


## A new age for a versatile excipient? Why not!



Rapid success with an easy-to-use  
Hypromellose for pharmaceutical,  
food & personal care applications.

# BonuCel® – the flexible polymer for your formulation needs:

Tablet & capsule formulation

Film coating

Wet granulation

Binder

Modify & control release agent

Contact lenses

Capsule shell

Eye drops

Thickener (rheology modifier)

Melt extrusion

Stabilizer

Direct compression

Suspensions

Creams, gel & ointments



BonuCel® provides easy-to-use cellulose ethers for pharmaceutical and nutritional products. The main application of Hypromellose is film coating. The fine, homogeneous blends of selected high quality cellulose ether polymers provide excellent film forming properties and sustained release profiles. A wide range of standard viscosities is offered to deal with different application requirements. Additionally, BIOGRUND offers an exclusive service by finely adjusting viscosities.

Film coating with hydroxypropylmethylcellulose is a well known, established and effective technique. These coatings are now in widespread use throughout the world. BonuCel® does not interact with drugs, and it has a superior stability and non-ionic character, so it is also effective as a binder. Due to its more stable characteristics, BonuCel® can also be used instead of gelatine for cellulose capsule manufacturing.

The high-viscosity BonuCel®-types are exclusively designed for a hydrophilic matrix agent. This is the easiest sustained release technology for oral dosage forms, consisting essentially of a drug and a water-soluble high viscous polymer.

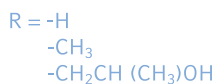
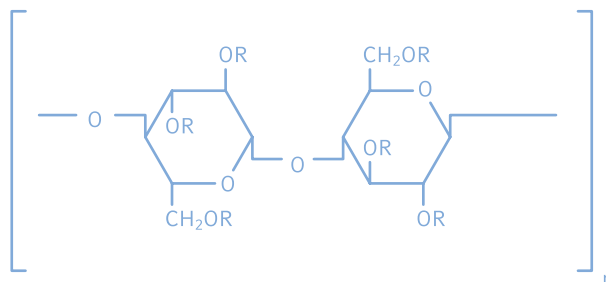
BonuCel® is produced in accordance with IPEC GMP guidelines and meets all requirements of USP/NF, Ph.Eur. and JP.

BonuCel® consists of highly purified cellulose fibres based on natural raw materials. Mainly renewable wood fibres are used as the primary raw material for the production of cellulose ethers.

## DESCRIPTION

Trade name	BonuCel®
Generic name	Hypromellose (Hydroxypropylmethylcellulose)
Abbreviation	HPMC
Chemical name	Cellulose, 2-hydroxypropyl methyl ether
CAS registry number	9004-65-3
Compendial status	USP / EP / JP

## STRUCTURAL FORMULA



## TYPICAL POLYMER PROPERTIES

film/gel forming, water-/organo-soluble, high swelling, viscosifying, non-caloric, hydrophilic, mucoadhesive

# How to dissolve pure BonuCel® H for a HPMC Solution

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## **IN WATER (A)**

Heat 1/3 of the total amount of water needed to above 70°C.

Quickly add all of the BonuCel® H to hot water while stirring well.

Add the remaining cold water (5 °C) to make the prescribed volume while stirring well.

Stir the solution for an additional 30 minutes, or until the solution is lump free.

If a high-power stirrer is used, BonuCel® H can be directly dissolved by adding it gradually to the water at below 30 °C with stirring. Care must be taken to avoid bubble or foam formation.

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## **IN ORGANIC SOLVENTS (B)**

Pour a prescribed volume of ethanol into a container and put all of the BonuCel® H in it while stirring.

When a uniform dispersion is obtained, add methylene chloride gradually and stir gently to form a well-wetted dispersion as the coating solution.

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## **TIPS**

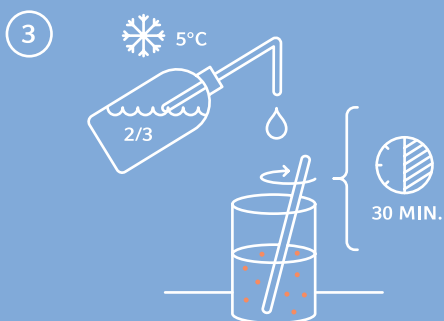
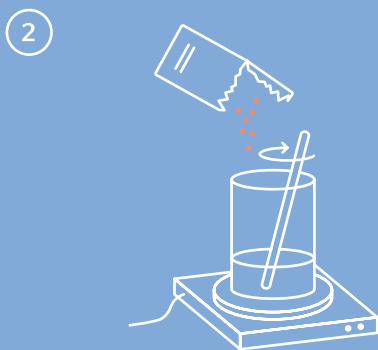
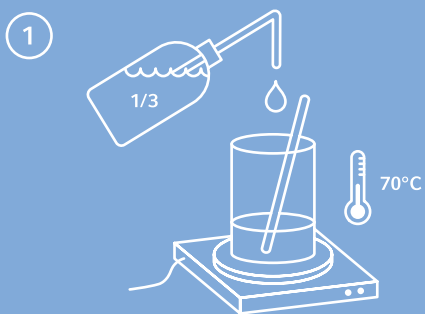
If BonuCel® H is added all at once into a previously prepared mixed solution, insoluble lumps will be formed.

