

Product Specification Bulletin

Avicel® DG, dry granulation binder

75% microcrystalline cellulose NF, Ph. Eur., JP

25% anhydrous dibasic calcium phosphate USP, FCC, Ph. Eur., JP

Test	Specification
Loss on drying, %	NMT 5.0
pH	5.5 - 7.5
Sieve fraction, %	2 - 35
Alpine +200 mesh	
PS Malvern d50, µm	35 - 55
LBD, g/cc	0.25 - 0.40
Assay DCP, %	21 - 29
ID test A, Ca ²⁺	Pass
ID test B, PO ₄ ³⁻	Pass
ID test C, cellulose	Pass
ID test D, degree of polymerization	Pass
Heavy metals, %	NMT 0.001
Water soluble substances, mg/5g	NMT 20.0
Ether soluble substances, mg/10g	NMT 5.0
Ether soluble substances, %	NMT 0.050
Microbial Limits	
Total aerobic microbial, count/g	NMT 1000
Total yeast and mold, count/g	NMT 100
<i>Pseudomonas aeruginosa</i>	None present in a 10g sample
<i>Escherichia coli</i>	None present in a 10g sample
<i>Staphylococcus aureus</i>	None present in a 10g sample
<i>Salmonella</i> species	None present in a 10g sample

NMT = Not More Than

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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

Avicel® colloid-forming, attrited mixtures of microcrystalline cellulose and carboxymethylcellulose sodium meet the standards set forth in the *United States Pharmacopeia/National Formulary* for microcrystalline cellulose and carboxymethylcellulose sodium and in the *European Pharmacopoeia* for microcrystalline cellulose and carmellose sodium.

Microcrystalline cellulose is generally recognized as safe (GRAS) by qualified experts. FMC maintains a Type IV Drug Master File at the U.S. Food and Drug Administration.

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