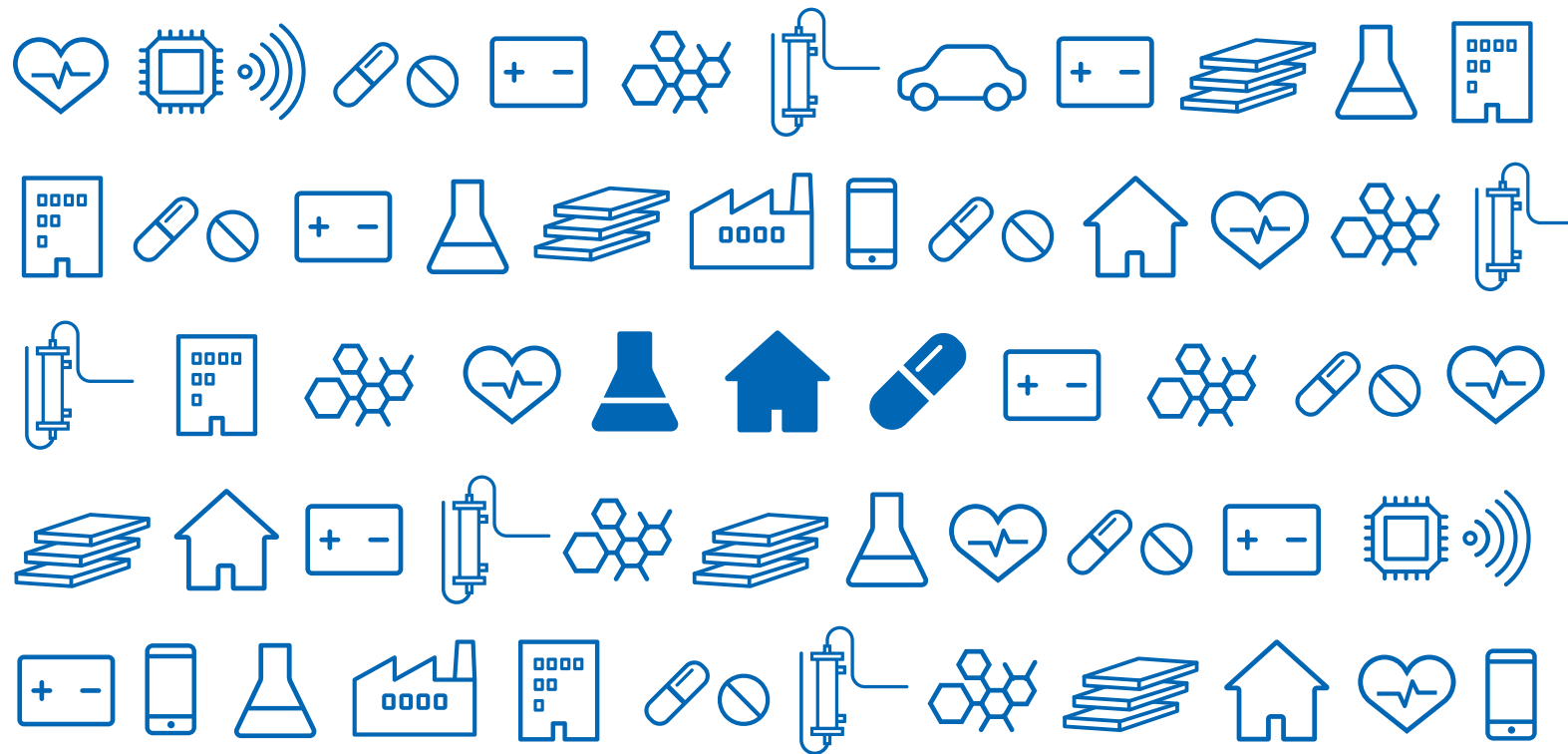


## PHARMACEUTICAL EXCIPIENTS PRODUCT GUIDE



**CEOLUS™**

**CELPHERE™**

**PC-10**

**KICCOLATE™**

## Creating for Tomorrow

The commitment of the Asahi Kasei Group:

To do all that we can in every era to help the people of the world make the most of life and attain fulfillment in living.

Since our founding, we have always been deeply committed to contributing to the development of society, boldly anticipating the emergence of new needs.

This is what we mean by “Creating for Tomorrow.”


