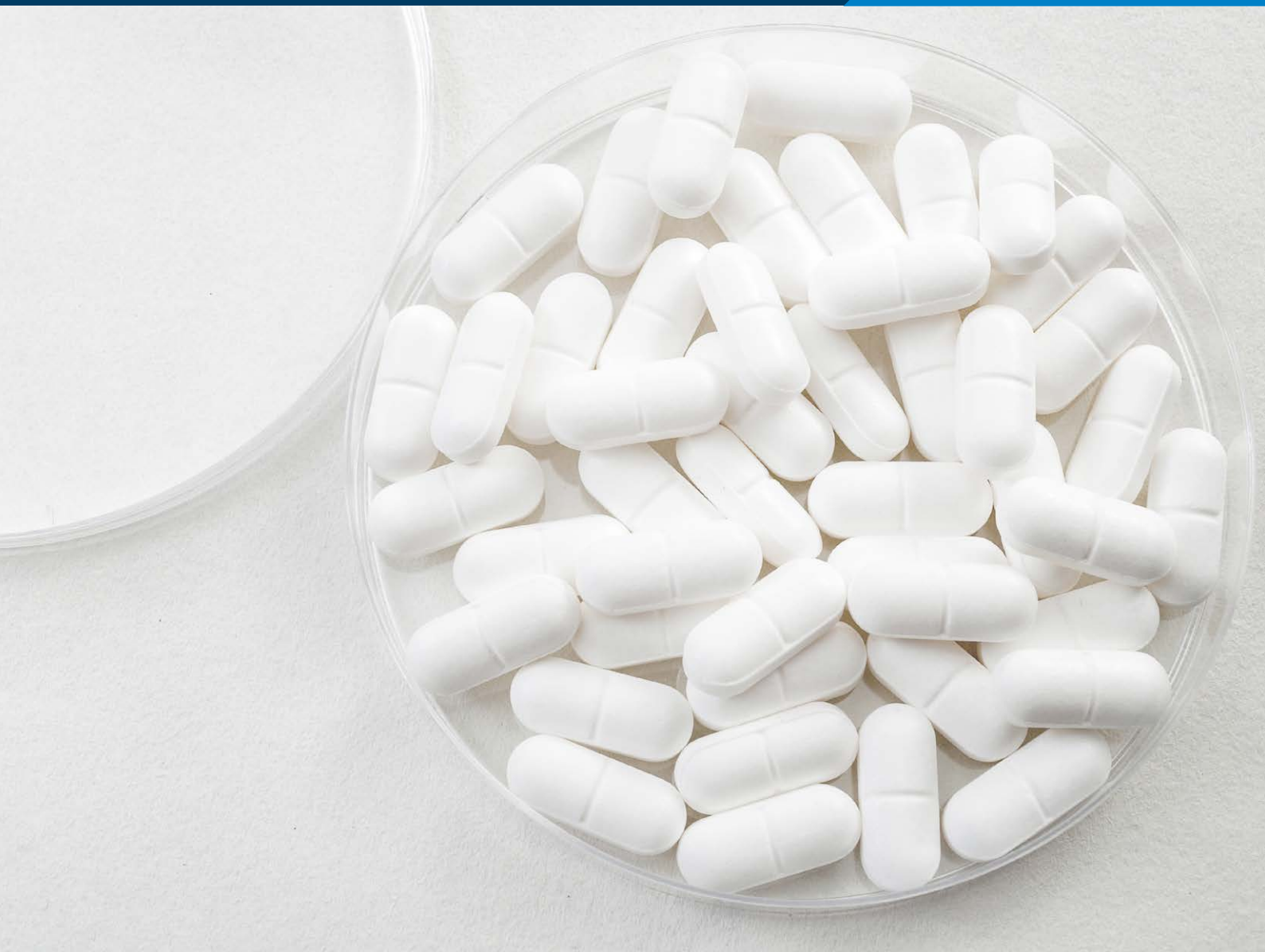
Where science
& creativity meet

Product selection guide

AVICEL® MICROCRYSTALLINE CELLULOSE (MCC) AND RELATED CO-PROCESSED PRODUCTS



QUICK SELECTION FOR PHARMACEUTICALS

Dosage form	Extrusion/ Spheroniza-tion	Chewable tablets	MUPS	Capsules	Liquids / Nasal suspensions	Dry suspension	Normal tablets						
API Specs							Moisture Sensitive APIs		Normal APIs				
Process							Direct Compression	MADG	Dry Granulation/ roller compaction	Wet granulation	Direct Compression		
											Best Choice	Low cost better flow	Low cost
Product	101/ 101LS	CE-15	105 + 200	301/ 302	RC-591	CL-611	112	200LM	DG	101	SMCC	200 / 200LS	102/ 102LS

