# JRS PHARMA MCC Microcrystalline Cellulose

Wide Range of Premium Quality MCC Binders for Specific Formulation Needs



# JRS PHARMA – The Global MCC Manufacturing Network

7 JRS PHARMA MCC Manufacturing Sites in 5 Countries Standardized Premium Processes High Product Quality – All Over the World

> JRS PHARMA – Leading in MCC Excellence





# JRS PHARMA - The Global MCC Manufacturing Network, Leading in MCC Excellence

### German MCC Technology - Produced in Seven JRS MCC Factories All Around the Globe

JRS PHARMA is one of the largest manufacturers of MCC binder products in the world. The core of our knowledge stems from 25 years of proven in-house developed JRS MCC production processes. That gives us the 100 % control and excellence of the process, the product and a consistent quality.

In 2018, the JRS Microcrystalline Cellulose Production Network expanded into Asia and opened a new state-of-the-art production site in Changzhou, China.

An additional site in India started production in 2019.

Both facilities stand for excellence in modern MCC Production Technology.

Advanced MCC Binders need a highly detailed and consistent production process. JRS refined and innovated the MCC production processes with advanced, specially designed equipment. The JRS PHARMA manufacturing strategy is based on sustainability, reliability and safety. All of our seven JRS PHARMA MCC Manufacturing Sites follow premium processes and fulfill high quality standards – all over the world. This includes utilizing the same premium quality raw materials.

Our Regional Manufacturing Plant Concept allows faster regional access and ensures optimized supply chain security. JRS PHARMA serves the global and regional markets with proven, branded and certified MCC Quality Products.

The JRS Process Know-How is backed by more than 25 years of experience in MCC production and innovation. The goal of JRS PHARMA is to serve the increasing demand in all markets with consistent high quality products.

## The Secure and Reliable MCC Premium Partnership

JRS PHARMA offers a perfect High Level Partnership for pharmaceutical industries all over the world – combining all synergies and advantages of a global manufacturing concept – based on standardized, regional production facilities:

Reliable premium quality level

Excellence in MCC know-how

Industry-leading supply security

Fast transportation times

Regional manufacturing to minimize duty, currency conversion and freight costs

Regional time zone customer service around the world Multiple state-of-the-art manufacturing sites across 3 continents guarantee supply chain security and business continuity, offering ultimate risk mitigation



















#### **VIVAPUR®**

The High Quality MCC with Reduced Carbon Footprint

#### **EMCOCEL®**

The Classic Premium MCC

Additional Wide Range of Special MCC Grades for Dedicated Needs

#### High Functionality Excipients:

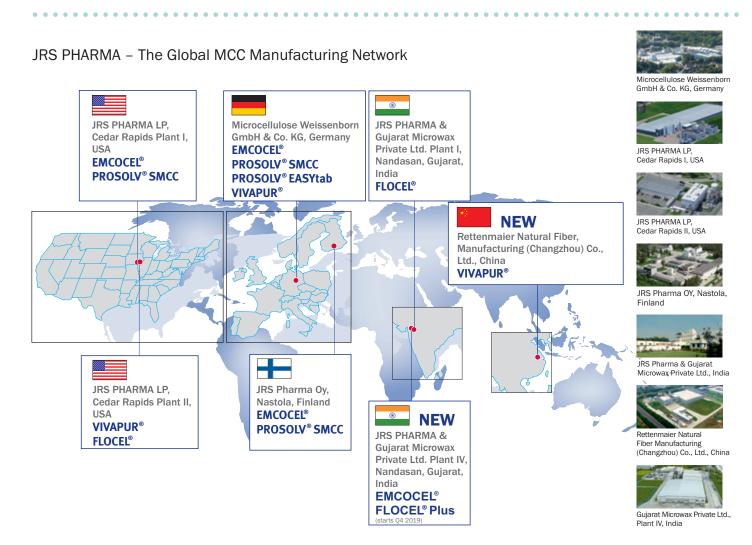
The Next Generation

#### **PROSOLV® EASYtab**

Ready-to-Use, High Functionality Excipient Composite

#### PROSOLV® SMCC

Silicified Microcrystalline Cellulose





# JRS PHARMA - System and Technology Partner, Added Value Solution Provider

## Expert Technical Support and Application Service

JRS PHARMA's portfolio of tableting excipients is the most comprehensive in the market. This includes not only classic ingredients but also innovative high functionality excipients. Still the backbone of this portfolio are the **VIVAPUR®** and **EMCOCEL®** MCCs.

