FMČ BioPolymer 1735 Market St. Philadelphia PA

Philadelphia, PA 19103

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FMCBioPolymer

Certificate of Analysis

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

Type : PH-102

Lot No:

Manufacturing Date: 14-Apr-2009 Customer Material number:

Customer Purchase Order:

Reevaluation Date: 13-Apr-2013 Delivery Number :

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, μm, d10 (FRC, Ph.eur) - 32 P.S.D., Malvern LD, μm, d50 (FRC, Ph.eur) - 239 Identification, A, B, C Pass Pass Retained on a 38μm screen opening, MT 5 Pass pH 5.5 - 7.0 6.0 Conductivity,μS/cm NMT 75 41 Residue on Ignition, % NMT 0.050 0.005 Water Soluble Substances, mg/5g NMT 12.5 5.0 Water soluble substances, mg/5g NMT 0.001 Pass Sol. in Cu Tetramine Hydroxide Soluble Pass Ether Soluble Substances, mg/10g NMT 5.0 1.1 Air Jet Particle Size, wt. % +60Mesh NMT 8.0 0.2 Air Jet Particle Size, wt. % +200Mesh NLT 45.0 62.8 Total Aerobic Microbial Count, cfu/gram NMT 100 Pass Total Yeast and Mold Count, cfu/gram NMT 20 Pass S	Standard	Specification	Lot Analysis
Degree of Polymerization, units NMT 350 214 P.S.D., Malvern LD, μm, d10 (FRC, Ph.eur) - 32 P.S.D., Malvern LD, μm, d50 (FRC, Ph.eur) - 117 P.S.D., Malvern LD, μm, d90 (FRC, Ph.eur) - 239 Identification, A, B, C Pass Pass Retained on a 38μm screen opening, MT 5 Pass pH 5.5 - 7.0 6.0 Conductivity, μS/cm NMT 75 41 Residue on Ignition, % NMT 0.050 0.005 Water Soluble Substances, mg/5g NMT 12.5 5.0 Water soluble substances, % NMT 0.25 0.10 Heavy Metals, % (Pb) NMT 0.001 Pass Sol. in Cu Tetramine Hydroxide Soluble Pass Ether Soluble Substances, mg/10g NMT 5.0 1.1 Air Jet Particle Size, wt. % +60Mesh NMT 8.0 0.2 Air Jet Particle Size, wt. % +200Mesh NLT 45.0 62.8 Total Aerobic Microbial Count, cfu/gram NMT 20 Pass Total Yeast and Mold Count, cfu/gram NMT 20 Pass	Loss on Drying, %	3.0 - 5.0	3.5
P.S.D., Malvern LD, μm, d50 (FRC, Ph.eur) - 32 P.S.D., Malvern LD, μm, d50 (FRC, Ph.eur) - 117 P.S.D., Malvern LD, μm, d90 (FRC, Ph.eur) - 239 Identification, A, B, C Pass Pass Retained on a 38μm screen opening, PH MT 5 Pass Conductivity, μS/cm NMT 5 41 Residue on Ignition, % NMT 0.050 0.005 Water Soluble Substances, mg/5g NMT 12.5 5.0 Water soluble substances, % NMT 0.05 0.10 Heavy Metals, % (Pb) NMT 0.001 Pass Sol. in Cu Tetramine Hydroxide Soluble Pass Ether Soluble Substances, mg/10g NMT 5.0 1.1 Air Jet Particle Size, wt. % +60Mesh NMT 8.0 0.2 Air Jet Particle Size, wt. % +200Mesh NLT 45.0 62.8 Total Aerobic Microbial Count, cfu/gram NMT 100 Pass Total Yeast and Mold Count, cfu/gram NMT 20 Pass Salmonella Species Absent in a 10g sample Pass Escherichia coli Absent in a 10g sample Pas	Loose Bulk Density, g/cc	0.28 - 0.33	0.31
P.S.D., Malvern LD, μm, d90 (FRC, Ph.eur) - 239 Identification, A, B, C Pass Pass Retained on a 38μm screen opening, pH MT 5 Pass Conductivity,μS/cm NMT 75 41 Residue on Ignition, % NMT 0.050 0.005 Water Soluble Substances, mg/5g NMT 12.5 5.0 Water soluble substances, % NMT 0.25 0.10 Heavy Metals, % (Pb) NMT 0.001 Pass Sol.in Cu Tetramine Hydroxide Soluble Pass Ether Soluble Substances, mg/10g NMT 5.0 1.1 Air Jet Particle Size, wt. % +60Mesh NMT 8.0 0.2 Air Jet Particle Size, wt. % +200Mesh NLT 45.0 62.8 Total Aerobic Microbial Count, cfu/gram NMT 100 Pass Total Yeast and Mold Count, cfu/gram NMT 20 Pass Salmonella Species Absent in a 10g sample 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 <td>Degree of Polymerization, units</td> <td>NMT 350</td> <td>214</td>	Degree of Polymerization, units	NMT 350	214
