



Azelis Deutschland GmbH
Zum Siegblick 37-45
D-53757 SANKT AUGUSTIN

Certificate of Analysis

Date: 06 Jan 2022
Our ref. no.: 42780093 10
Your ref. PO237010195

Material:	GP379-NFDR025	Gelcarin® GP 379 NF
Customer material no.:	134049	Carrageenan NF
Batch No.:	2183940415	Retest date: 10 Aug 2023 Production date: 10 Aug 2021

Test	Result	Specification	Unit
Loss on drying	8,5	<= 12,5	%
pH 1)	9,8	7,5 - 10,5	
Screen <149µ (100mesh)	99,5	95,0 - 100,0	%
Viscosity 2)	21	>= 5	mPa sec
Water Dessert Gel Strength	94,0	70,0 - 150,0	g
Solubility	Passes test	Passes test	
Identification	Passes test	Passes test	
Total Aerobic Microbial Count (cfu/g)	20	<= 200	/g
Salmonella absent in 25 g	Passes test	Passes test	
Yeasts and Moulds (cfu/10g)	30	<= 100	/10g
E.Coli absent in 10 g	Passes test	Passes test	
Pseudomonas aeruginosa absent in 10g	Passes test	Passes test	
Staph. Aureus absent in 10 g	Passes test	Passes test	
Acid Insoluble Matter	1,2	<= 2,0	%
Arsenic	0,1	<= 3,0	mg/kg
Lead	0,1	<= 10,0	mg/kg
Ash	27,2	<= 35,0	%

Comments



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We certify that, as of the date of shipment, product conforms with DuPont and current USP-NF specifications. When tested, this product meets the requirements for Residual Solvents in the United States Pharmacopeia general chapter 467 and the ICH guideline Q3C. Test methods are defined on the Product Specification and are either compendial methods or internally developed methods. Where an internally developed method is used instead of a compendial method, such internally developed method has been validated as a suitable alternative in accordance with relevant compendial requirements.

This product has been manufactured in the DuPont Rockland, Maine USA facility using excipient good manufacturing practices.

Refer to the Product Specification for non-batch related information.

The material property data reported in this COA are representative values obtained in laboratory tests conducted on a product sample taken from the batch produced. DuPont certify that the values reported are the results of the tests conducted. DuPont makes no warranties regarding those values or the product in this COA, including as to fitness for a particular purpose or merchantability of goods produced from this supplied product or the supplied product itself, except for warranties expressly stated in the DuPont Product Description (PD) or Product Specification (PS) or otherwise agreed in writing by DuPont. All other warranties are specifically excluded. DuPont standard terms and conditions apply to the sale of the supplied product unless otherwise agreed in writing by DuPont.

- 1) Measurement conditions: 1.5%
- 2) Measurement conditions: 1.5%

This certificate is generated automatically

Kristen Y. Freeman

Quality Control Department