

Asahi Kasei Microcrystalline Cellulose (MCC)

for Oral Solid Dosage Forms of Pharmaceuticals and Nutraceuticals

High Performance MCC



MCC Sphere



Business overview

Brand concept

Asahi Kasei Functional Additives Division

Asahi Kasei is a leading manufacturer of microcrystalline cellulose which has been continuously developing high performance MCC products steaming from innovative particle morphology.

Our first plant started its production in 1970 in Nobeoka, Miyazaki, Japan which has been the cradle of Asahi Kasei and has been supplying MCC products in the Japanese pharmaceutical market for over 50 years.

We have leveraged our expertise in the science and technology of developing standard and premium grades of microcrystalline cellulose which have caused our products to now hold a majority share in this market because of their reliability.

From 2023, we will operate a second manufacturing site in Kurashiki-shi, Okayama, Japan to meet the increase in demand and to achieve a stable supply through multiple production sites.

The most important value proposition of our MCC products is their ability to facilitate challenging and/or innovative formulations of pharmaceuticals and nutraceuticals that customers are bringing to market.

About Asahi Kasei

Asahi Kasei is a diversified Japanese chemical company with over a century of history.

We operate in the three business sectors of Material, Homes, and Health Care.



Material

Environmental Solutions Mobility & Industrial Life Innovation



Homes **Construction Materials**



Acute Critical Care

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."

Make The Smart Choice

There are a number of MCC products to choose from, but Asahi Kasei MCC products bring a key difference: they reflect the principle of what we call "Property Optimization." We at Asahi Kasei Functional Additives Division have adopted this concept to frame how our MCC products can help our customers achieve their intended product development objectives at a number of levels.

We define "property" as not only the physical attributes and performance standards of our MCC product, but also how it can affect development, approval and production issues our customers face as they bring their product to market. Our idea of "optimization" is to provide the MCC product that can best enable and enhance this process of developing the right formulation, facilitating regulatory approvals, implementing efficient production, and providing a quality product as a business deliverable for all of our customers' stakeholders.

Why are Asahi Kasei MCCs **The Smart Choice** for you?

Facilitating formulations

Our MCC products facilitate challenging formulations, solve tableting issues and enable unique and patient-friendly dosage forms.

The base for quality

Less black particles, less impurities and high-quality consistency of our MCC products directly contribute to the quality improvement of your formulations.

Production efficiency

Our MCC products contribute to your production efficiency by enabling high-speed tableting and reducing production problems.

High Performance MCC



MCC Sphere



Grade lineup

Product Name		Grades	Features
High Performance MCC Binder for oral solid dosage forms of pharmaceuticals and nutraceuticals	Ceolus™ KG	KG-1000 KG-802	Ceolus™ KG is a highly compactible MCC with fibrous particles. It enables poorly compactible and/or high dose formulations. It solves tableting issues such as insufficient hardness, sticking or capping.
CEOLUS TM Just Pure Performance	Ceolus [™] UF	UF-702 UF-711	Ceolus™ UF is a porous MCC with balance of compactibility and flowability. It enables a balance of tablet hardness and tablet disintegration. It solves tableting issues such as insufficient API content uniformity or over-lubrication.
	Ceolus [™] PH	PH-101, 102 PH-200 PH-301, 302 PH-F20JP	Ceolus™ PH covers every standard grade with high quality.
MCC Sphere Seed core for oral solid dosage forms of pharmaceuticals CELPHERE Reliability At The Core	Celphere™	CP-102 CP-203 CP-305 CP-507 CP-708	A 100 % MCC sphere, Celphere™ facilitates precise dissolution profiles of controlled release formulations by it's high sphericity and narrow particle size distribution.

