaric acid	<=0,2	0,1	%	Data producer
Stearic acid	<=3,0	1,4	%	Data producer
Oleic acid	62,0 - 86,0	65,6	%	Data producer
Linoleic acid	20,0 - 30,0	25,7	%	Data producer
Linolenic acid	<=0,4	0,1	%	Data producer
Arachidic acid	<=0,2	0,1	%	Data producer
Eicosenoic acid	<=0,3	0,1	%	Data producer
Behenic acid	<=0,2	<0,1	%	Data producer
Erucic acid	<=0,1	<0,1	%	Data producer
Sterols	Conform	Conform		Data producer
Water (Karl Fischer)	<=0,1	0,03	%	
Residual solvents	CPMP/ICH/283/95	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Release:

Drs. M.V. Garcia Alia

Pharmacist - QA Manager / QP

16-07-12

Expiration: 05-2014

Conclusion: APPROVED

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