The compliance with compendial monographs and additional internal specifications, such as high degree of brightness, is tested by our local quality control labs. Beyond that the JRS PHARMA Technical Competence Centers (TCC) carry out regularly functionality testing of our excipients in terms of tableting performance. Here at JRS PHARMA, we are always one step ahead – our two TCCs (Technical Competence Centers), in Germany and the USA, plus five regional application labs allow us to give customers just-in-time technical support and advice. This translates into more production efficiency and shorter time to market for our customers.

Make use of the leading JRS PHARMA MCC Excellence!

## JRS PHARMA Makes Business Life Much Easier and More Secure

As a dedicated global solution provider, JRS PHARMA meets all needs for excellent support and service:

- · Technical Support
- · Worldwide Logistics and Warehousing
- · Certified Quality and Regulatory Management













# JRS PHARMA – **Glo**bal Concept and Lo**cal** Presence – Your Strategic "**Glocal**" MCC Manufacturing Source

"Hightech MCC Binders need a highly detailed and consistent production process.

We refined and innovated the MCC production process and designed advanced special equipment. In-house by the central process and engineering department of JRS in Germany.

That gives us the 100 % control and excellence of the process, the product and a consistent quality.

I would like to invite you to use our world-wide MCC Manufacturing Network as your strategic global <u>and</u> regional MCC source. A win-win partnership in secure MCC supply – embedded in the global JRS supply network concept.

Future-oriented we expand our excipient business globally to fulfill our customers needs all around the globe.

You are most welcome in the JRS PHARMA Excipients Family!"

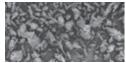
Josef Otto Rettenmaier

CEO of the Global JRS Company Group

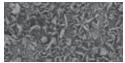


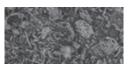
Josef Otto Rettenmaier, CEO JRS













#### The Globally Active JRS Company Group

- JRS PHARMA is part of the JRS Company Group J. RETTENMAIER & SÖHNE, Germany
- With over 140 years of experience, the JRS Group is a privately owner-led company with more than 3.500 employees and 90 sales and production facilities
- The Rettenmaier Family stands for a long-term, future-oriented philosophy, based on economical independency
- · The JRS manufacturing strategy is founded on stability, reliability and security
- All JRS Business Units follow our unique 'Green' philosophy. Originating from sustainable JRS Cellulose and Plant Fiber Technology

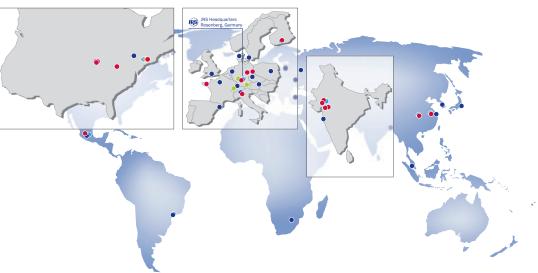


#### The Global Excipient Maker

#### **Global Network**

#### **GMP Manufacturing** and Service Sites

- Excipients
- Coatings
- Biopharma Services
- JRS Sales Companies (Additionally, dedicated representatives in almost every country.)
- **Technical Competence Centers**
- **Application Labs**



#### HIGH FUNCTIONALITY EXCIPIENTS

PROSOLV® SMCC

PROSOLV® EASYtab SP Microcrystalline Cellulose, Colloidal Silicon Dioxide, Sodium Starch Glycolate, Sodium Stearyl Fumarate

