

Avicel[®] PH-302 microcrystalline cellulose NF, Ph. Eur., JP

Product Specifications:

Chemical and Physical:

Loss on drying Bulk density Identification A, B Degree of polymerization pH Conductivity Residue on ignition Water soluble substances Water soluble substances Ether soluble substances Heavy metals Solubility in Copper Tetrammine Hydroxide	3.0 - 5.0 % * 0.35 - 0.46 g/cc Passes NMT 350 units 5.5 - 7.0 * NMT 75 µS/cm NMT 0.05 % NMT 12.5 mg/5g NMT 0.25 % NMT 5.0 mg/10g NMT 0.001 % Soluble	
Microbiological:		
Total aerobic microbial count	NMT 100 cfu/g*	
Total yeast and mold count	NMT 20 cfu/g*	
Pseudomonas aeruginosa	Absent in a 10g sample	
Escherichia coli	Absent in a 10g sample	
Staphylococcus aureus	Absent in a 10g sample	
Salmonella species	Absent in a 10g sample	
Coliform species	Absent in a 10g sample	
Additional Specifications		
Particle size distribution	D10 D50 D90 12-58 86-165 180-340	
Particle size (Air Jet): wt. % + 60 mesh (250 microns) wt. % + 200 mesh (75 microns)	NMT 8 NLT 45	

This product meets the requirements for Residual Solvents in the United States Pharmacopeia <467> and complies with the ICH Guide Q3C for Residual Solvents.

*More restrictive than compendium NLT = Not Less Than NMT = Not More Than

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Product Shelf-life / Re-evaluation Date

Store at ambient conditions. Keep containers sealed; material is very hygroscopic. Re-evaluation date is four (4) years from date of manufacture, if storage conditions stated above are observed. DuPont recommends that after the above re-evaluation date, the customer perform the loss on drying test. Typical Degree Polymerization range for Avicel PH microcrystalline cellulose is 100 to 300.

Safety Data Sheets (SDS) available upon request.

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