



Certificate of Analysis

Productname: Vaselinum album 1712

Inspection No: G00897/0219/536
Batchnumber: 18K01-T06-063754
Expiration date: 31.10.2021
Analysed according to: ČL 2017, Ph.Eur.9.0

Sample Unit: 2 x 50 g
Batch Size: 59 x 10 kg

Identification of producer: V00230
Batch no. of vendor: 1260333

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	(Almost) white, translucent, soft unctuous mass.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	35 - 70	57	°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
Acidity or alkalinity	<= 0,5	Conform	ml		Data Producer
Consistency	60 - 300	169			Data Producer
Polycyclic aromatic hydrocarbons	Conform	Conform			Data Producer
Sulfated ash	<=0,05	<0,05	%		Data Producer
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/82 260/06	Conform			Data Producer
Metallic residues	CHMP/SWP/4446/2000	Conform			Data Producer

BHT 45,6 mg/kg

Performed by: Kamila Wisnerová

Responsible: Mgr. Kateřina Jokešová, QC
 PharmDr. Hana Běhalová, QP

Date: 27.02.2019

Conclusion: APPROVED

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