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:

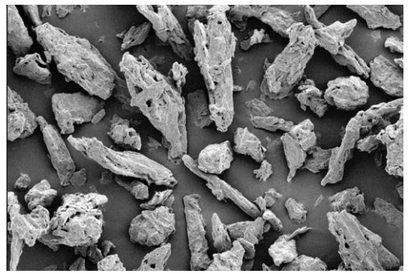
- Improved powder flow
- Broad wet granulation processing windows
- Optimum granule properties
- Ideal tablet compactibility
- Uniform tablet content
- Increased batch size
- Reduced moisture related API degradation

AVICEL® PH 101/101 LS

Most common used binder and extrusion aid in wet granulation and spherionization

KEY SPECIFICATIONS

Avicel® PH 101	
Nominal Particle Size, µm	50
Moisture, %	3.0 to 5.0
Loose Bulk Density, g/cc	0.26 – 0.31



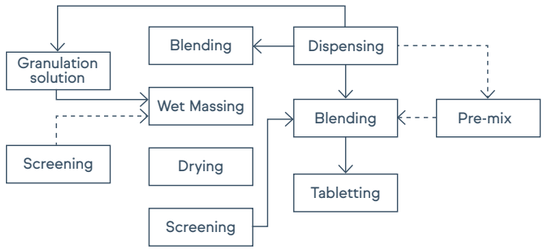
APPLICATIONS

DOSAGE FORMS
- Tablets
- Extrusion spheres

PROCESS
- Wet granulation
- Spheronization

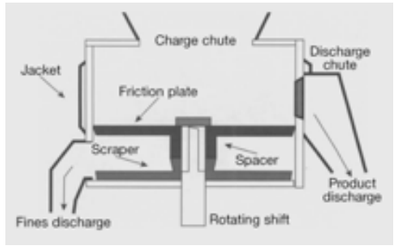
REASONS TO RECOMMEND
- Rapid and improve wet mass consistency
- Promotes rapid release and evaporation of liquid from the wet granulation
- Less screen blocking

PROCESS & FORMULATION GUIDE



FORMULATION GUIDE*

Material	Formulation (mg/tablet)
Acetaminophen	325.00
Dextropropoxyphen Hydrochloride	32.00
Povidone	8.00
Maize Starch	7.50
Water	
Avicel® PH 101	10.00
Talc purified	5.00
Magnesium Stearate	2.00



FORMULATION GUIDE**

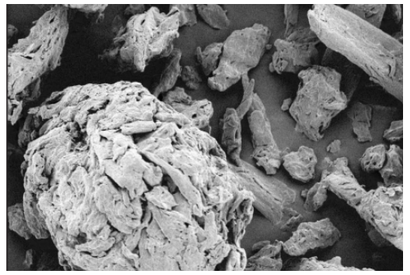
Material	Formulation, %
Acetaminophen	30
HPC LF	3
Lactose Monohydrate	35
Avicel® PH 101	45
Water	30
1 mm pellets	

AVICEL® PH 102/102LS

The most cost effective binder in direct compression

KEY SPECIFICATIONS

Avicel® PH 102	
Nominal Particle Size, µm	100
Moisture, %	3.0 to 5.0
Loose Bulk Density, g/cc	0.28 – 0.33



APPLICATIONS

DOSAGE FORMS
- Tablets

PROCESS
- Direct compression

REASONS TO RECOMMEND
- Super flowability for direct compression
- Rational cost

PROCESS & FORMULATION GUIDE

DIRECT COMPRESSION

FORMULATION GUIDE*

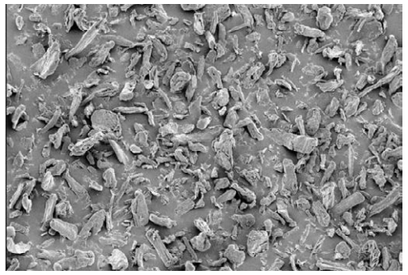
Material	Formulation (mg/tablet)
Atorvastatin	10.00
Calcium carbonate	36.00
Lactose monohydrate	65.00
Avicel® PH 102	30.00
PVP K30	3.00
Tween 80	0.40
Ac-Di-Sol®	4.00
Magnesium Stearate	0.60

AVICEL® PH 105

Excellent cushioning agent combining Avicel® PH 105 & 200 in Multiple-Unit Pellet System (MUPS) Tablets