If difficulties arise concerning the dissolution apparatus, removal of bubbles in the coating solution or filtration of solutions, BIOGRUND can offer technical advice based on extensive experience and know-how.

Great care should be taken to avoid any foreign material contamination. However, we recommend sieving the product and/or filtering the product solution before usage.

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A



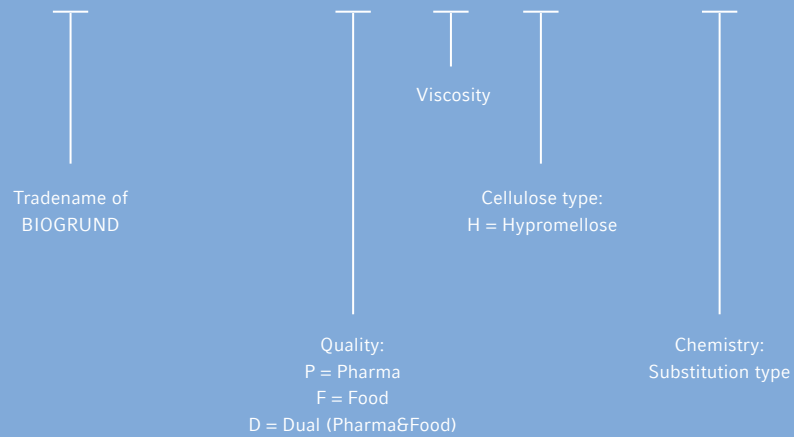
B



# Nomenclature

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BonuCel<sup>®</sup> D 6 H 2910



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#### NOTE

The suffix "BR" can be added to the end of some BonuCel<sup>®</sup> types. It identifies better release products.

# Specifications

Standard Grades	Viscosities (mPa-s)	Methoxy Content	Hydroxypropoxy Content	Typical Application	Function
BonuCel® D 3 H 2910	2.4–3.6	28.0–30.0 %	7.0–12.0 %	Film coating / Wet granulation	Film / Binder
BonuCel® D 5 H 2910	4.0–6.0	28.0–30.0 %	7.0–12.0 %	Film coating	Film
BonuCel® D 6 H 2910	4.8–7.2	28.0–30.0 %	7.0–12.0 %	Film coating	Film
BonuCel® D 15 H 2910	12.0–18.0	28.0–30.0 %	7.0–12.0 %	Film coating	Film
BonuCel® D 50 H 2910	40.0–60.0	28.0–30.0 %	7.0–12.0 %	Film coating / Suspensions	Film / Thickener
BonuCel® D 4000 H 2910	3000–5600	28.0–30.0 %	7.0–12.0 %	Thickening agent	Thickener
BonuCel® D 4000 H 2906	3000–5600	27.0–30.0 %	4.0–7.5 %	Thickening agent	Thickener
BonuCel® D 100 H 2208	80–120	19.0–24.0 %	4.0–12.0 %	Thickening agent / Sustained release	Thickener / Matrix
BonuCel® D 4000 H 2208	3000–5600	19.0–24.0 %	4.0–12.0 %	Thickening agent / Sustained release	Thickener / Matrix
BonuCel® D 15000 H 2208	11250–21000	19.0–24.0 %	4.0–12.0 %	Thickening agent / Sustained release	Thickener / Matrix
BonuCel® D 100000 H 2208	75000–140000	19.0–24.0 %	4.0–12.0 %	Thickening agent / Sustained release	Thickener / Matrix

**NOTE**

Other viscosities and grades with adjusted properties can be provided on request.

