

Certificate of Analysis

Productname: **Macrogolglyceroli ricinoleas**

Inspection No: I05089/0721/536
Batchnumber: **21C25-T11-087613**
Expiration date: 11.09.2022
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 11.9.2020

Sample Unit: 0 x
Batch Size: 186 x 50 g


Identification of producer: V01464
Batch no. of vendor: 15086347G0

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear, yellow viscous liquid or semi-solid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
Relative density	About 1,05	1,05			Data Producer
Viscosity	500 - 800	727	mPa.s	25 °C	Data Producer
IDENTIFICATION					
Identification A	25 - 35	31		Iodine value	Fagron CZ
Identification B	60 - 75	67		Saponification value	Fagron CZ
Identification C	Conform	Conform		TLC	Fagron CZ
Identification D	Conform	Conform		Black colored paper	Fagron CZ
TESTS					
Appearance of solution	<=ref.susp.III, <= BY6	Conform			Fagron CZ
Alkalinity	Conform	Conform		0,1 mol/l HCl	Fagron CZ
Acid value	<=2,0	0,47			Fagron CZ
Hydroxyl value	65 - 82	74			Fagron CZ
Iodine value	25 - 35	31			Fagron CZ
Saponification value	60 - 75	67			Fagron CZ
Ethylene oxide	<=1	<0,4	µg/g		Contract Lab
Dioxane	<=10	4,5	µg/g		Contract Lab
Water	<=3,0	2,4	%	Karl Fischer	Fagron CZ
Total ash	<=0,3	0	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 ³	Conform	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	Conform	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

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Performed by: Lucie Kubáňová DiS.

Responsible: Ing. Pavel Mišák, QC
PharmDr. Ivana Urbánková, QA

Date: 07.07.2021 

Conclusion: APPROVED

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