Fagron personalizing medicine

Certificate of Analysis

Productname: **Vaselinum album 1712**

Inspection No: I07416/1021/536
Batchnumber: **20H06-T02-090074**
Expiration date: 31.07.2023
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 31.7.2020

Sample Unit: 0 x 25 kg
Batch Size: 10 x 25 kg

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

	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
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 103	Conform	CFU/g		Contract Lab
TYMC	<=2 x 102	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

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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:	09.11.2021
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.

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