

FMC BioPolymer  
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Philadelphia, PA 19103  
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**FMC BioPolymer**

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## Certificate of Analysis

Avicel® Microcrystalline Cellulose, NF, Ph. Eur, JP

Type : PH-102

Lot No :

Manufacturing Date: 14-Apr-2009

Reevaluation Date: 13-Apr-2013

Customer Material number:

Customer Purchase Order :

Delivery Number :

Standard	Specification	Lot Analysis
Loss on Drying, %	3.0 - 5.0	3.5
Loose Bulk Density, g/cc	0.28 - 0.33	0.31
Degree of Polymerization, units	NMT 350	214
P.S.D., Malvern LD, $\mu\text{m}$ , d10 (FRC, Ph.eur)	-	32
P.S.D., Malvern LD, $\mu\text{m}$ , d50 (FRC, Ph.eur)	-	117
P.S.D., Malvern LD, $\mu\text{m}$ , d90 (FRC, Ph.eur)	-	239
Identification, A, B, C	Pass	Pass
Retained on a 38 $\mu\text{m}$ screen opening, pH	MT 5	Pass
Conductivity, $\mu\text{S}/\text{cm}$	5.5 - 7.0	6.0
Residue on Ignition, %	NMT 75	41
Water Soluble Substances, mg/5g	NMT 0.050	0.005
Water soluble substances, %	NMT 12.5	5.0
Heavy Metals, % (Pb)	NMT 0.25	0.10
Sol. in Cu Tetramine Hydroxide	NMT 0.001	Pass
Ether Soluble Substances, mg/10g	Soluble	Pass
Air Jet Particle Size, wt. % +60Mesh	NMT 5.0	1.1
Air Jet Particle Size, wt. % +200Mesh	NMT 8.0	0.2
Total Aerobic Microbial Count, cfu/gram	NLT 45.0	62.8
Total Yeast and Mold Count, cfu/gram	NMT 100	Pass
Salmonella Species	NMT 20	Pass
Escherichia coli	Absent in a 10g sample	Pass
Staphylococcus aureus	Absent in a 10g sample	Pass
Pseudomonas aeruginosa	Absent in a 10g sample	Pass
Coliform species	Absent in a 10g sample	Pass
Enterobacteria	Absent in 1g	Pass

The product is manufactured in accordance to GMP as detailed in IPEC GMP guide for Bulk Excipients. FMC test methods are used when the test is not listed in the Pharmacopeia. The Product meets the requirement for Residual Solvents USP < 467 > and ICH Guide Q3C. We certify that as of the date of shipment the product conforms with the current USP / NF Ph.Eur and JP specifications on the date of manufacture.

**FRC.s (Ph.Eur)** Hausner Ratio Typical values: For all Avicel PH grades: 1.18 - 1.45. Degree of Crystallinity Typical Values: For all Avicel PH grades, approximately 80% by Intensity and 66% by Area.

**Storage Conditions:** Store at ambient conditions, keep containers sealed, Material is hygroscopic.

**Expiry date:** None, but FMC recommend retesting for Loss on Drying after re-evaluation date listed above.

Typical Degree of Polymerization range for Avicel PH Microcrystalline Cellulose is 100 to 300.

**ISO 9001:2000 Certified Quality System.** Refer to package label for Kosher status.

MT-More than, NMT-Not more than, LT-Less than, NLT-Not less than.

Manufactured under GMPs and Issued by:  
FMC BioPolymer  
Wallingstown, Little Island,  
Co. Cork, Ireland