Avicel® PH-112 microcrystalline cellulose NF, Ph. Eur., JP

Product Specifications:

**Chemical and Physical:**
- Loss on drying: NMT 1.5 %*
- Bulk density: 0.28 - 0.34 g/cc
- Identification A, B: Passes
- Degree of polymerization, (Identification C): NMT 350 units
- pH: 5.5 - 7.0*
- Conductivity: NMT 75 µS/cm
- Residue on ignition: NMT 0.05 %
- Water soluble substances: NMT 12.5 mg/5g
- Ether soluble substances: NMT 5.0 mg/10g
- Heavy metals: NMT 0.001 %
- Solubility in Copper Tetrammine Hydroxide: 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 FMC Specifications**
- Particle size distribution: D10, D50, D90
  - wt. % + 60 mesh (250 microns): NMT 8
  - wt. % + 200 mesh (75 microns): 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
Product Shelf-life / Re-evaluation Date

Store at ambient conditions. Keep containers sealed; material is very hygroscopic. 18 months from date of manufacture, if storage conditions stated above are observed. FMC recommends that after the above re-evaluation date, the customer perform the loss on drying test.

Safety Data Sheets (SDS) are available upon request.

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Product Suitability

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