

PRODUCT
SPECIFICATION
BULLETIN

Gelcarin® PH-379

Carrageenan, NF, Ph Eur

NF, Ph Eur Specifications:		FMC QCP No.
Loss on drying (NF)	NMT 12%	10003
Loss on drying (Ph Eur)	NMT 12%	10006
Water viscosity	NLT 5 mPa•s	15002
Water gel	750 - 150g	22001
Total bacterial count	NMT 200 cfu/gram	40007
Salmonella	not detected by test	40101
E. coli	not detected by test	40302
Ash	NMT 35%	50201
Acid insoluble matter	NMT 2%	50801
Acid insoluble ash	NMT 2%	50202
Lead	NMT 0.001% (10 ppm)	52901
Heavy metals	NMT 0.002% (20 ppm)	52902
Arsenic	NMT 3 ppm	59205
Solubility	passes	53501
Identification (NF PhEur)	passes	53502

Additional FMC Specifications:		
pH, 1.5%	8.0 to 10.5	10102
Particle size	NLT 95.0% through	
	USSS 150um (series #100)	10204
Mold and yeast	NMT 100 cfu/gram	40203
Staphylococcus aureus	not detected by test	40401
Pseudomonas aeruginosa	not detected by test	40901

Product Ingredients and Labeling: Predominantly Iota Carrageenan

C of A Statements: We certify that, as of the date of shipment, the above mentioned product conforms with FMC, current USP / NF and Ph. Eur. Specifications. FMC test methods are used when the test is not listed in the Pharmacopoeia. This product meets the requirements for Organic Volatile Impurities in the United States Pharmacopoeia <467> and ICH guideline Q3C for residual solvents.

Storage conditions: Store at ambient conditions. Keep containers sealed; material is hygroscopic.

Re-evaluation date: FMC recommends that after the 'Best if used by' date, the customer perform loss on drying and viscosity tests and water gel tests.

Manufactured following IPEC Excipient GMPs by FMC BioPolymer, Rockland, Maine, USA

NMT = Not More Than

NLT = Not Less Than

FMC Corporation

FMC BioPolymer

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