

## Certificate of Analysis

**Productname:** **Vaselineum album 1712**

**Inspection No:** I08800/1221/536  
**Batchnumber:** **20H06-T02-091190**  
**Expiration date:** 31.07.2023  
**Analysed according to:** ČL 2017, Ph.Eur.10.0  
**Original Manuf. Date:** 31.7.2020

**Sample Unit:** 0 x 50 g  
**Batch Size:** 10 x 5 kg

**Identification of producer:** V00230  
**Batch no. of vendor:** 1352192

	Requirement	Result	Unit	Standard remark	Insp. Site
<b>CHARACTERS</b>					
Appearance	(Almost) white, translucent, soft unctuous mass, slightly fluorescent in daylight when melted.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
<b>IDENTIFICATION</b>					
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
<b>TESTS</b>					
Appearance	Conform	Conform			Fagron CZ
Acidity or alkalinity	<= 0,5	<=0,5	ml		Data Producer
Consistency	60 - 300	180			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 <sup>3</sup>	Conform	CFU/g		Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	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

BHT <50 µg/g

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

The product conforms to ČL 2017, Ph.Eur.10.0.

**Performed by:** Lucie Kubáňová DiS.

**Responsible:** Ing. Pavel Mišák, QC  
MVDr. Zdenka Borská, QA

**Date:** 08.12.2021



**Conclusion:** I certify that the above-mentioned batch of pharmaceutical raw material has been manufactured and tested in accordance with the requirements of Marketing Authorization (License) and requirements of Good Manufacturing Practice.

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