Avicel® PH-101 microcrystalline cellulose NF, Ph. Eur., JP

Product Specifications:

Chemical and Physical:

Loss on Drying	3.0 - 5.0 %*
Loose Bulk Density	0.26 - 0.31 g/cc
Identification A	Pass
Degree of Polymerization	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
Water Soluble Substances	NMT 0.25 %
Ether Soluble Substances	NMT 5.0 mg/10g
Heavy Metals	NMT 0.001 %
Solubility in Copper Tetrammine Hydroxide	Soluble
Identification 2(JP)	Pass

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

	D10	D50	D90
Particle Size Distribution	14-30	40-75	77-156

Particle Size (Air Jet):

wt. % + 60 mesh (250 microns)	NMT 1.0
wt. % + 200 mesh (75 microns)	NMT 30

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. 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.

Safety Data Sheets (SDS) available on request.

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Avicel®

The renowned binder for tablets

Avicel® microcrystalline cellulose (MCC) is a purified, partially depolymerized alphacellulose excipient made by acid hydrolysis of specialty wood pulp.

For nearly 60 years, Avicel® has exceeded the performance of common pill binders by pushing the boundaries of science in tablet binding, leading to a premier product supported by true experts in the field. Today, Avicel® is produced in state of the art, GMP qualified facilities located in the US and Europe with rigid quality control and robust, flexible supply chains.

Multiple functionalities in one product

Avicel® PH MCC is most often used in tableting as a compression aid, flow aid, and filler for directly compressed tablets. Avicel® PH is an ideal wet granulation binder which rapidly produces robust granules that remain stable in high shear environments, enabling broad processing windows and maximizing batch to batch reproducibility.

With the development of differentiated grades, Avicel® PH remains an indispensable pharmaceutical formulation tool, with versatile functionality:

- Improved powder flow
- Broad wet granulation processing windows
- Optimum granule properties
- Ideal tablet compactibility
- Uniform tablet content
- Increased batch size
- Reduced moisture related API degradation

Product Recommendations*

Available Grades	Particle Size, µm	Moisture, %	Differentiating Features
Avicel® PH-101	50	3.0 to 5.0	Premier Binder
Avicel® PH-102	100	3.0 to 5.0	
Avicel® PH-105	20	NMT 5.0	Superior Compactibility
Avicel® PH-102 SCG	150	3.0 to 5.0	Superior Flow
Avicel® PH-200	180	2.0 to 5.0	
Avicel® PH-301	50	3.0 to 5.0	High Density
Avicel® PH-302	100	3.0 to 5.0	
Avicel® PH-103	50	NMT 3	Low Moisture
Avicel® PH-113	50	NMT 2	
Avicel® PH-112	100	NMT 1.5	
Avicel® PH-200 LM	180	NMT 1.5	

*Examples only and not representative of a complete list of recommended products or benefits.

Key Applications

- Direct Compression Tableting
- Granulation
- Extrusion and Spheronization

The application possibilities are endless. We want to help you be successful in whatever application you are considering, so please contact us if you need more assistance. Our experts are eager to tackle your challenges.

Did you know that with the development of differentiated grades, Avicel® remains an indispensable formulation tool, boosting productivity and meeting tough formulation challenges. This short video summarizes the value proposition of our Avicel® - A versatile excipient addressing your critical formulation needs.

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To read more about the product, download

