



## Certificate of Analysis

**Productname:** Vaselineum album 1712

**Inspection No:** L02397/0524/536

**Batchnumber:** 23J13-T08-110879

**Expiration date:** 30.09.2026

**Analysed according to:** Ph.Eur.11.0

**Customer:** FAGRON a.s.

**Sample Unit:** 0 x

**Batch Size:** 50 x 25 kg

**Batch no. of vendor:** 1529787

	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, translucent, soft unctuous mass, transparent in thin layer even after cooling to 0 °C.	Conform		
Solubility	Conform	Conform		
Identification A	35 - 70	60	°C	Drop point
Identification B	Conform	Conform		IR-spectrum
Identification D	Conform	Conform		Appearance
Appearance	Conform	Conform		
Acidity or alkalinity	<=0,5	0,05	ml	0.01 M NaOH
Consistency	60 - 300	76		
Polycyclic aromatic hydrocarbons	<= 75	<75	ppm	
Sulfated ash	<=0,05	0,0	%	
TAMC	<=2 x 10 <sup>3</sup>	<10	CFU/g	
TYMC	<=2 x 10 <sup>2</sup>	<10	CFU/g	
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform		
Residual solvents	ICH Q3C	Conform		
Metallic residues	ICH Q3D	Conform		

Quality: Excipient

BHT <50 µg/g

**Performed by:** QC Fagron a.s. (CZ)

**Responsible:** Mgr. Zdeňka Šinclová, QC  
MVDr. Zdenka Borská, QA/ QP

**Date:** 18.04.2024

**Conclusion:** APPROVED

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

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