KEY SPECIFICATIONS

Avicel® PH 105	
Nominal Particle Size, µm	20
Moisture, %	NMT 5.0
Loose Bulk Density, g/cc	0.20 – 0.30



APPLICATIONS

DOSAGE FORMS
- Multi pellets tablets

PROCESS
- Multi pellets tablets compression

REASONS TO RECOMMEND
- The combination improves compactibility for a robust MUPS tablets with desired better hardness and much lower friability
- Excellent plastic deformation and superior compactibility

PROCESS & FORMULATION GUIDE

MUPS

1. BLEND metoprolol sustained release pellets , MCC, Ac-Di-Sol® and SiO2 in Turbula mixer at 46rpm for 5min .

2. LUCRICATION - Add lubricant Alubra® PG-100 and mix at 46rpm for 2min.

3. TABLETING - Compress tablets on ZP-8 rotary tablet press.

FORMULATION GUIDE*

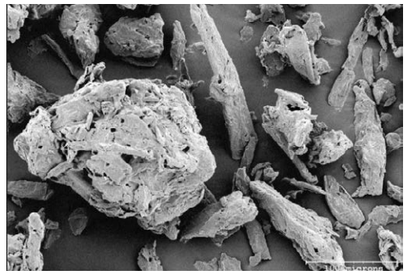
Material	Formulation, %	Function
Metoprolol sustained release pellets	46.00	API
Avicel® PH-200	37.00	Cushioning agent
Avicel® PH-105	15.00	Cushioning agent
Ac-Di-Sol® SD-711	0.50	Disintegrant
Colloidal silicon dioxide	0.50	Glidant
Alubra® PG-100	1.00	Lubricant
Total	100.00	

AVICEL® PH 112

Extreme low moisture content for moisture sensitive drug in dry granulation

KEY SPECIFICATIONS

Avicel® PH 112	
Nominal Particle Size, µm	100
Moisture, %	NMT 1.5
Loose Bulk Density, g/cc	0.28 – 0.34



APPLICATIONS

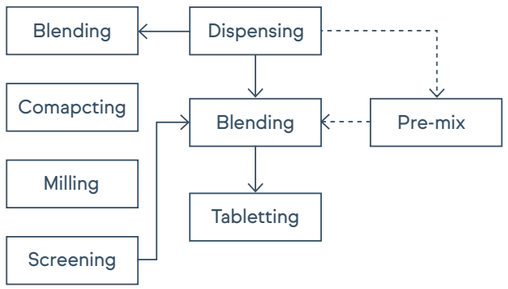
DOSAGE FORMS
- Tablets

PROCESS
- Dry granulation

REASONS TO RECOMMEND
- Extreme low moisture
- Excellent flowability

PROCESS & FORMULATION GUIDE

DRY GRANULATION



FORMULATION GUIDE*

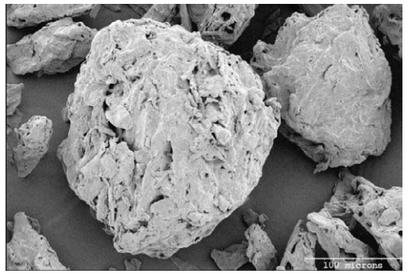
Material	Formulation (mg/tablet)
Norfloxacin	400.00
Avicel® PH 112	90.00
Ac-Di-Sol®	26.00
Magnesium Stearate	4.00

AVICEL® PH 200LM

Process enabler for MADG (Moisture Activated Dry Granulation)

KEY SPECIFICATIONS

Avicel® PH 200LM	
Nominal Particle Size, µm	200
Moisture, %	NMT 1.5
Loose Bulk Density, g/cc	0.30 – 0.38



APPLICATIONS

DOSAGE FORMS
- Tablets

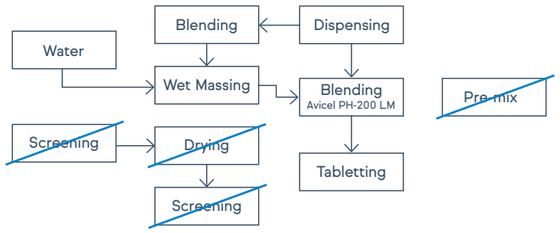
PROCESS
- MADG

REASONS TO RECOMMEND
- Outstanding production efficiencies without drying
- Cost reduction with higher yield
- Absorb more water