P.S.D., Malvern LD, µm, d90 (FRC, Ph.eur) Identification, A, B, C Retained on a 38µm screen opening, Pass Retained on a 38µm screen opening, Pass Pass Pass Pass Retained on a 38µm screen opening, Pass Pass Pass Pass Pass Pass Pass Pas	P.S.D., Malvern LD, µm, d10 (FRC, Ph.eur)	-	32
Identification, A, B, CPassPassRetained on a 38μm screen opening, pH5.5 - 7.06.0Conductivity,μS/cmNMT 7541Residue on Ignition, %NMT 0.0500.005Water Soluble Substances, mg/5gNMT 12.55.0Water soluble substances, %NMT 0.250.10Heavy Metals, % (Pb)NMT 0.001PassSol.in Cu Tetramine HydroxideSolublePassEther Soluble Substances,mg/10gNMT 5.01.1Air Jet Particle Size, wt. % +60MeshNMT 8.00.2Air Jet Particle Size, www. % +200MeshNLT 45.062.8Total Aerobic Microbial Count, cfu/gramNMT 100PassTotal Yeast and Mold Count, cfu/gramNMT 20PassSalmonella SpeciesAbsent in a 10g samplePassEscherichia coliAbsent in a 10g samplePassStaphylococcus aureusAbsent in a 10g samplePassPseudomonas aeruginosaAbsent in a 10g samplePassColiform speciesAbsent in a 10g samplePass	P.S.D., Malvern LD, µm, d50 (FRC, Ph.eur)	-	117
Retained on a 38µm screen opening, pH 5.5.5 - 7.0 6.0 Conductivity,µS/cm NMT 75 41 Residue on Ignition, % NMT 0.050 0.005 Water Soluble Substances, mg/5g NMT 12.5 5.0 Water soluble substances, % NMT 0.25 0.10 Heavy Metals, % (Pb) NMT 0.001 Pass Sol.in Cu Tetramine Hydroxide Soluble Pass Ether Soluble Substances,mg/10g NMT 5.0 1.1 Air Jet Particle Size, wt. % +60Mesh NMT 8.0 0.2 Air Jet Particle Size, wt. % +60Mesh NLT 45.0 62.8 Total Aerobic Microbial Count, cfu/gram NMT 100 Pass Total Yeast and Mold Count, cfu/gram NMT 20 Pass Salmonella Species Absent in a 10g sample Pass Escherichia coli Absent in a 10g sample Pass Staphylococcus aureus Absent in a 10g sample Pass Pass Coliform species Absent in a 10g sample Pass	P.S.D., Malvern LD, µm, d90 (FRC, Ph.eur)	-	239
pH Conductivity,µS/cm NMT 75 41 Residue on Ignition, % NMT 0.050 Water Soluble Substances, mg/5g Water soluble substances, % NMT 0.25 NMT 0.25 NMT 0.25 NMT 0.001 Pass Sol. in Cu Tetramine Hydroxide Ether Soluble Substances,mg/10g NMT 5.0 NMT 5.0 NMT 5.0 NMT 8.0 NMT 8.0 NMT 8.0 NMT 8.0 NMT 8.0 O.2 Air Jet Particle Size, wt. % +60Mesh NMT 8.0 NLT 45.0 Total Aerobic Microbial Count, cfu/gram NMT 100 Pass Total Yeast and Mold Count, cfu/gram NMT 20 Pass Salmonella Species Absent in a 10g sample Pass Staphylococcus aureus Pass Coliform species Absent in a 10g sample Pass Coliform species Absent in a 10g sample Pass Coliform species Absent in a 10g sample Pass	Identification, A, B, C	Pass	Pass
Conductivity,µS/cm Residue on Ignition, % NMT 0.050 Water Soluble Substances, mg/5g NMT 12.5 S.0 Water soluble substances, % NMT 0.25 NMT 0.25 O.10 Heavy Metals, % (Pb) NMT 0.001 Pass Sol.in Cu Tetramine Hydroxide Soluble Soluble Pass Ether Soluble Substances,mg/10g NMT 5.0 1.1 Air Jet Particle Size, wt. % +60Mesh NMT 8.0 O.2 Air Jet Particle Size, wt. % +200Mesh NLT 45.0 G2.8 Total Aerobic Microbial Count, cfu/gram NMT 100 Pass Salmonella Species Absent in a 10g sample Pass Escherichia coli Staphylococcus aureus Pass Pseudomonas aeruginosa Coliform species Absent in a 10g sample Pass Coliform species Absent in a 10g sample Pass Pass Pass Pass Pass Pass Pass Pas	Retained on a 38µm screen opening,	MT 5	Pass