### ASAHI KASEI AT A GLANCE

- Founding: 1922
- Sales: 19.7 billion USD (in 2018)\*
- Operating Profit: 1.8 billion USD (in 2018)\*
- Employee: 34,670 all over the world (as of March 31, 2018)




\* 1USD = 110JPY


### DIVERSIFIED CHEMICAL COMPANY WITH THREE BUSINESS SECTORS

#### Asahi Kasei Corp. (Holding Company Function)






**Material**

-  **Fibers & Textiles**
-  **Chemicals**  
Asahi Kasei Corp.
-  **Electronics**  
Asahi Kasei Corp.  
Asahi Kasei Microdevices Corp.  
Polypore International Inc.






**Homes**

-  **Homes**  
Asahi Kasei Homes Corp.
-  **Construction Materials**  
Asahi Kasei Construction Materials Corp.



**Health Care**

-  **Pharmaceuticals**  
Asahi Kasei Pharma Corp.
-  **Medical Care**  
Asahi Kasei Medical Co., Ltd.
-  **Acute Critical Care**  
ZOLL Medical Corporation

## OVERVIEW OF FUNCTIONAL ADDITIVES DIVISION

- We, Asahi Kasei started MCC production in 1970 in Nobeoka, a city in the South edge of Japan, which is the birthplace of Asahi Kasei group.
- Since the 2000s, we have been continuously developing MCC products that have unique performance which derives from our patented unique morphology design.
- Our products have helped customers with technical challenges among several product development stages such as lab, scale-up, and production.
- We will keep with our commitment to develop high performance and/or highly functional products that will benefit our customers.

## PRODUCTS LINE-UP

Product	Chemical Name	Main Application	Pharmacopoeia			
			USP/NF	Ph.Eur	JP	JPE
<b>CEOLUS™</b>	Microcrystalline cellulose (MCC)	Binder	●	●	●	
<b>CELPHERE™</b>	Microcrystalline cellulose (MCC)	Seed Core	●	●		●
<b>PC-10</b>	Pregelatinized starch	Binder Filler Granulation aid Disintegrant	●	●		●
<b>KICCOLATE™</b>	Croscarmellose sodium	Disintegrant	●	●	●	

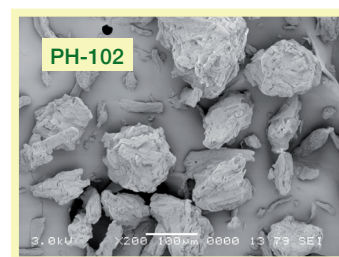
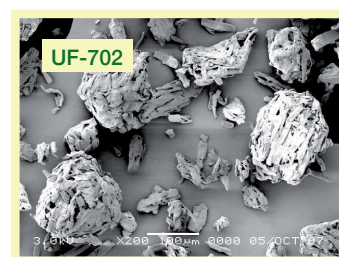
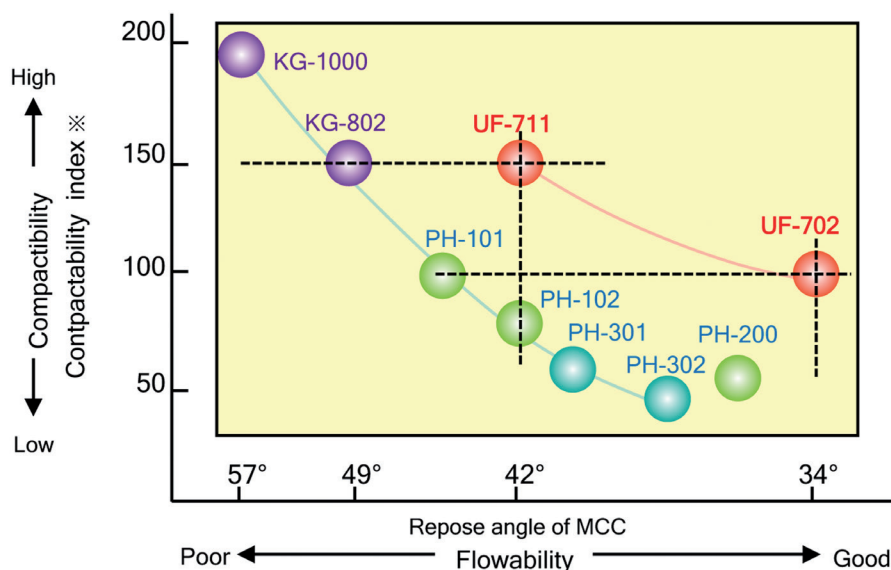
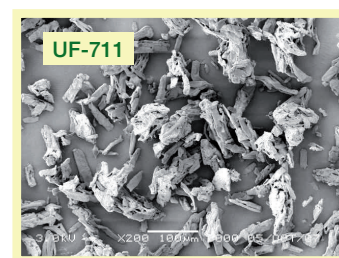
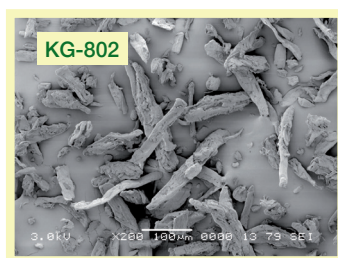
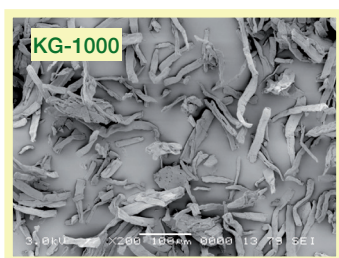
## KEY ATTRIBUTES