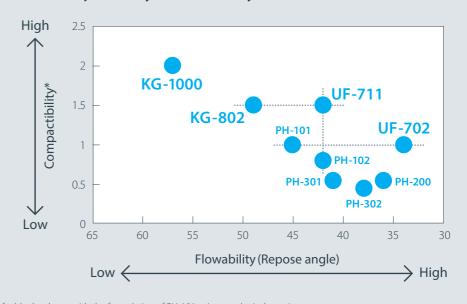
General properties of Ceolus™

Grade	Average particle size (μm)	Bulk density (g/cm³)	Repose angle (°)	Flowability	Compactibility	Disintegration
KG-1000	50	0.12	57		**	
KG-802	50	0.21	49		*	
UF-702	90	0.29	34	**		*
UF-711	50	0.22	42	*	*	*
PH-101	50	0.29	45	Standard	Standard	Standard
PH-102	90	0.30	42	*		
PH-200	170	0.35	36	*		
PH-301	50	0.41	41	*		*
PH-302	90	0.43	38	*		*
PH-F20JP	20	0.23	≥ 60	-	-	-

All values presented here are solely for the purpose of basic reference and should not be regarded as specifications.

*: Superior to Standard **: Very Superior to Standard Blank: Same as or Inferior to Standard -: No Data

Map of Ceolus™ Compactibility vs. Flowability



^{*} Comparison of tablet hardness, with the formulation of PH-101 = 1 set as the index point Formulation: Acetaminophen/MCC = 70/30



Ceolus[™] **UF**



Ceolus™ KG is a highly compactible MCC with fibrous particles. It enables poorly compactible and/or high dose formulations. It solves tableting issues such as insufficient hardness, sticking or capping.

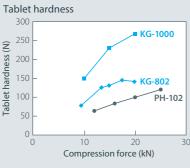
Functional benefits

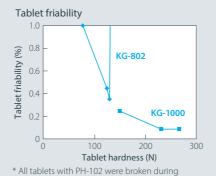
- Enables poorly compactible and/or high dose formulations
- Solves tableting issues Insufficient hardness, sticking, capping, high friability
- Enables unique and patient-friendly dosage forms MUPS, ODT, multiple-layer tablets, multiple-API-combination tablets, small tablets, mini tablets
- Enables low-pressure tableting Applicable for pressure-sensitive API tablets and coated granules

Function & features

- High compactibility
- High oil absorption
- Fibrous particles

Experimental example





the friability test due to inherent capping tendency

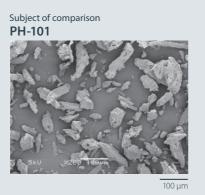
Metformin HCl/MCC/CCS/SiO₂/Mg-St=70.8/26.1/2.1/0.5/0.5(%),

Direct compression (Rotary Press), Tablet size: 760 mg, Φ12.0 mm -16 R

Grade lineup KG-1000







General properties

Grade	Average particle size (µm)	Bulk density (g/cm³)	Repose angle (°)	Loss on drying (%)	Water absorption (%)	Oil absorption (%)
KG-1000	50	0.12	57	2.0-6.0	290	210
KG-802	50	0.21	49	2.0-6.0	230	160

All values presented here are solely for the purpose of basic reference and should not be regarded as specifications.

Pharmacopoeia listings

JP: Microcrystalline Cellulose
USP/NF: Microcrystalline Cellulose
Ph. Eur.: CELLULOSE, MICROCRYSTALLINE

Packaging information

5 5		
Grade	Net weight	Packaging type
KG-1000	10 kg	Polyethylene bag in kraft paper bag
KG-802	15 kg	Polyethylene bag in kraft paper bag

Ceolus™ UF is a porous MCC with balance of compactibility and flowability. It enables a balance of tablet hardness and tablet disintegration. It solves tableting issues such as insufficient API content uniformity or over-lubrication.

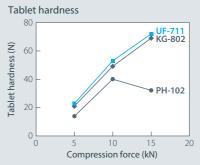
Functional benefits

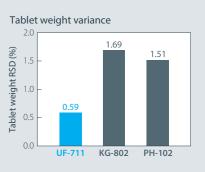
- Enables a balance of tablet hardness and tablet disintegration
- Solves tableting issues (Insufficient API content uniformity, over-lubrication)
- Enables poorly flowable and/or low dose formulations
- Enables high speed tableting

Function & features

- Balance of compactibility and flowability
- High swellability
- Low sensitivity to lubricant
- Porous particles