Residue on Ignition, % Water Soluble Substances, mg/5g Water soluble substances, % NMT 0.25 NMT 0.25 O.10 Heavy Metals, % (Pb) NMT 0.001 Pass Sol.in Cu Tetramine Hydroxide Soluble Ether Soluble Substances,mg/10g NMT 5.0 1.1 Air Jet Particle Size, wt. % +60Mesh NMT 8.0 O.2 Air Jet Particle Size, wt. % +200Mesh NLT 45.0 Total Aerobic Microbial Count, cfu/gram NMT 100 Pass Total Yeast and Mold Count, cfu/gram NMT 20 Pass Salmonella Species Absent in a 10g sample Pass Staphylococcus aureus Pseudomonas aeruginosa Coliform species Absent in a 10g sample Pass Coliform species Absent in a 10g sample Pass Coliform species Absent in a 10g sample Pass	pH	5.5 - 7.0	6.0
Water Soluble Substances, mg/5g Water soluble substances, % NMT 0.25 O.10 Heavy Metals, % (Pb) NMT 0.001 Pass Sol.in Cu Tetramine Hydroxide Soluble Soluble Pass Ether Soluble Substances,mg/10g NMT 5.0 Air Jet Particle Size, wt. % +60Mesh NMT 8.0 O.2 Air Jet Particle Size, wt. % +200Mesh NLT 45.0 Total Aerobic Microbial Count, cfu/gram NMT 100 Pass Total Yeast and Mold Count, cfu/gram NMT 20 Pass Salmonella Species Absent in a 10g sample Pass Staphylococcus aureus Pseudomonas aeruginosa Coliform species Absent in a 10g sample Pass Coliform species Absent in a 10g sample Pass Coliform species Absent in a 10g sample Pass	Conductivity, µS/cm	NMT 75	41
Water soluble substances, % Heavy Metals, % (Pb) NMT 0.001 Pass Sol.in Cu Tetramine Hydroxide Soluble Substances,mg/10g NMT 5.0 NMT 5.0 NMT 8.0 NMT 8.0 NMT 8.0 NMT 8.0 NMT 8.0 NMT 8.0 O.2 Air Jet Particle Size, wt. % +60Mesh NLT 45.0 Total Aerobic Microbial Count, cfu/gram NMT 100 Pass Total Yeast and Mold Count, cfu/gram NMT 20 Pass Salmonella Species Absent in a 10g sample Pass Escherichia coli Absent in a 10g sample Pass Staphylococcus aureus Pass Pseudomonas aeruginosa Absent in a 10g sample Pass Coliform species Absent in a 10g sample Pass Pass Pass Pass Pass Pass Pass Pas	Residue on Ignition, %	NMT 0.050	0.005
Heavy Metals, % (Pb) Sol.in Cu Tetramine Hydroxide Ether Soluble Substances,mg/10g Air Jet Particle Size, wt. % +60Mesh Air Jet Particle Size, wt. % +200Mesh Total Aerobic Microbial Count, cfu/gram Total Yeast and Mold Count, cfu/gram Salmonella Species Escherichia coli Staphylococcus aureus Pass Pass Coliform species NMT 0.001 Pass NMT 5.0 NMT 8.0 NLT 45.0 62.8 NMT 100 Pass NMT 100 Pass NMT 20 Pass Absent in a 10g sample Pass Staphylococcus aureus Absent in a 10g sample Pass Pass Pass Pass Absent in a 10g sample Pass Pass Pass Pass Absent in a 10g sample Pass	Water Soluble Substances, mg/5g	NMT 12.5	5.0
Sol.in Cu Tetramine Hydroxide Ether Soluble Substances,mg/10g NMT 5.0 1.1 Air Jet Particle Size, wt. % +60Mesh Air Jet Particle Size, wt. % +200Mesh Total Aerobic Microbial Count, cfu/gram Total Yeast and Mold Count, cfu/gram NMT 100 Pass Salmonella Species Absent in a 10g sample Pass Staphylococcus aureus Pass Pseudomonas aeruginosa Coliform species Soluble Pass NMT 5.0 1.1 NMT 8.0 0.2 Absent in 200 Pass Absent in a 10g sample Pass Pass Pass Absent in a 10g sample Pass Pass Absent in a 10g sample Pass	Water soluble substances, %	NMT 0.25	0.10