PROCESS & FORMULATION GUIDE

MADG

DRUG + FILLER + BINDER
↓ Blend
DRY BLEND
↓ Blend + Spray Water
MOIST AGGLOMERATES
↓ Blend + Add Drying Agent (drug/Avicel PH-200 LM/SiO_2)
DRY-FREE FLOWING GRANULES
↓ Blend + Add Disintegrant
UN-LUBRICATED GRANULES
↓ Blend + Add Lubricant
LUBRICATED GRANULES
↓ Sieve / Size
SIZED GRANULES
↓ Blend
FINAL BLEND



FORMULATION GUIDE*

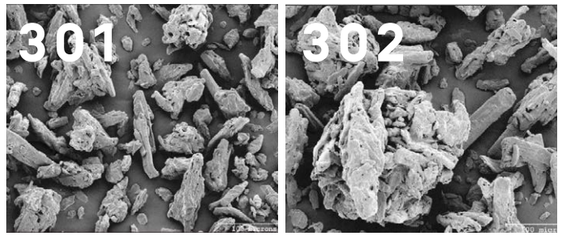
Material	%	LOD (%)
PVP K-12	6	1.65
Avicel® PH-200 LM	25	1.26
Aeroperl 300	2.5	1.45
Lactose	63	0.13
Disintegrant	3	3.83
Lubricant	0.5	2.92
Total	100	0.66

AVICEL® PH 301/302

Consistent powder flowability for capsule filling

KEY SPECIFICATIONS

Avicel® PH 301/302	
Nominal Particle Size, µm	50/100
Moisture, %	3.0 – 5.0
Loose Bulk Density, g/cc	0.34 – 0.45/ 0.35 – 0.46



APPLICATIONS

DOSAGE FORMS
- Capsules

PROCESS
- Casule filling

REASONS TO RECOMMEND
- High density and consistent flowability
- Less water absorption
- Choose 301 or 302 based on particle size requirement

PROCESS & FORMULATION GUIDE

Figure 1: Diagrammatic representation of the dosing disc filling principle. Five tamping stations (1–5) and plug ejection are illustrated.

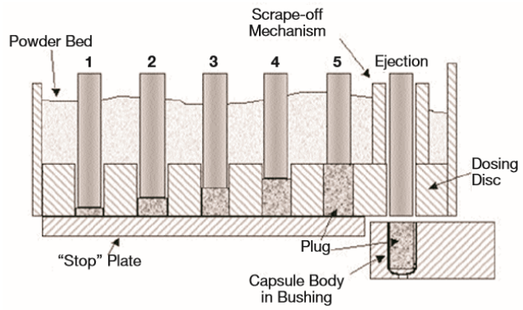
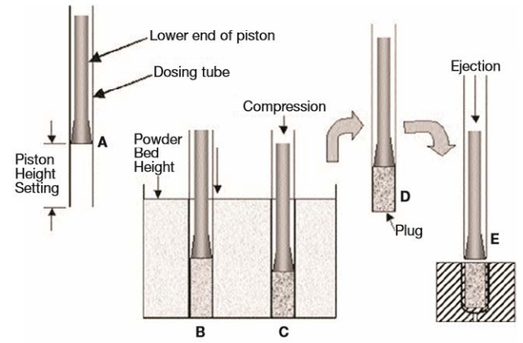


Figure 2: Diagrammatic representation of the dosator filling principle.



Key: **A** – Initial piston height setting;
B – Modest plug compression as dosator dips into powder bed;
C – Active piston compression of the plug;
D – Plug transport to ejection station;
E – Ejection of plug into capsule body.

AVICEL® SMCC

Super flowability and compactibility for ANY tablets formulation in direct compression

KEY SPECIFICATIONS

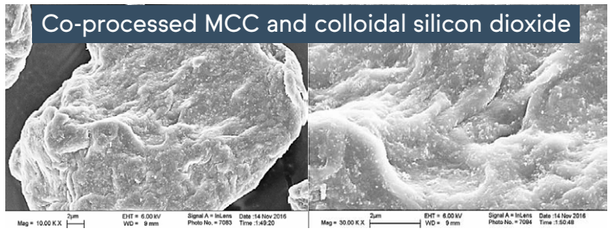
Avicel® PH SMCC 50/90/HD90	
Nominal Particle Size, d50 µm	45-80 90-150 90-160
Moisture, %	NMT 6.0
Loose Bulk Density, g/cc	0.25-0.37 0.25-0.37 0.38-0.50