- High Performance (Problem Solver)
- Reliability (Made in Japan)
- High & Consistent Quality recognized in Japanese Pharma Industry
- Provided with good Regulatory Services  
(Statements/ Audit Report by third party /IPEC Standard Questionnaire)
- Quality Management System (JPEC-GMP /ISO9001/ ISO14001)
- Innovations (Product technology: Patented know-how/Special particle morphology)

# CEOLUS™

Our particle design and production technology produce high-performance MCCs. They are problem solvers for challenging solid dosage formulations.

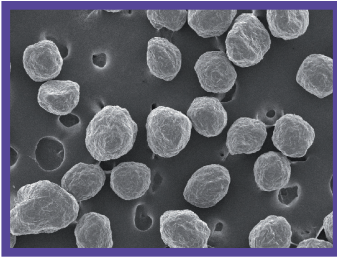
Product	Grade	Features	Performance	Benefits for Customers
Ceolus KG	KG-1000 KG-802	Rod-shaped particles	Super-compactability MCC	<ul style="list-style-type: none"> <li>Facilitate high-dose formulation</li> <li>Realize low pressure tableting</li> <li>Lower tablet friability</li> <li>Preventing sticking and capping</li> <li>Suitable for roller compaction</li> <li>Suitable for ODT, bilayer tablets, MUPS tablets</li> </ul>
Ceolus UF	UF-702	Round shaped and Porous MCC particle	<ul style="list-style-type: none"> <li>Super-flowability</li> <li>Swellability</li> <li>Adsorption on the particle surface</li> </ul>	<ul style="list-style-type: none"> <li>Improve poorly flowable formulations</li> <li>Fast disintegration and dissolution with sufficient hardness</li> <li>Prevent segregation and over-lubrication</li> <li>Facilitate high speed tableting</li> </ul>
	UF-711	Porous MCC particle	Well-balanced compactability and flowability	Optimized for tableting of poorly compactable and flowable formulations



※Tablet Hardness of PH-101 formulation defined as 100.  
Formulation : Acetaminophen / MCC=70 / 30, Tablet size : 500mg-φ11.3mm, Compression force : 7kN

## PACKAGE INFORMATION

- Polyethylene bag in kraft paper bag
- Net weight KG-1000: 10kg KG-802 /UF-702/ UF-711: 15 kg



## CELPHERE™

Celphere is a 100% MCC spherical seed core.

