

PRODUCT  
SPECIFICATION  
BULLETIN

Avicel® HFE-102  
microcrystalline cellulose (NF, Ph. Eur., JP)  
and mannitol (USP, Ph. Eur., JP)

Test	Specification
Loss on drying, %	NMT 5
pH	5 – 7
Identification, IR	Passes
Sieve fraction, Wt. % Alpine	
+ 60 mesh	NMT 8
+ 200 mesh	40 – 70
% Mannitol	8 – 12
Microbial limits:	
Total aerobic microbial count/g	NMT 1000
Total yeast and mold count/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</i> species	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 re-valuation date, the customer perform the loss on drying test.

## FMC Corporation

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#### Patents

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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 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 HFE is a physical combination of never-dried microcrystalline cellulose co-spray dried with mannitol.

The microcrystalline cellulose and mannitol used are produced to meet the standards set forth in the *United States Pharmacopeia/National Formulary*, the *European Pharmacopoeia* and the *Japanese Pharmacopoeia*.

The microcrystalline cellulose and mannitol used are produced to meet the appropriate regulations of the United States, European Union and Japan as applicable to its use in dietary supplements.

This product is in substantial compliance with the IPEC-PQG Guidelines for Bulk Pharmaceutical Excipient GMP.

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