

Certificate of Analysis

Productname: Vaselineum album

Inspection No: I08247/1021/536
Batchnumber: 21I01-T07-090265
Expiration date: 31.08.2024
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 22.8.2021

Sample Unit: 1 x 20 g
Batch Size: 2 657 x 1 kg

Identification of producer: V01479
Batch no. of vendor: 1419033

	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	54	°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	0,822	g/cm3	60°C, USP	Data Producer
Acidity or alkalinity	<=0,5	0,2	ml	0.01 M NaOH	Fagron CZ
Consistency	60 - 300	69			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	<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

Name Fagron a.s. (CZ)
 Kontrolní laboratoř č. 536

Address Holická 1098/31m, Olomouc
Post Code 779 00

Phone No. +420585222590
Fax No. +420 585 226 521

Performed by: Lucie Kubáňová DiS.
Responsible: Ing. Pavel Mišák, QC
PharmDr. Ivana Urbánková, QA
Date: 01.11.2021
Conclusion: **APPROVED**

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

Name	Fagron a.s. (CZ) Kontrolní laboratoř č. 536	Address	Holická 1098/31m, Olomouc	Phone No.	+420585222590
		Post Code	779 00	Fax No.	+420 585 226 521