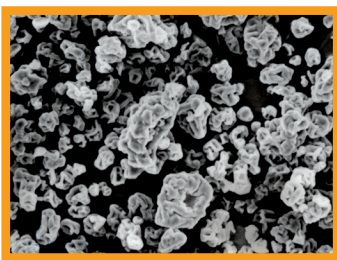
Features	Key Performance	Benefits for Customers
<ul style="list-style-type: none"> <li>• 100% MCC sphere</li> <li>• Smooth surface</li> <li>• Excellent sphericity</li> <li>• Narrow size distribution</li> </ul>	<ul style="list-style-type: none"> <li>• High Mechanical strength</li> <li>• Moderate water absorption</li> <li>• Low reactivity</li> <li>• Stable particle property</li> </ul>	<ul style="list-style-type: none"> <li>• Tolerant with high stress and coating machine varieties</li> <li>• Reduce aggregation</li> <li>• Yield improvement in coating</li> <li>• Stable storage stability</li> <li>• Suitable for controlled released formulations like MUPS</li> </ul>

## PARTICLE SIZE RANGE

CP-102	CP-203	CP-305	CP-507	CP-708
106~212µm	150~300µm	300~500µm	500~710µm	710~850µm

## PACKAGE INFORMATION

- Polyethylene bag in carton box
- Net weight: 20 kg



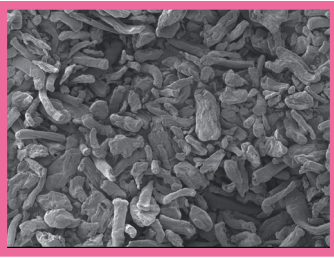
## PC-10

PC-10 is anaturally derived excipient manufactured by thermal treatment of raw corn starch, pregelatinized starch.

Features	Key Performance	Benefits for Customers
Partly pregelatinized starch with outer shell structure	<ul style="list-style-type: none"> <li>• High water retention capacity</li> <li>• Lower water-soluble content</li> <li>• pH independent disintegration</li> <li>• Low reactivity</li> </ul>	<ul style="list-style-type: none"> <li>• Toler-Stabilizer for moisture sensitive API</li> <li>• Granulation aid</li> <li>• Carrier for extracts</li> <li>• Dissolution enhancer</li> </ul>

## PACKAGE INFORMATION

- Polyethylene bag in kraft paper bag
- Net weight: 20 kg



## KICCOLATE™

Kiccolate is a croscarmellose sodium, which is widely used in oral pharmaceutical formulations as a super disintegrant for tablets.

Features	Key Performance	Benefits for Customers
High swellability Two grades with different setting volumes (swelling volume)	<ul style="list-style-type: none"> <li>Fast disintegration and dissolution</li> <li>Excellent API stability</li> </ul>	<ul style="list-style-type: none"> <li>High disintegration with small addition</li> <li>Storage stability</li> <li>Grade selection according to API</li> <li>Improvement in the disintegration of poorly soluble APIs</li> </ul>

Grade	Bulk density (g/cm <sup>3</sup> )		Particle size	Settling volume (cm <sup>3</sup> /g)
	loose	tapped		
ND-200	0.45	0.69	≤ 5% on 75µm	15
ND-2HS	0.44	0.65		23