PROSOLV® EASYtab NUTRA

PROSOLV® ODT G2

Mannitol, Fructose, Crospovidone

#### **BINDERS**

VIVAPUR®, EMCOCEL®

**EMDEX**®

VIVAPHARM® Povidones

#### **FUNCTIONAL FILLERS**

ARBOCEL®

**EMCOMPRESS®** 

**COMPACTROL®** 

#### **DISINTEGRANTS**

VIVASTAR®, EXPLOTAB®

VIVASOL®

**EMCOSOY®** 

VIVAPHARM® Crospovidone

#### **LUBRICANTS**

PRUV®

LUBRITAB®

egetable Oil, Hydrogenated Oil

LUBRI-PREZ™

#### THICKENERS • STABILIZERS • GELLING AGENTS

VIVAPUR® MCG

VIVAPHARM® Alginates

VIVAPHARM® Alginates

VIVAPHARM® Alginates

VIVAPHARM® Pectins

#### **COATINGS**

VIVACOAT®

VIVACOAT® protect

Ready-to-Use High Functional Coating System

VIVAPHARM® HPMC

VIVAPHARM® PVA

#### **CARRIERS**

VIVAPUR® MCC SPHERES

VIVAPHARM® Sugar Spheres

#### **BIOPHARMA SERVICES**



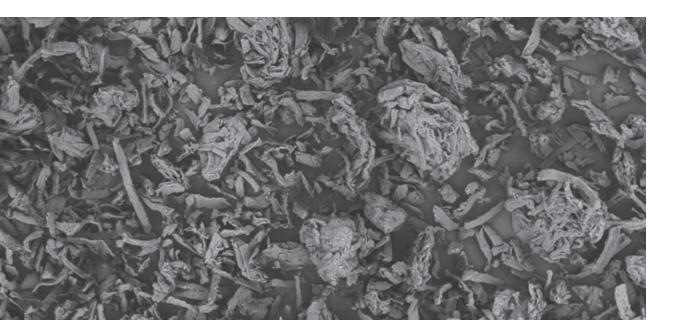


Members of the JRS PHARMA Family



**Business Unit Excipients** 73494 Rosenberg (Germany) Phone: +49 7967 152-312 ExcipientsService@JRSPharma.de

# **VIVAPUR®**Microcrystalline Cellulose



The High Quality MCC with Reduced Carbon Footprint





#### VIVAPUR® - The High Quality MCC with Reduced Carbon Footprint

## Premium Quality MCC for Direct Compression and Wet Granulation

VIVAPUR® MCC (microcrystalline cellulose) is an odorless, tasteless white powder with a high degree of brightness, derived from highly purified wood pulp. With a wide range of chemical, technical, and economic benefits, MCC is one of the most widely used binder/filler excipients for tablet formulations. The VIVAPUR® brand offers the most complete range of JRS Pharma's high quality MCC - with twelve grades designed for specific formulation needs. Decades of manufacturing high quality MCC in large volumes ensure high batch-to-batch consistency. In addition, Funtionality Related Characteristics, such as flowability, are analysed and certified for all twelve VIVAPUR® MCC grades.

#### Benefits include

- · High compactability
- · Robust tablets with low friability
- · High production yield
- Practically inert compatible with most APIs
- Created from sustainable organic materials
- Contains no additives, impurities, or irradiated components
- Advanced carton packaging design for fast NIR identification (see pictures page 4)