Avicel® Product Selection Guide

Other Brands

Ac-Di-Sol®

Co-Processed Avicel®

METHOCEL™

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Nutrition & Biosciences

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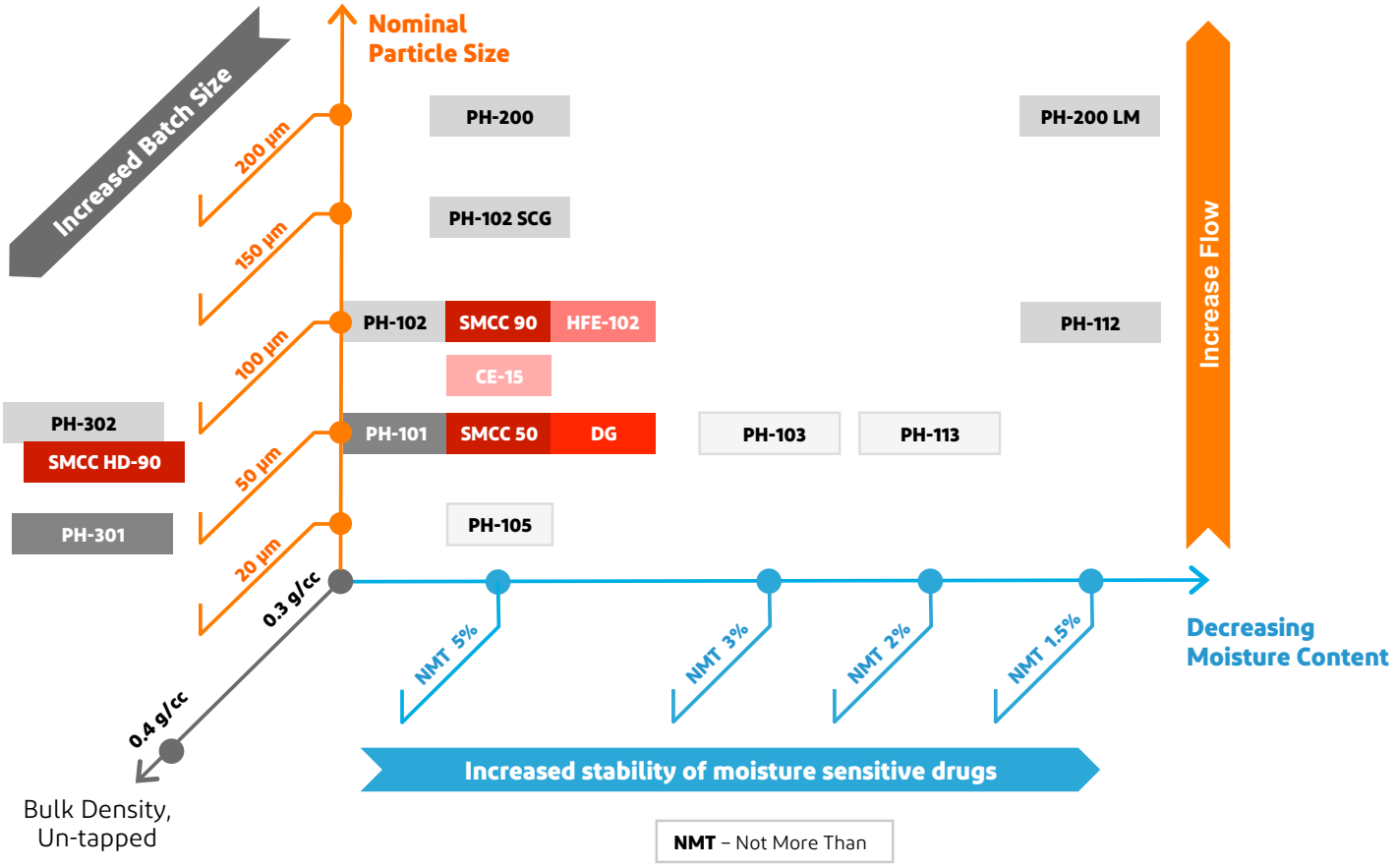
Pharma Solutions

Avicel® Selection Guide

A versatile excipient addressing your critical formulation needs.