APPLICATIONS

DOSAGE FORMS
- Tablets

PROCESS
- Direct compression

Co-processed MCC and colloidal silicon dioxide



PROCESS & FORMULATION GUIDE

- SMCC 90 is the 1st choice
- HD90 is recommended for high density formulations

FORMULATION GUIDE*

Ingredients	Functionality	mg/tablet
Chlorpheniramine	MaleateDrug	4.00
Avicel® SMCC 50, 90, HD-90	Compression aid	60.00
Lactose	Filler	33.00
Ac-Di-Sol®	Disintegrant	2.00
Alubra®	Lubricant	1.00
Total		100.00

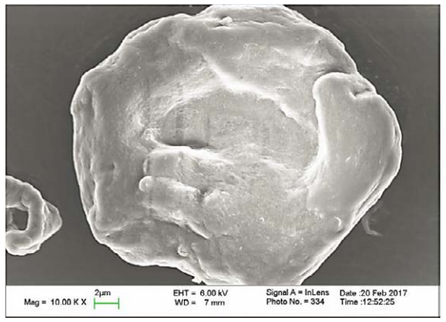
Ingredients	Functionality	mg/tablet
Metformin	Drug	500.00
Avicel® SMCC 50, 90 , HD 90	Compression aid	327.60
Avicel® PH102	Filler	49.90
Ac-Di-Sol	Disintegrant	13.50
Magnesium stearate	Lubricant	9.00
Total		900.00

AVICEL® CE-15

Provide excellent mouth feel in chewable tablets

KEY SPECIFICATIONS

Co-processed
MCC (85%), guar gum (15%)



APPLICATIONS

DOSAGE FORMS
- Tablets

PROCESS
- Direct compression

REASONS TO RECOMMEND
- Reduces grittiness and tooth packing
- Minimal chalkiness
- Improved compactibility
- Improved overall mouth feel

PROCESS & FORMULATION GUIDE

Product	Problem	Approach
Adult chewable Acetaminophen tablet	Gritty, chalky mouth feel	10% in formulation
Adult chewable Antacid tablet	Extreme hardness and High friability (1.5%)	9% Avicel® CE-15 extragranular
Adult Chewable Aspirin tablet	Gritty, chalky residue	10% Avicel® CE-15 in formulation
Large Chewable Antacid tablet	Large 2 gm size, mouth feel, high friability	Add 3% Avicel® CE-15 allowing approximate 40% reduction of other ingredients
Chewable Antacid tablet	Poor overall Mouth feel	2% Avicel® CE-15 in formulation

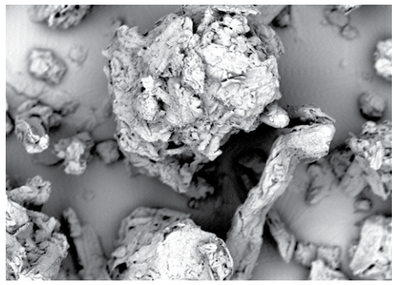
AVICEL® DG

Super compactibility and less use level to create smaller herbal extraction tablets in roller compaction

KEY SPECIFICATIONS

Co-processed
MCC (85%), guar gum (15%)

Avicel® PH DG	
Nominal Particle Size, µm	45
Moisture, %	NMT 5.0
Loose Bulk Density, g/cc	0.25 – 0.40



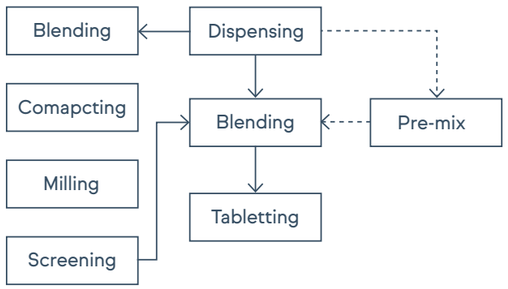
APPLICATIONS

DOSAGE FORMS
- Tablets

PROCESS
- Dry granulation
- Roller compaction

REASONS TO RECOMMEND
- Improved yields due to enhanced compactibilty and recompactability
- Reduced costs by minimizing process steps
- Simplified the formulation with less excipients and use level

PROCESS & FORMULATION GUIDE



FORMULATION GUIDE**

Ingredients	Formulation, %
Ginko Biloba	94.50
Avicel® DG	5.00
Alubra®	0.50
Total	100.00

AVICEL® RC-591

Excellent suspension aid and emulsion stabilizer in oral liquid and nasal suspensions

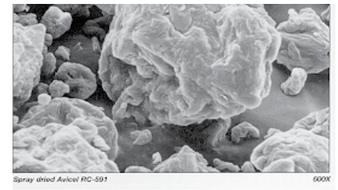
KEY SPECIFICATIONS

Compendial Standards	Specifications
Viscosity, 1.2% solids, cps	39 – 91
pH	6.0 – 8.0
Loss on drying, %	NMT 6.0
Residue on ignition, %	NMT 5.0
Heavy metals, %	NMT 0.001
Assay for sodium carboxymethylcellulose, %	8.3 – 13.8
Clarity of solution	Passes
Air jet particle size, wt. % + 60 mesh ~250 microns	NMT 0.5
Air jet particle size, wt. % + 325 mesh ~45 microns	NMT 45