Ether Soluble Substances,mg/10g Air Jet Particle Size, wt. % +60Mesh Air Jet Particle Size, wt. % +60Mesh NMT 8.0 O.2 Air Jet Particle Size, wt. % +200Mesh Total Aerobic Microbial Count, cfu/gram NMT 100 Pass Total Yeast and Mold Count, cfu/gram NMT 20 Pass Salmonella Species Absent in a 10g sample Pass Staphylococcus aureus Pass Pseudomonas aeruginosa Coliform species Absent in a 10g sample Pass Absent in a 10g sample Pass Absent in a 10g sample Pass Pass Absent in a 10g sample Pass Pass Absent in a 10g sample Pass Pass Pass Coliform species	Heavy Metals, % (Pb)	NMT 0.001	Pass
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Air Jet Particle Size, wt. % +200Mesh Total Aerobic Microbial Count, cfu/gram NMT 100 Pass Total Yeast and Mold Count, cfu/gram NMT 20 Pass Salmonella Species Escherichia coli Staphylococcus aureus Pass Pseudomonas aeruginosa Coliform species NLT 45.0 Pass NMT 100 Pass NMT 20 Pass Absent in a 10g sample Pass Absent in a 10g sample Pass Pass Absent in a 10g sample Pass Absent in a 10g sample Pass Pass Coliform species	Ether Soluble Substances, mg/10g	NMT 5.0	1.1
Total Aerobic Microbial Count, cfu/gram Total Yeast and Mold Count, cfu/gram Salmonella Species Escherichia coli Staphylococcus aureus Pass Pass Absent in a 10g sample Pass Staphylococcus aureus Absent in a 10g sample Pass Pass Pass Pass Absent in a 10g sample Pass Pass Pass Pass Absent in a 10g sample Pass Pass Pass Pass Pass Absent in a 10g sample Pass	Air Jet Particle Size, wt. % +60Mesh	NMT 8.0	0.2
Total Yeast and Mold Count, cfu/gram Salmonella Species Escherichia coli Staphylococcus aureus Pass Absent in a 10g sample Pass Staphylococcus aureus Absent in a 10g sample Pass Pass Pass Pass Coliform species NMT 20 Pass Absent in a 10g sample Pass Absent in a 10g sample Pass Absent in a 10g sample Pass Pass Coliform species	Air Jet Particle Size, wt. % +200Mesh	NLT 45.0	62.8
Salmonella Species Escherichia coli Absent in a 10g sample Pass Staphylococcus aureus Pseudomonas aeruginosa Coliform species Absent in a 10g sample Pass Pass Pass Absent in a 10g sample Pass Pass Pass Pass Coliform species Absent in a 10g sample Pass Pass	Total Aerobic Microbial Count, cfu/gram	NMT 100	Pass
Escherichia coli Staphylococcus aureus Pseudomonas aeruginosa Coliform species Absent in a 10g sample Pass Absent in a 10g sample Pass Pass Pass Absent in a 10g sample Pass Pass Pass	Total Yeast and Mold Count, cfu/gram	NMT 20	Pass
Staphylococcus aureus Pseudomonas aeruginosa Coliform species Absent in a 10g sample Pass Absent in a 10g sample Pass Pass Absent in a 10g sample Pass	Salmonella Species	Absent in a 10g sample	Pass
Pseudomonas aeruginosa Coliform species Absent in a 10g sample Pass Absent in a 10g sample Pass	Escherichia coli	Absent in a 10g sample	Pass
Coliform species Absent in a 10g sample Pass	Staphylococcus aureus	Absent in a 10g sample	Pass
	Pseudomonas aeruginosa	Absent in a 10g sample	Pass
Enterobacteria Absent in 1g 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.

150 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

Eileen Dennehy