

Certificate of Analysis

Productname: Vaselineum album 1712

Inspection No: H03481/0420/536

Batchnumber: 19H05-T01-074341

Expiration date: 31.07.2022

Analysed according to: ČL 2017, Ph.Eur.9.0

Original Manuf. Date: 31.7.2019

Sample Unit: 0 x 50 g

Batch Size: 45 x 10 kg

Identification of producer: V00230

Batch no. of vendor: 1299172

	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	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	166			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	<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

BHT 48,6 µg/g

Performed by: Dominika Stropková

Responsible: Mgr. Kateřina Jokešová, QC
PharmDr. Ivana Urbánková, QA

Date: 30.04.2020

Conclusion: APPROVED

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