

PRODUCT
SPECIFICATION
BULLETIN

Avicel® PH-113
microcrystalline cellulose NF, Ph. Eur., JP

Compendial Standards	Specifications
Loss on drying, %	NMT 2.0 *
Bulk density, g/cc	0.27 - 0.34
Identification A, B	Passes
Degree of polymerization, units	NMT 350
pH	5.5 - 7.0 *
Conductivity, μ S/cm	NMT 75
Residue on ignition, %	NMT 0.05
Water soluble substances, mg/5g	NMT 12.5
Water soluble substances, %	NMT 0.25
Ether soluble substances, mg/10g	NMT 5.0
Heavy metals, %	NMT 0.001
Solubility in Copper Tetrammine Hydroxide	Soluble
Microbial limits:	
Total aerobic microbial count, cfu/g	NMT 100 *
Total yeast and mold count, cfu/g	NMT 20 *
<i>Pseudomonas aeruginosa</i>	Absent in a 10g sample
<i>Escherichia coli</i>	Absent in a 10g sample
<i>Staphylococcus aureus</i>	Absent in a 10g sample
<i>Salmonella</i> species	Absent in a 10g sample
<i>Coliform</i> species	Absent in a 10g sample
Additional FMC Specifications	
Particle size (Air Jet):	
wt. % + 60 mesh (250 microns)	NMT 1
wt. % + 200 mesh (75 microns)	NMT 30

This product meets the requirements for Residual Solvents in the *United States Pharmacopeia* <467> and complies with the ICH Guide Q3C for Residual Solvents.

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

Re-evaluation date: One (1) year from date of manufacture, if storage conditions stated above are observed.

Re-evaluation requirements: FMC recommends that after the above re-evaluation date, the customer perform the loss on drying test. Typical Degree Polymerization range for Avicel PH microcrystalline cellulose is 100 to 300.

*More restrictive than compendium
NLT = Not Less Than
NMT = Not More Than

FMC Corporation

FMC BioPolymer

United States:

Philadelphia, Pennsylvania
Sales/Technical

Assistance: 1 215 299 6534
Fax: 1 215 299 6669
Customer Service: 1 800 526 3649
Fax: 1 215 299 6475

Europe:

Brussels, Belgium
Sales/Technical

Assistance: + 32 2 775 8311
Fax: + 32 2 775 8300
Customer Service: + 353 21 4354 133
Fax: + 353 21 4353 057

Asia-Pacific:

Hong Kong

Tel: + 852 2839 6600
Fax: + 852 2576 3770

Tokyo, Japan

Tel: + 81 3 3402 3739
Fax: + 81 3 3402 3700

Shanghai, China

Tel: + 8621 5427 1177
Fax: + 8621 5427 0193

Latin America:

Montevideo, Uruguay

Tel/Fax: + 5982 6043030
Tel/Fax: + 5982 6043104

Middle East:

Amman, Jordan

Tel: + 962 6 4618150
Fax: + 962 6 4618156

Visit our web site at
www.fmcbiopolymer.com
e-Mail: pharm_info@fmc.com

Patents

FMC Corporation does not warrant against infringement of patents of third parties by reason of any uses made of the product in combination with other material or in the operation of any process, and purchasers assume all risks of patent infringement by reason of any such use, combination or operation. The products, processes and uses thereof described herein are covered by one or more patent applications or patents.

Warranty

Because of the numerous factors affecting results, FMC ingredients are sold on the understanding that purchasers will make their own tests to determine the suitability of these products for their particular purpose. The several uses suggested by FMC BioPolymer are presented only to assist our customers in exploring possible applications. All information and data presented are believed to be accurate and reliable, but are presented without the assumption of any liability by FMC BioPolymer.

Technical Service

The information contained in this bulletin is intended to be general in nature. Techniques and data pertaining to specific uses for FMC ingredients and new developments will be published periodically in the form of supplemental application bulletins. Our technical staff is ready to offer assistance in the use of Avicel® microcrystalline cellulose products.

Regulatory Status

Avicel® microcrystalline cellulose meets the standards set forth in the *United States Pharmacopeia/National Formulary*, the *European Pharmacopoeia*, and the *Japanese Pharmacopoeia*.

Avicel microcrystalline cellulose is produced to meet the appropriate regulations and compendial standards of the United States, European Union and Japan as applicable to its use in or dietary supplements.

This product is in substantial compliance with the requirements for Bulk Pharmaceutical Excipient GMP as developed by IPEC-America and also published in the USP General Chapter <1678>.

The following are trademarks or service marks of FMC Corporation or its subsidiaries, which may be Registered U.S. Patent & Trademark Office and in other countries: FMC Logo, Avicel, The Science of Formulation.

© 2005 FMC Corporation. All rights reserved. 04/01/09.RS