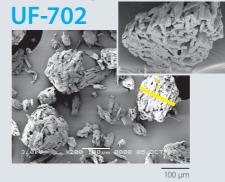
Experimental example

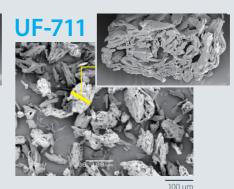


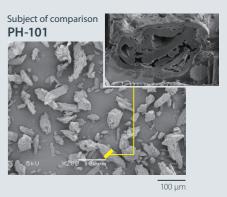


Ascorbic acid/MCC/Spray dried lactose/CCS/Mg-St=75/20/3/2/1.5 (extra) (%), Direct compression (Rotary press), Tablet size: 180 mg, Φ8 mm -12 R

Grade lineup







General properties

Grade	Average particle size (µm)	Bulk density (g/cm³)	Repose angle (°)	Loss on drying (%)	Water absorption (%)	Oil absorption (%)
UF-702	90	0.29	34	2.0-6.0	240	160
UF-711	50	0.22	42	2.0-6.0	240	150

All values presented here are solely for the purpose of basic reference and should not be regarded as specifications.

Pharmacopoeia listings

JP: Microcrystalline Cellulose
USP/NF: Microcrystalline Cellulose
Ph. Eur.: CELLULOSE, MICROCRYSTALLINE

Packaging information

Grade	Net weight	Packaging type
UF-702	15 kg	Polyethylene bag in kraft paper bag
UF-711	15 kg	Polyethylene bag in kraft paper bag



Celphere™



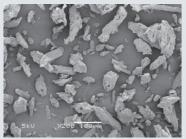
Ceolus™ PH covers every standard grade with high quality.

Grade lineup

PH-101, PH-102, PH-200, PH-301, PH-302, PH-F20JP

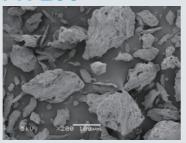
SEM images of particles

PH-101

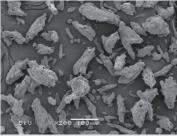


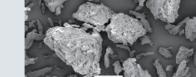


PH-200

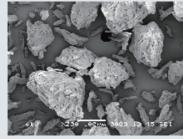


PH-301





PH-302



General properties

Grade	Average particle size (μm)	Bulk density (g/cm³)	Repose angle (°)	Loss on drying (%)	Water absorption (%)	Oil absorption (%)
PH-101	50	0.29	45	2.0-6.0	200	120
PH-102	90	0.30	42	2.0-6.0	200	140
PH-200	170	0.35	36	2.0-6.0	200	140
PH-301	50	0.41	41	2.0-6.0	150	90
PH-302	90	0.43	38	2.0-6.0	170	100
PH-F20JP	20	0.23	≥ 60	≤ 7.0	220	100

All values presented here are solely for the purpose of basic reference and should not be regarded as specifications.

Pharmacopoeia listings

Microcrystalline Cellulose USP/NF: Microcrystalline Cellulose Ph. Eur.: CELLULOSE, MICROCRYSTALLINE

Packaging information

i ackagiii	g iiiioiiiiati	OII
Grade	Net weight	Packaging type
PH-101	20 kg	Polyethylene bag in kraft paper bag
PH-102	20 kg	Polyethylene bag in kraft paper bag
PH-200	20 kg	Polyethylene bag in kraft paper bag
PH-301	25 kg	Polyethylene bag in kraft paper bag
PH-302	25 kg	Polyethylene bag in kraft paper bag
PH-F20JP	20 kg	Polyethylene bag in carton box

controlled release formulations by its high sphericity and narrow particle size distribution.

A 100% MCC sphere, Celphere[™] facilitates precise dissolution profiles of

Functional benefits

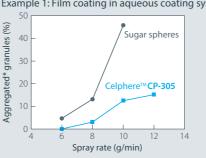
- Facilitates precise dissolution profile of controlled released formulation
- Yield improvement Reduces agglomeration, tolerance with high stress and coating machine varieties

Function & features

- High sphericity
- Narrow particle size distribution
- High mechanical strength

Experimental example

Example 1: Film coating in aqueous coating system



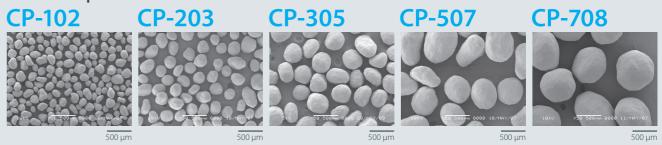
*Percentage of particles with particle size larger than 500 µm

