

Certificate of Analysis

Product name: Gelatum basale hydrophobicum/Hydrophobes Basisgel DAC
Inspection No: I01334/0221/536 **Sample Unit:** 0 x 50 g
Batch number: 21B09-T02-082627 **Batch Size:** 200 x 1 kg
Expiration date: 31.01.2023
Analysed according to: DAC 2019
Original Manuf. Date: 31.1.2021
Identification of producer: V00230
Batch no. of vendor: 1382028

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Colourless, translucent, soft gel not washable with water from skin.	Conform			Fagron CZ
Odour (2.3.4)	Slight paraffin odour.	Conform			Fagron CZ
IDENTIFICATION					
Freezing point	68 - 78	76	°C		Fagron CZ
Consistency	Conform	Conform			Fagron CZ
TESTS					
pH or alkalinity	Conform	Conform			Fagron CZ
Refractive index (2.2.6)	1,475 - 1,495	1,483			Fagron CZ
Insol. in petroleum ether	4,5 - 5,5	5,5	%		Fagron CZ
Stability	Conform	Conform			Fagron CZ
Total ash	≤0,1	0	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
ATC	≤2 x 10 ³	Conform	CFU/g		Contract Lab
ATC	≤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/82 260/2006	Conform			Data Producer
Heavy metal residues	ICH Q3D on elemental impurities	Conform			Data Producer

Performed by: Lucie Kubáňová DiS.
Responsible: Ing. Mgr. Kateřina Jokešová, QC
 PharmDr. Ivana Urbánková, QA

Date: 08.03.2021

Conclusion: APPROVED

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