#### Twelve Grades Designed for Specific Formulation Needs

Туре	Average Particle Size by Laser Diffraction (µm)	Bulk Density (g/mL) VIVAPUR®	Main Application
VIVAPUR® 105	15	max 0.26	Very fine grade, which gives a pleasant mouth feeling, masks bitter tastes and supports flavors.
VIVAPUR® 101	65	0.26 - 0.31	Fine standard MCC grade, especially suited for wet granulation, roller compaction and spheronization. Very high compactability.
VIVAPUR® 103	65	0.26 - 0.31	Same quality as grade 101, but very low moisture content (< 1.5 %) for processing water-sensitive actives.
VIVAPUR® 301	65	0.35 - 0.46	Same quality as grade 101, but increased bulk density and improved flow properties.
VIVAPUR® 102	130	0.28 - 0.33	Medium size standard MCC grade, suited for the majority of directly compressible actives. Combines good flow and high compactability.
VIVAPUR® 112	130	0.30 - 0.36	Same quality to grades 102, but very low moisture content (< 1.5 %) for processing water-sensitive actives.
VIVAPUR® 302	130	0.35 - 0.50	Same quality to grade 102, but increased bulk density and improved flow properties. Especially suited for high speed tableting and processing high density actives.
VIVAPUR® 102 SCG	170	0.28 - 0.34	Coarse, DC-grade MCC.
VIVAPUR® 12	180	0.30 - 0.36	Coarse grade MCC, combines good compactability and high binding capacity with outstanding flow. Provides good content uniformity at low weight variation – even when used with low concentrations of fine actives.
VIVAPUR® 14	170	0.32 - 0.40	Same quality as grade 12, but very low moisture content (<1.5 %) for processing water-sensitive actives.
VIVAPUR® 200	250	0.31 - 0.37	Large size MCC grade with excellent flow properties for a variety of direct compression formulations.
VIVAPUR® 200 XLM	250	0.33 - 0.40	Same quality to grades 200, but very low moisture content ( $<$ 1.5 %) for processing water-sensitive actives.

#### Regulatory and Quality Assurance

EXCiPACT<sup>™</sup> certification in progress (MCW)

Conforms to Ph.Eur., NF, JP monograph requirements

CEP, US and Chinese Drug Master Files (DMFs)

QbD and historical production data

Audit questionnaire according to the IPEC GMP Audit guideline for bulk pharmaceutical excipients (BPE)

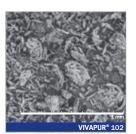
Full documentation package and regulatory support

TUP profile according to IPEC guideline

Tableting functionality regularly tested to ensure consistent quality and performance

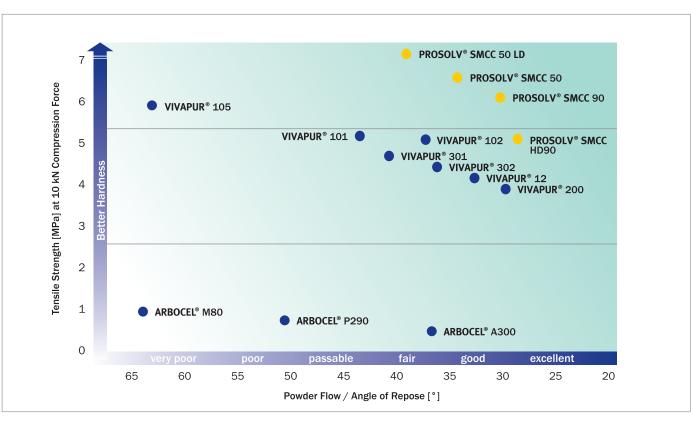
- √ 100 % Plant derived avoid BSE / TSE risks
- ✓ Genetically Modified Organism (GMO) free
- ✓ Pesticide & Herbicide free
- ✓ Halal certified
- √ Kosher certified
- ✓ Allergen free







#### Cellulose Compactability Map





#### The Global Excipient Maker

#### Logistics

- Seven state-of-the-arts manufacturing sites around the world, three of them particularly for VIVAPUR®, guarantee supply chain security and business continuity, offering risk mitigation
- Regional manufacturing of VIVAPUR® in Europe, USA, and Asia to minimize duty, currency conversion and freight costs
- · Global sales network, local technical support
- Bar code labeling and vendor managed inventory possible
- · Warehouses in line with global pharmaceutical standards

