Fagron personalizing medicine

Certificate of Analysis

Productname: **Polysorbatum 20**

Inspection No: J08128/0822/536
Batchnumber: **22H10-T06-097062**
Expiration date: 31.07.2024
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 5.7.2022

Sample Unit: 1 x 10 ml
Batch Size: 255 x 100 ml

Identification of producer: V01687
Batch no. of vendor: 1/2545258

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Oily, yellow or brownish-yellow, clear or slightly opalescent liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
Relative density	About 1,10	1,10			Fagron CZ
Viscosity	About 400	400	mPa.s	25 °C	Fagron CZ
IDENTIFICATION					
Identification A	Conform	Conform		IR-spectrum	Fagron CZ
Identification D	Conform	Conform		Composition of fatty acids	Contract Lab
TESTS					
Acid value	<=2,0	0,27			Fagron CZ
Hydroxyl value	96 - 108	105			Fagron CZ
Peroxide value	<=10,0	0,684			Fagron CZ
Saponification value	40 - 50	47			Fagron CZ
Composition of fatty acids	Conform	Conform		GC	Contract Lab
Caproic acid	<=1,0	<0,05	%		Contract Lab
Caprylic acid	<=10,0	4,4	%		Contract Lab
Capric acid	<=10,0	8,3	%		Contract Lab
Lauric acid	40,0 - 60,0	51,6	%		Contract Lab
Myristic acid	14,0 - 25,0	16,1	%		Contract Lab
Palmitic acid	7,0 - 15,0	10,4	%		Contract Lab
Stearic acid	<=7,0	2,1	%		Contract Lab
Oleic acid	<=11,0	5,2	%		Contract Lab
Linoleic acid	<=3,0	0,8	%		Contract Lab
Ethylene oxide	<=1	<0,3	ppm	GC	Contract Lab
Dioxane	<=10	<3,5	ppm	GC	Contract Lab
Water (Karl Fischer)	<=3,0	2,3	%		Fagron CZ
Total ash	<=0,25	0,040	%		Fagron CZ
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

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Performed by: Ludmila Stochlebová

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

Date: 14.09.2022

Conclusion: **APPROVED**

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

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