Functionalities tailored to requirements of dosage form, formulation and technology



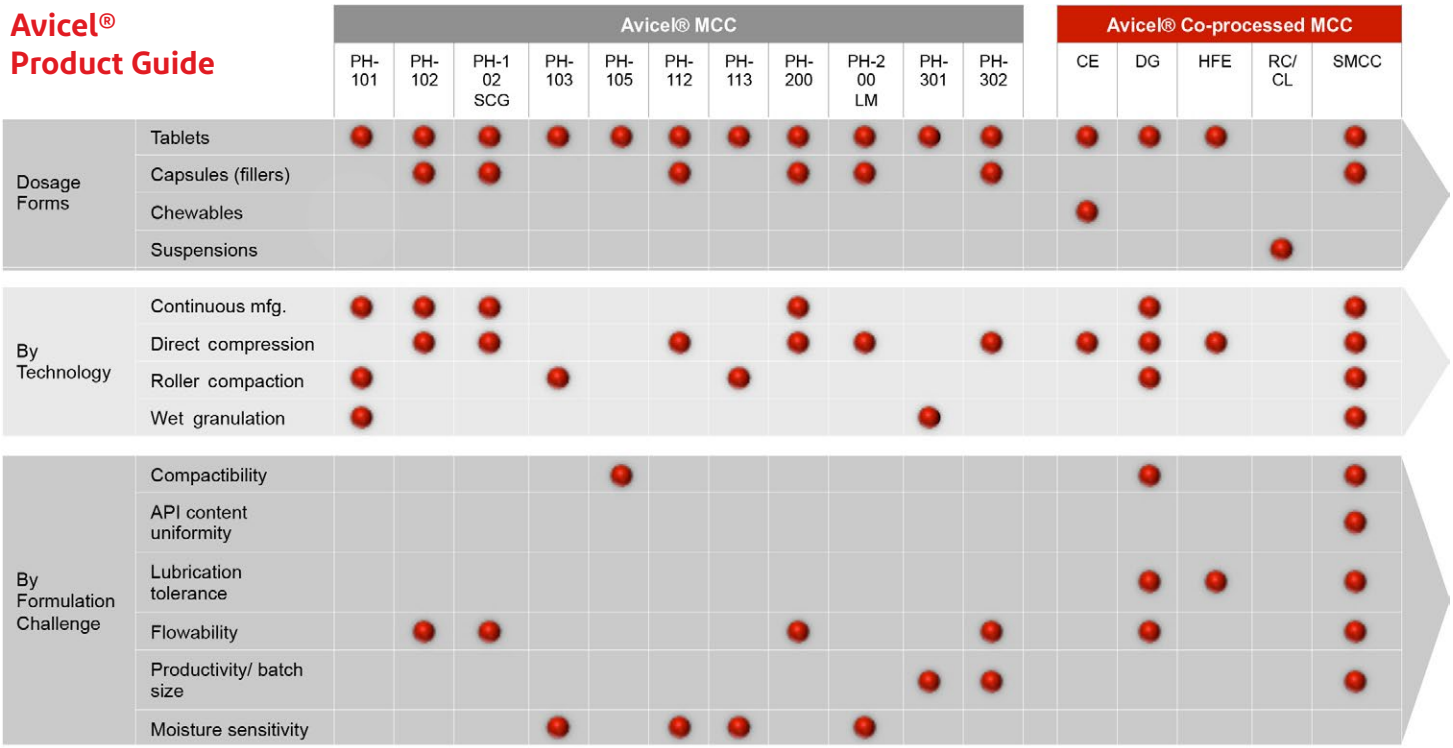
Avicel® MCC

- Direct Compression
- Wet Granulation

Co-processed Avicel®

- MCC + SiO_2
- MCC + DCP
- MCC + Mannitol
- MCC + Guar Gum

Avicel® Product Guide



Market Trends and Needs

- Use of direct compression, high-speed tabletting machines
- Implementation of continuous manufacturing
- Need for safe and reliable drug performance
- Formulation flexibility e.g. immediate, controlled, delayed release
- Increasing demand on excipient's functionality
- Reliable and simplified supply chain set ups
- Particle engineering and co-processing are attractive tools to meet market needs

With the development of differentiated grades, Avicel® remains an indispensable formulation tool, boosting productivity and meeting tough formulation challenges. Contact DuPont for assistance with choosing the optimal Avicel® grade or for help with your tableting formulation issues.

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