#### Packaging and Sample Size

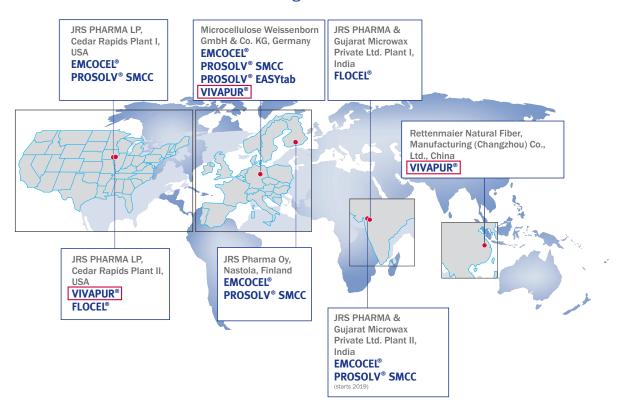
	Packaging Size	Pallet Size
VIVAPUR® All Types	20 kg carton box	400 kg US pallets, 320 kg EURO pallets
VIVAPUR® 105	17.5 kg paper bag	262.50 kg EURO pallets
Supersacks and Drum Packaging	available upon request	

Sample size: 400 g and 2 kg





#### JRS PHARMA - The Global MCC Manufacturing Network



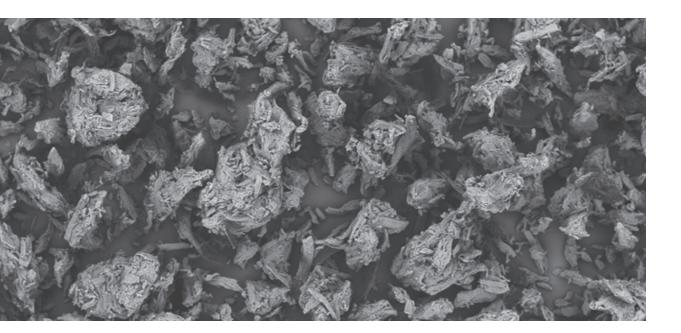


#### www.jrspharma.com

#### JRS PHARMA GMBH & CO. KG

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# **EMCOCEL®**Microcrystalline Cellulose



The Classic Premium MCC





#### **EMCOCEL®** - The Classic Premium MCC

#### Premium Quality MCC for Best-in-Class Performance in Direct Compression and Wet Granulation

**EMCOCEL® MCC** (Microcrystylline Cellulose) is an odorless, tasteless, white powder with a high degree of brightness, derived from highly purified wood pulp. With a wide range of chemical, technical, and economic benefits, MCC is one of the most widely used binder/filler excipients for tablet formulations. The **EMCOCEL®** line is JRS PHARMA's premium spray-dried MCC – with six grades available for common formulation needs. Decades of manufacturing high quality MCC in large volumes ensure high batch-to-batch consistency. In addition, Functionality Related Characteristics, such as bulk and tapped density, are analyzed and certified for all **EMCOCEL®** grades.

#### Benefits include

- · High compactability
- · Robust tablets with low friability
- · High production yields
- Practically inert compatible with most APIs
- Created from sustainable organic materials
- Contains no additives, impurities, or irradiated components
- Advanced carton packaging design for fast NIR identification (see pictures page 4)

#### Six Grades for Common Formulation Needs

Grade	Average Particle Size by Laser Diffraction (µm)	Bulk Density (g/mL)	Main Application
EMCOCEL® 50 M	65	0.25 - 0.37	Fine standard MCC grade, especially suited for wet granulation, roller compaction and spheronization.  Very high compactability.
EMCOCEL® 90 M	130	0.25 - 0.37	Medium size standard MCC grade, suited for the majority of directly compressible actives.  Combines good flow and high compactability.
EMCOCEL® XLM90	130	0.25 - 0.37	Same quality to grade 90M, but very low moisture content (< $1.5\%$ ) for processing water-sensitive actives.
EMCOCEL® HD90	130	0.38 - 0.50	Same quality to grade 90M, but increased bulk density and improved flow properties. Especially suited for high speed tableting and processing high density actives.
EMCOCEL® 90 M COARSE	170/175	0.25 - 0.37	Coarse, DC-grade MCC with excellent flow.
EMCOCEL® LP200	220	0.20 - 0.37	Coarse grade MCC, combines good compactability and high binding capacity with outstanding flow. Provides good content uniformity at low weight variation – even when used with low concentrations of fine actives.