Base granules : Vitamin B2 (2%) layered on Celphere™ or sugar sphere Film coating: Ethylcellulose aqueous dispersion/Triethyl citrate/HPMC/Water= 10.9/2.7/1.4/85 (up to 10% against base granules) Equipment: Wurster fluid bed coater

Example 2: Dissolution profile affected by shear stress

Drug layering: Theophylline/Corn starch/Sucrose=10/10/20 + HPC-L aq. (3 wt%)

Grade lineup



General properties

Grade	Particle size range (μm)	Sphericity	Bulk density (g/cm³)	Water absorption (%)	
CP-102	106-212	1.2	0.83	100	
CP-203	150-300	1.1	0.87	100	
CP-305	300-500	1.1	0.97	110	
CP-507	500-710	1.2	0.97	70	
CP-708	710-850	1.2	0.93	65	

All values presented here are solely for the purpose of basic reference and should not be regarded as specifications.

Pharmacopoeia listings

JPE: Microcrystalline Cellulose Spheres USP/NF: Microcrystalline Cellulose Ph. Eur.: CELLULOSE, MICROCRYSTALLINE

Packaging information

Net weight	Packaging type
20 kg	Polyethylene bag in carton box

Contact information

Worldwide locations of Functional Additives Division



Head office

Tokyo

Asahi Kasei Corporation

Hibiya Mitsui Tower, 1-1-2 Yurakucho, Chiyoda-ku, Tokyo 100-0006, Japan Phone: +81-(0)3-6699-3361 E-mail: ceolus_2@om.asahi-kasei.co.jp

Manufacturing sites

Nobeoka

1st Manufacturing site **Asahi Kasei Corporation**304 Mizushiri-machi,
Nobeoka-shi, Miyazaki 882-0015, Japan

Kurashiki

2nd Manufacturing site **Asahi Kasei Corporation**3-13 Ushiodori,

Kurashiki-shi, Okayama 712-8054, Japan

Marketing offices

Mumbai

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

New York

Asahi Kasei America, Inc.

800 Third Avenue, 30th Floor, New York, NY 10022, U.S.A. Phone: +1-212-371-9900

Düsseldorf

Asahi Kasei Europe GmbH

Fringsstraße 17 40221, Düsseldorf, Germany Phone: +49-(0)211-33-99-2000

Beijing

Asahi Kasei Corp., Beijing Office

Suite 2008, Gemdale Plaza, 91 Jianguo Road, Chaoyang District, Beijing, China Phone: +86-(0)10-6569-3939

110116. +60-(0) 10-0

Shanghai

Asahi Kasei (China) Co., Ltd.

8/F, One ICC, Shanghai International Commerce Centre, No. 999 Huai Hai Zhong Road, Shanghai 200031, China

Phone: +86-(0)21-6391-6111

Membership registration on the Asahi Kasei Functional Additives website

Benefits of membership:

- Download technical data sheets by specific applications
- Download quality assurance documents (e.g., SDSs, specifications, statements)
- News updates regarding Asahi Kasei MCC products (e.g., New technical data sheets)

To register, simply follow these steps:

- 1. Scan the QR code below to open the registration form.
- 2. Fill in your information as indicated on the web page.
- 3. Confirm the invitation e-mail that will be sent to your email address to complete your registration.



www.ceolus.com/en/members/signin/

Disclaimer of warranty and liability

- All information in this publication is provided in good faith and believed correct, but Asahi Kasei Corporation undertakes no
 obligation, liability, warranty, or other responsibility, express or implied, for its completeness or accuracy.
- It is the responsibility of the user to determine the suitability of the product for the intended use, and the information herein is provided only on this condition.
- Asahi Kasei Corporation is under no obligation whatsoever, whether express or implied, in relation to any loss or damage occurring in or arising out of the use of any product or information described herein.
- This publication does not represent and is not to be construed as a recommendation for any application or use of products, processes, equipment, or formulations described herein which may be in conflict with any valid patent.
- In relation to any and all of the above, Asahi Kasei Corporation is under no obligation or liability of any nature for any loss or damage, and undertakes no warranty relating thereto.

10

Asahi **KASEI**

