

Certificate of Analysis

Productname: Gelatum basale hydrophobicum/Hydrophobes Basisgel DAC
Inspection No: I09126/1221/536 **Sample Unit:** 0 x 50 g
Batchnumber: 21D19-T01-091197 **Batch Size:** 40 x 250 g
Expiration date: 31.03.2023
Analysed according to: DAC 2019
Original Manuf. Date: 31.3.2021
Identification of producer: V00230
Batch no. of vendor: 1395078

	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					
Identification A	68 - 78	73	°C	Freezing point	Fagron CZ
Identification B	Conform	Conform		Consistency	Fagron CZ
TESTS					
Acidity or alkalinity	Conform	Conform			Fagron CZ
Refractive index (2.2.6)	1,475 - 1,495	1,485			Fagron CZ
Subs. insol. in petroleum ether	4,5 - 5,5	5,4	%		Fagron CZ
Quality	Conform	Conform			Fagron CZ
Total ash	≤0,1	0	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	≤2 x 10 ³	Conform	CFU/g		Contract Lab
TYMC	≤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
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer

The product conforms to DAC 2019.

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.

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