

PRODUCT SPECIFICATION BULLETIN

Avicel® CE-15 microcrystalline cellulose and guar gum

Avicel CE-15 microcrystalline cellulose and guar gum is an excipient offering superior mouthfeel performance in chewable tablets. When chewing a tablet formulated with Avicel CE-15, the user experiences:

- Less grittiness
- Reduced tooth packing
- Minimal chalkiness
- Improved overall palatability

Avicel CE-15 is compatible with conventional formulation excipients and processes and demonstrates excellent scale-up performance.

Test	Specification
Identification, IR	Passes
Loss on drying, %	NMT 8.0
Heavy metals, %	NMT 0.001
Particle size, wt. % +325 mesh (45 microns)	NMT 80
pH, 5% solids	4.0 - 7.0
Microbial limits:	
Total aerobic microbial count, cfu/g	NMT 1000
Total yeast and mold count, cfu/g	NMT 100
<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 species</i>	Absent in a 10g sample

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: Three (3) years 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 pH and loss on drying tests.

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

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

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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 Corporation 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 Corporation.

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

In the United States, microcrystalline cellulose co-processed with guar gum is Generally Recognized As Safe (GRAS) when used as a tableting aid in dietary supplements at a level no greater than 10%. FMC maintains a Type IV Drug Master File (Excipients) for Avicel CE-15 at the US Food and Drug Administration to support its use in drugs. The guar gum used to produce Avicel CE-15 is NF grade. This product is produced in compliance with the appropriate requirements for Bulk Pharmaceutical Excipient Good Manufacturing Practices as developed by IPEC-America (and also published in the USP as General Chapter <1078>).

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