APPLICATIONS

DOSAGE FORMS
- Oral liquid suspensions
- Nasal suspensions

REASONS TO RECOMMEND
- 1.2-1.5% use level
- Excellent thixotropic suspending aid
- Emulsion stabilizer
- Compatible with most gums



PROCESS & FORMULATION GUIDE

1. Prepare an Avicel® Premix: disperse 9g Avicel® in 420g water using a propeller mixer at 900 rpm for 5 min
2. Dissolve the sodium benzoate in 100mL water
3. Pass the suspension through the Inline High Shear mixer, at 150 pump speed and at maximum mixer speed (24000 rpm). Stop the pump when you obtain 280g of dispersion
4. Disperse the Paracetamol in lycasin (with propeller mixer at 1000 rpm), add the dissolved benzoate and polysorbate with a low shear mixer for 10 min (at 450 rpm)
5. Add the dispersed Paracetamol to 280g Avicel® dispersion while mixing with propeller mixer at 700-1000 rpm
6. Add DI water to obtain a total volume of 500 mL
7. Mix the final suspension for additional 10 min (at 700 rpm)

FORMULATION GUIDE**

Material	Formulation, % w/v
Paracetamol	2.40
Avicel® RC 591	1.20
Polysorbate 80	0.20
Lycasin de maltitol	20.00
Sodium benzoate	0.50
Deionized water	q.s.100

AVICEL® CL-611

Excellent suspension aid in dry suspensions

KEY SPECIFICATIONS

Compendial Standards	Specifications
Viscosity, 1.2% solids, cps	50 – 118
pH	6.0 – 8.0
Loss on drying, %	NMT 6.0
Residue on ignition, %	NMT 5.0
Heavy metals, %	NMT 0.001
Assay for sodium carboxymethylcellulose, %	11.3 – 18.8
Clarity of solution	Passes
Air jet particle size, wt. % + 60 mesh ~250 microns	NMT 0.1
Air jet particle size, wt. % + 325 mesh ~45 microns	NMT 50

APPLICATIONS

DOSAGE FORMS
- Dry suspensions

REASONS TO RECOMMEND
- 2.4-2.6% use level
- Effective drug suspension
- Reduced clumping
- Easily dispersible

PROCESS & FORMULATION GUIDE

1. Crush potassium sorbate with a mortar and pestle
2. Sieve the powder mix with a 710 µm sieve
3. Weigh all powders and mix them using a turbula mixer at 49 rpm for 10 min
4. Place powder mix in a bottle/container
5. Add DI water to obtain 250 mL suspension and shake manually for 1 min to form the suspension

FORMULATION GUIDE**

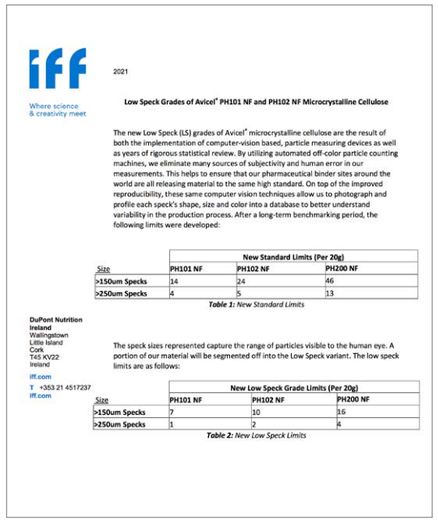
Material	Formulation, % w/v
Avicel® CL 611	4.00
Sugar S1	30.50
Calcium carbonate	15.30
Potassium sorbate	0.20
Sodium benzoate	0.50
Deionized water	q.s.100

AVICEL® LS (LOW SPECKS)

Super low specks to improve product quality

KEY SPECIFICATIONS

		Limits LS Grade
Limits (>250µm)	pH101	1
	pH102	2
	pH200	4
Limits (>150µm)	pH101	7
	pH102	10
	pH200	16



iff
Where science & creativity meet

2021

Low Speck Grades of Avicel® PH101 NF and PH102 NF Microcrystalline Cellulose

The new Low Speck (LS) grades of Avicel® microcrystalline cellulose are the result of both the implementation of computer-vision based, particle measuring devices as well as years of rigorous statistical review. By utilizing automated off-color particle counting machines, we eliminate many sources of subjectivity and human error in our measurements. This helps to ensure that our pharmaceutical binder sites around the world are all releasing material to the same high standard. On top of the improved reproducibility, these same computer vision techniques allow us to photograph and profile each speck's shape, size and color into a database to better understand variability in the production process. After a long-term benchmarking period, the following limits were developed:

