

Certificate of Analysis

Productname: Vaselineum album

Inspection No: I07438/1021/536
Batchnumber: 21F03-T03-090266
Expiration date: 31.05.2024
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 31.5.2021

Sample Unit: 1 x 20 g
Batch Size: 12 x 5 kg

Identification of producer: V01515
Batch no. of vendor: 1401170

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	(Almost) white, translucent, soft unctuous mass, slightly fluorescent in daylight when melted.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	35 - 70	56	°C	Drop point	Fagron CZ
Identification B	Conform	Conform		IR-spectrum	Fagron CZ
Identification D	Conform	Conform		Appearance	Fagron CZ
TESTS					
Appearance	Conform	Conform			Fagron CZ
Density	Conform	0,821	g/cm3	60°C, USP	Data Producer
Acidity or alkalinity	<=0,5	0,05	ml	0.01 M NaOH	Fagron CZ
Consistency	60 - 300	78			Contract Lab
Polycyclic aromatic hydrocarbons	Conform	Conform			Contract Lab
Sulfated ash	<=0,05	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: 01.10.2021
Conclusion: **APPROVED**

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