#### Regulatory and Quality Assurance

EXCiPACT<sup>™</sup> certification in progress (Plant Microcellulose Weissenborn)

Audit questionnaire according to the IPEC GMP Audit guideline for bulk pharmaceutical excipients (BPE)

Conforms to Ph. Eur., NF, JP monograph requirements

CEP, US and Chinese\* Drug Master Files (DMFs) available

QbD data and historical production data available

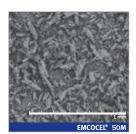
Full documentation package and regulatory support available

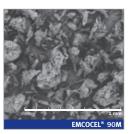
Elemental Impurity Information according to ICH O3D Guideline

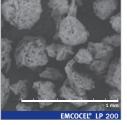
TUP profile according to IPEC guideline available Tableting functionality regularly tested to ensure consistent quality and performance

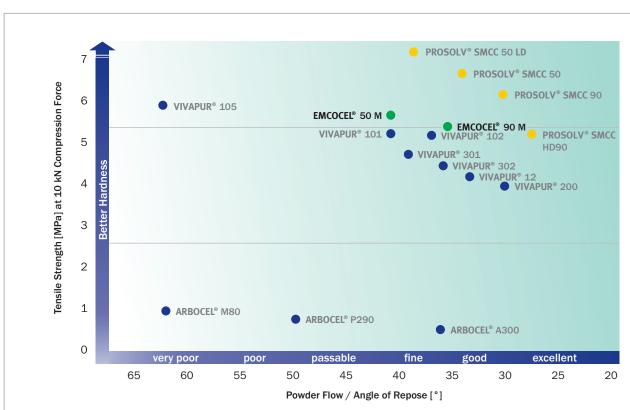
\*Chinese DMF, only for EMCOCEL® 90 M Coarse

- 100 % Plant Derived no BSE / TSE risks
- Genetically Modified Organisms (GMO) Free
- · Pesticide & Herbicide Free
- · Halal Certified
- · Kosher Certified
- Allergen free











#### The Global Excipient Maker

#### Logistics

- Regional manufacturing to minimize duty, currency conversion and freight costs
- · Global sales network, local technical support
- Bar code labeling and vendor managed inventory possible
- Warehouses in line with global pharmaceutical standards
- Multiple state-of-art manufacturing sites around the world guarantee supply chain security and business continuity, offering risk mitigation

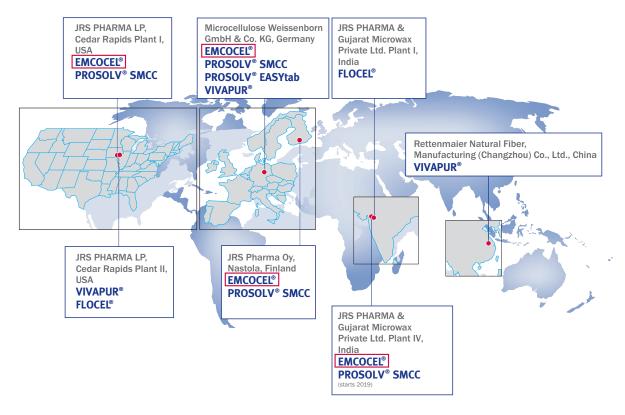
#### Packaging and Sample Size

All Types	Packaging Size	Pallet Size
Cartons	20 kg carton box with PE liner	400 kg US pallets, 320 kg EURO pallets
Paper Bags	20 kg paper bags with PE liner	400 kg US pallets, 320 kg Euro pallets
Supersacks and Drum Packaging	available upon request	

