

Viscarin® PH 209 carrageenan, NF, PhEur

NF, PhEur Specifications		QCP No.
Loss on Drying	NMT 12.0%	10006
Water Viscosity,1.5%	450 -750 mPa•s	15002
Heat and Cool Viscosity, 0.5%	100 - 130 mPa•s	17001
Total Bacterial Count	NMT 200 cfu/g	40007
Salmonella	Not detected by test	40104
E. coli	Not detected by test	40302
Ash	NMT 35.0%	50201
Acid Insoluble Matter	NMT 2.0%	50801
Acid Insoluble Ash	NMT 2.0%	50202
Lead	NMT 0.0005% (5 ppm)	52901
Arsenic	NMT 3 ppm	59205
Solubility	Passes	53501
Identification (NF, PhEur)	Passes	53502
Mercury	NMT 1 ppm	52904
Cadmium	NMT 2 ppm	52907
Additional DuPont Specifications		
pH, 1.5%	8.0 - 10.5	10102
Particle Size	NLT 95.0% through	
	USSS 150 µm (series #100)	10204
Mold and Yeast	NMT 100 cfu/g	40203
Staphylococcus aureus	Not detected by test	40401
Pseudomonas aeruginosa	Not detected by test	40901

Ingredient Declaration/Labeling:

Carrageenan*

C of A Statement: We certify that, as of the date of shipment, the above-mentioned product conforms with DuPont, current USP / NF and PhEur specifications for carrageenan. Cadmium and Mercury are tested on the intermediate carrageenan material semi-annually and results have been within PhEur limits. This product meets the requirements for Residual Solvents in the United States Pharmacopeia <467> and ICH guideline Q3C. When tested, residual isopropyl alcohol in the product is < 0.1 %. 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.

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

Re-evaluation Date: DuPont recommends that after the re-evaluation date, the customer perform loss on drying, viscosity and water gel tests.

Manufactured following IPEC Excipient GMPs by DuPont Nutrition, Rockland, Maine, USA

NMT = Not More Than NLT = Not Less Than

^{*}Predominantly Lambda Carrageenan



Safety Data Sheet (SDS) available on request.

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