## PACKAGE INFORMATION

- Polyethylene bag in fiber drum
- Net weight: 25 kg

## Notes and Precautions

### IMPORTANT PRECAUTIONS ON HANDLING AND USE

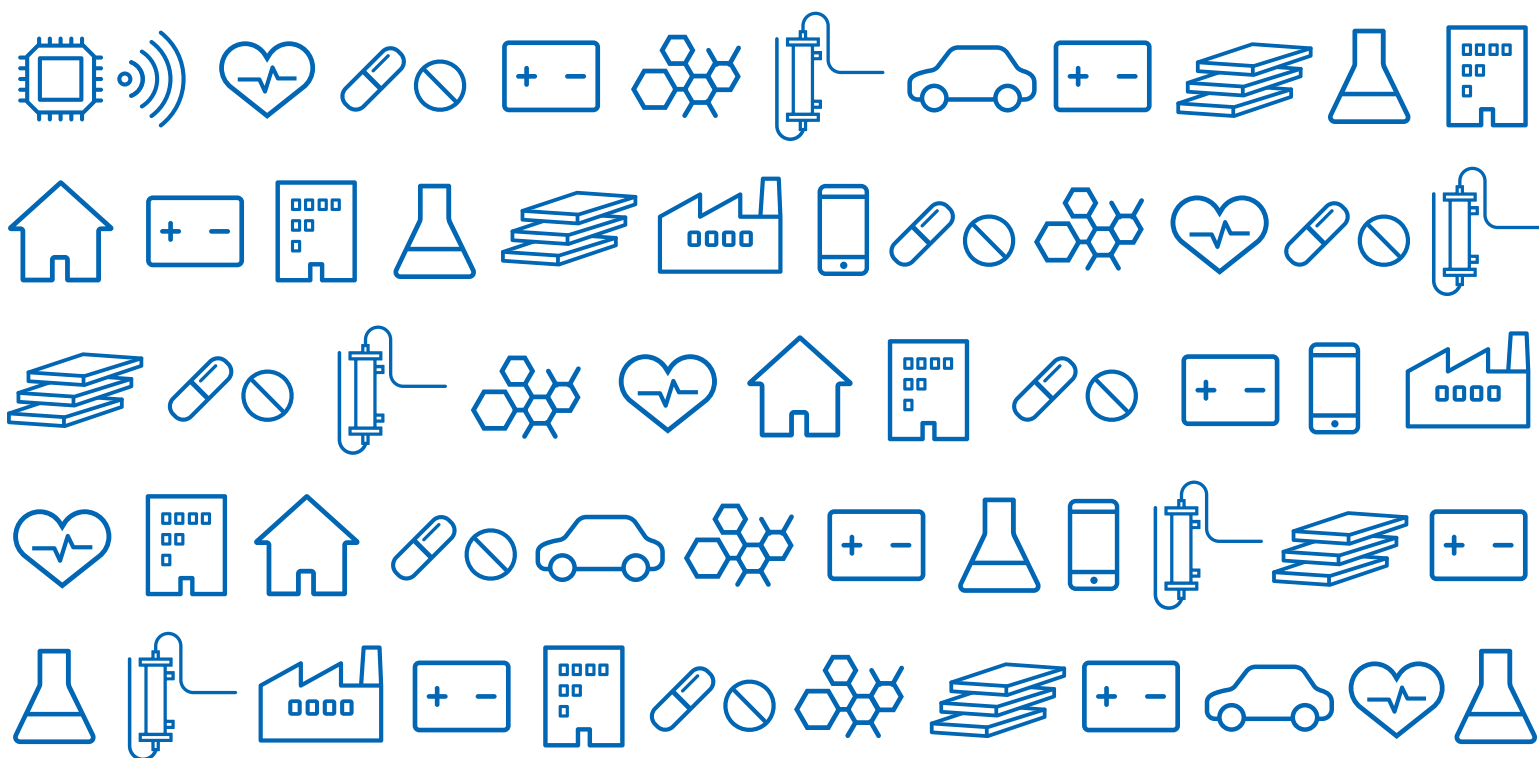
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- Consult Safety Data Sheet (SDS) before handling and/or use.
- May form explosive air-powder mixture on dispersion in handling, use, or from accumulated deposits on horizontal surfaces.
- Avoid contact with eyes. In case of eye contact, rinse with water for at least 15 minutes and get medical treatment if irritation occurs or persists.

### DISCLAIMER OF WARRANTY AND LIABILITY

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## ASAHI KASEI CORPORATION

CEOLUS Marketing & Sales Department  
 Functional Additives Division  
 1-1-2, Yurakucho, Chiyoda-ku, Tokyo 100-0006, Japan  
 Phone: +81-(0)3-6699-3361  
[ceolus@om.asahi-kasei.co.jp](mailto:ceolus@om.asahi-kasei.co.jp)

EUROPE:  
 Asahi Kasei Europe GmbH  
 Am Seestern 4, 40547 Düsseldorf Germany  
 Phone: +49-(0)211-8822-030

USA:  
 Asahi Kasei America Inc.  
 800 Third Avenue, 30th Floor, New York,  
 NY 10022 USA  
 Phone: +1-212-371-9900

INDIA:  
 Asahi Kasei India Pvt. Ltd.  
 The Capital 1502B, Plot No. C70 G Block,  
 Bandra Kurla Complex Bandra(East),  
 Mumbai 400051 India  
 Phone: +91-22-6710-3962

CHINA:  
 Asahi Kasei (China)Co.,Ltd.  
 8/F, One ICC, Shanghai International Commerce Centre,  
 No.999 Huaihai Zhong Road,  
 Shanghai 200031 China  
 Phone: +86-21-6391-6111

Asahi Kasei Corp., Beijing Office  
 Room 1407, New China Insurance Tower NO.12  
 Jian Guo Men Wai Avenue, Chao Yang District,  
 Beijing 100022 China  
 Phone: +86-10-6569-3939