

Certificate of Analysis

Productname: Gelatum basale hydrophobicum/Hydrophobes Basisgel DAC
Inspection No: G12071/0120/536 **Sample Unit:** 0 x 50 g
Batchnumber: 19D01-T04-072587 **Batch Size:** 100 x 250 g
Expiration date: 31.03.2021
Analysed according to: DAC 2011
Original Manuf. Date: 31.3.2019
Identification of producer: V00230
Batch no. of vendor: 1281741

	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					
A.Freezing point	68 - 78	73	°C		Fagron CZ
B.Consistency	Conform	Conform			Fagron CZ
TESTS					
Acidity or alkalinity	Conform	Conform			Fagron CZ
Refractive index (2.2.6)	1,475 - 1,495	1,484			Fagron CZ
Subs. insol. in petroleum ether	4,5 - 5,5	5,4	%		Fagron CZ
Quality	Conform	Conform			Fagron CZ
Total ash	<=0,1	0,0	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 ³	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	<10	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	CHMP/ICH/353369/2013	Conform			Data Producer

Performed by: Bc. Andrea Šmídová

Responsible: Mgr. Kateřina Jokešová, QC
PharmDr. Ivana Urbánková, QA



Date: 17.01.2020

Conclusion: APPROVED

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