	New Standard Limits (Per 20g)		
Size	PH101 NF	PH102 NF	PH200 NF
>150um Specks	14	24	46
>250um Specks	4	5	13

Table 1: New Standard Limits

DuPont Nutrition Ireland
Wallingstown
Little Island
Cork
T45 KV22
Ireland

iff.com
T +353 21 4517237
iff.com

The speck sizes represented capture the range of particles visible to the human eye. A portion of our material will be segmented off into the Low Speck variant. The low speck limits are as follows:

	New Low Speck Grade Limits (Per 20g)		
Size	PH101 NF	PH102 NF	PH200 NF
>150um Specks	7	10	16
>250um Specks	1	2	4

Table 2: New Low Speck Limits

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Where science & creativity meet

Being a significantly tighter specification, the LS variant will be held to a higher standard for off colored particles. We are always looking for ways to produce the highest quality product possible for our customers. These improvements are expected to result in a more visibly appealing tablet by reducing the probability that an off colored particle will appear on the surface.

Signed on behalf of DuPont Nutrition USA, Inc.

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AUTOMATED COUNTER TECHNOLOGY

PROCESS UPGRADE*

Specifications for pupls on allowed dirt and resin levels

Monitoring of TUPs levels via in-process and finished product sample testing

Product which meets internal limits for TUPs is released for shipping

Raw Material Specs. → Process/ Equipment Cleaning → In Process Monitoring → End Product Testing → Advanced Customer Support → Lower TUP Profile

- Process equipment is cleaned to remove build up of process-derived material (resins from raw material)
- Spray dryers are frequently washed to remove build up charred product adhering to chamber walls

Finished product testing improved through deployment of Automated Machine counting

AVICEL®: BINDERS FOR CONSUMER - FRIENDLY TABLETS

For decades, cellulose-based Avicel® binders have been used to manufacture dietary supplements that deliver nutritional ingredients in a consumer-friendly format like small-sized tablets, capsules, chewables and orally disintegrating tablets (ODTs). With the largest and broadest portfolio of premium cellulose-based binders, manufacturers around the world turn to Avicel® to create nutraceuticals with less dust formation and improved mouthfeel to appeal to the widest possible consumer base. IFF extracts Avicel® from naturally derived materials like wood pulp, making them ideal ingredients for crafting sustainable products. We source our raw, renewable materials directly from environmentally conscious suppliers, all of which are certified by the, the Programme for the Endorsement of Forest Certification or both.

Multiple Functionalities in One Product
Avicel® MCC is commonly used for improving the physical formulation properties of tablets and enabling easier processing of more robust dosage forms and ingredients, while Avicel® SMCC, a multifunctional ingredient, provides superior formulation processability and functionality. Avicel® CE-15 improves the sensory experience for the consumer with superior taste and texture attributes, which create a creamier mouthfeel for chewables.
With the development of differentiated grades, Avicel® distinguishes itself as indispensable tools for developing dietary supplements. Its versatile functionality brings many benefits to the table, including:

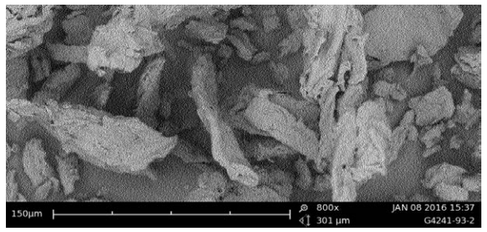
- Improved powder flow
- Broad wet granulation processing windows
- Optimum granule properties
- Ideal tablet compactibility
- Uniform tablet content
- Increased batch size
- Reduced moisture related API degradation

ENDURANCE® VE-50/90

Super compressibility and carrying capability for herbal extraction tablets with affordable cost

KEY SPECIFICATIONS

	VE-50	VE-90
Average particle size (um)	50	90
Moisture (% LOC)	3.5	3.5
Loose Density (g/ml)	0.28	0.3
Tapped Density (g/ml)	0.45	0.45
Mass Flow Rate (Kg/min)	0.52	1.13
pH (15% solids dispersion)	6.5	6.5