Sample size: 400 g and 2 kg



#### JRS PHARMA - The Global MCC Manufacturing Network





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#### JRS PHARMA GMBH & CO. KG

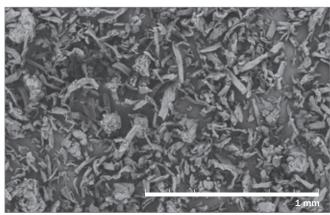
Business Unit Excipients 73494 Rosenberg (Germany) Phone: +49 7967 152-312 ExcipientsService@JRSPharma.de



#### **HEWETEN®** – The Essential MCC

# MCC for Direct Compression, Granulation, Spheronization, Capsules

Microcrystalline cellulose (MCC) is an odorless, tasteless, white powder derived from highly purified wood pulp. With a wide range of chemical, technical, and economic benefits, MCC is one of the most widely used binder excipients for tablet formulations.



Micrograph HEWETEN® 101

#### Benefits include

- · High compactability
- · Robust tablets with low friability
- High production yields
- Practically inert compatible with most APIs
- Contains no additives, impurities, or irradiated components
- Created from sustainable organic materials

#### Five Grades for Various Formulation Needs

Grade	Average Particle Size by Laser Diffraction (µm)	Bulk Density (g/mL) HEWETEN®	Main Application
HEWETEN® 101	65	0.25 - 0.31	Fine standard MCC grade, especially suited for wet granulation, roller compaction and spheronization.  Very high compactability.
HEWETEN® 102	130	0.27 - 0.33	Medium size standard MCC grade, suited for the majority of directly compressible actives.  Combines good flow and high compactability.
HEWETEN® 112	130	0.28 - 0.36	Same quality to grades 90M, but very low moisture content (< 1.5 %) for processing water-sensitive actives.
HEWETEN® 12	180	0.29 - 0.36	Coarse grade MCC, combines good compactability and high binding capacity with outstanding flow. Provides good content uniformity at low weight variation – even when used with low concentrations of fine actives.
HEWETEN® 200	250	0.31 - 0.38	Large size MCC grade with excellent flow properties for a variety of direct compression formulations.



#### Regulatory and Quality Assurance

EXCiPACT<sup>™</sup> certification in progress (Plant Microcellulose Weissenborn)

Conforms to Ph.Eur., NF, JP monograph requirements

Regulatory information including a US Drug Master File (DMF) available for easy registration in all major markets

Audit questionnaire according to the IPEC GMP Audit guideline for bulk pharmaceutical excipients (BPE)

Full documentation package and regulatory support available

TUP profile according to IPEC guideline available

- √ 100 % Plant Derived no BSE / TSE risks
- ✓ Genetically Modified Organisms (GMO) Free
- ✓ Pesticide & Herbicide Free
- ✓ Halal Certified
- ✓ Kosher Certified
- ✓ Allergen free

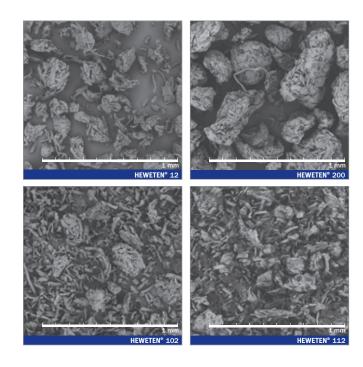
#### Logistics

- Regional manufacturing to minimize duty, currency conversion and freight costs
- Global sales network, local technical support
- Warehouses in line with global pharmaceutical standards
- Multiple state-of-the-art manufacturing sites around the world guarantee supply chain security and business continuity, offering risk mitigation

#### Packaging and Sample Size

	Packaging Size	Pallet Size
HEWETEN® All Types	20 kg carton box	400 kg US pallets, 320 kg EURO pallets
Supersacks and Drum Packaging	available upon request	

Sample size: 400 g and 2 kg





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