APPLICATIONS

DOSAGE FORMS
- Tablets

PROCESS
- Direct compression

REASONS TO RECOMMEND
- Smaller size Endurance VE-050 allows for superior granulation and compactibility
- Larger particle size of Endurance 90 (90 µm) improves flow, without sacrificing compactibility

PROCESS & FORMULATION GUIDE

FORMULATION GUIDE*

Niacinamide Tablets, 100mg

Material	Formulation, mg
Niacinamide, USP	100.00
Dibasic Calcium Phosphate Anhydrous, USP	122.50
Endurance® VE-50	25.00
Stearic Acid, NF	1.00
Magnesium Stearate, NF	1.50

B-Complex with Vc Tablets, 610mg

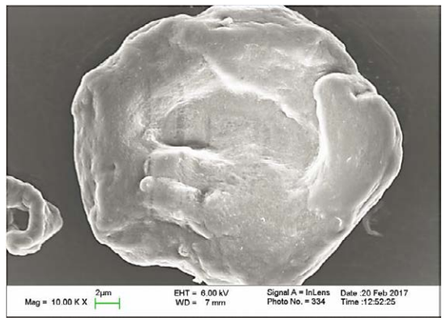
Material	Formulation, mg
Pyridoxine Hydrochloride, USP	5.50
Riboflavin, USP	11.22
D-Calcium Pantothenate, USP	13.50
Thiamine Mononitrate, USP	16.50
Niacinamide, USP	52.50
Vit.C (Ascorbic Acid)	350.00
Endurance® VE-90	129.67
Ac-Di-Sol®	24.40
Stearic Acid, NF	1.83
Magnesium Stearate, NF	4.88

AVICEL® CE-15

Provide excellent mouth feel in chewable tablets

KEY SPECIFICATIONS

Co-processed
MCC (85%), guar gum (15%)



APPLICATIONS

DOSAGE FORMS
- Tablets

PROCESS
- Direct compression

REASONS TO RECOMMEND
- Reduces grittiness and tooth packing
- Minimal chalkiness
- Improved compactibility
- Improved overall mouth feel

PROCESS & FORMULATION GUIDE

Material	Percentage	weight/tablet (mg)
Probiotics	6%	60.00
Sorbitol (NEOSORB 60)	37.50%	375.00
Mannitol (Pearlitol 200SD)	40%	400.00
Avicel® CE-15	8%	80.00
Strawberry powder	6%	60.00
Magnesium Stearate	1%	10.00
Strawberry flavor	1%	10.00
Citric acid	0.50%	5.00
Total Weight	100%	1000mg
Concertation	30B/tablet	

* PharmaSolutions AP team's work with Probiotics business in 2020

AVICEL® SMCC

Super flowability and compactibility for ANY tablets formulation in direct compression

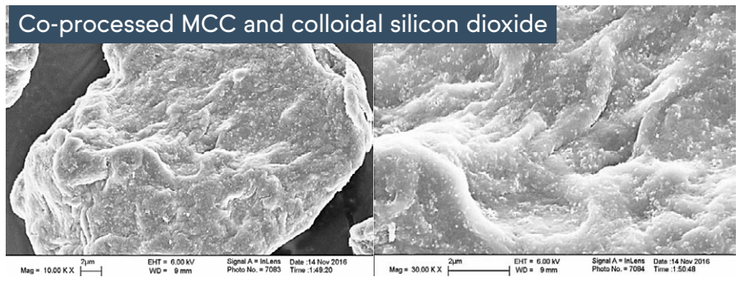
KEY SPECIFICATIONS

Avicel® PH SMCC 50/90/HD90	
Nominal Particle Size, d50 µm	45-80 90-150 90-160
Moisture, %	NMT 6.0
Loose Bulk Density, g/cc	0.25-0.37 0.25-0.37 0.38-0.50

APPLICATIONS

DOSAGE FORMS
- Tablets

PROCESS
- Direct compression



PROCESS & FORMULATION GUIDE

- SMCC 90 is the 1st choice
- HD90 is recommended for high density formulations

FORMULATION GUIDE*

B-Complex with Vc Tablets, 610mg

Material	Functionality mg/tablet
Protec D3V Vitamin D3	5.00
Balchem Albion Zinc Biglycinate Chelate	37.50
Vitamin A	824.40
NNGL 1010 (Reishi mushroom)	75.00
NNAM10 Astragalus membranaceus	450.00
Avicel® SMCC HD90	157.05
Fumed Silica	0.45
Hydroxypropyl cellulose	35.00
Ac-Di-Sol® SDW 802	20.00
Magnesium Stearate, NF	20.00

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& creativity meet

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