# Application

## Example of coating parameters for an aqueous solution (production scale)

### COMPOSITION OF COATING SOLUTION

BonuCel® D 6 H 2910	6 % BonuCel® / 94 % water
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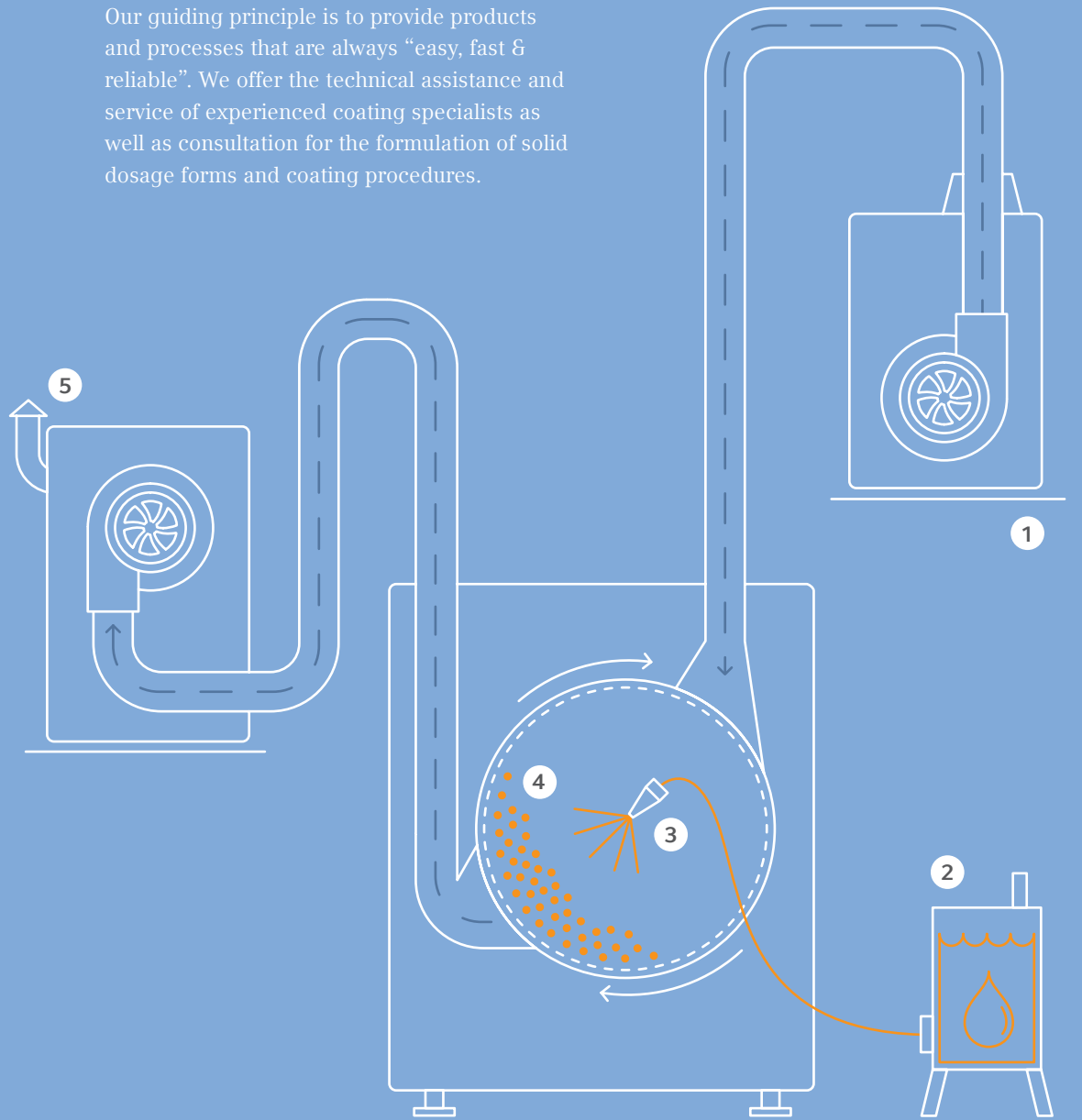
### COATING CONDITIONS

Apparatus	New Hi-Coater HC-130N (Freund corporation)
Dimension	1300 mm
Pan speed	8 min <sup>-1</sup>
Spray gun	Air spray gun X3 (AT type nozzle diameter 1.2 mm)
Drying air	80°C
Air flow rate	15 m <sup>3</sup> /min
Spray speed	70 g/min x3
Nozzle air	170 L/min
Nozzle air + pattern air	250 L/min
Tablet bed temperature	46°C
Charge per batch	120 kg
Dosage form	6.5 mm, 120 mg/Tablet



# Coating Process

Our guiding principle is to provide products and processes that are always “easy, fast & reliable”. We offer the technical assistance and service of experienced coating specialists as well as consultation for the formulation of solid dosage forms and coating procedures.



- 1 Blower (Air in)
- 2 Solution/Dispersion with Pump
- 3 Spray Gun
- 4 Tablet Bed
- 5 Blower (Air out)

# Specifications

## valid for all BonuCel<sup>®</sup> H (Hypromellose) Types

Appearance	white to slightly off-white powder	
Solubility	Practically insoluble in hot water, in acetone, in anhydrous ethanol and toluene. It dissolves in cold water giving a colloidal solution.	PhEur
Identity A, B, C, D, E	passed	USP/PhEur
Appearance of solution	passed	PhEur
Organic volatile impurities	passed	USP
Loss on drying	<5%	USP/PhEur
pH value	5.0 – 8.0	USP/PhEur
Sulphated ash	<1.5%	USP/PhEur
Heavy metals	<20 ppm	USP
Standard plate count	<10 <sup>3</sup> cfu/g	USP/PhEur
Yeast and mold	<10 <sup>2</sup> cfu/g	USP/PhEur
Coliforms	abs/g	USP/PhEur
Samonella	abs/10g	USP/PhEur

### REGULATORY AND QUALITY ASPECTS

All BonuCel<sup>®</sup>-types are developed to meet the official regulatory requirements of the user's country for pharmaceutical products and for nutritional or dietary supplements.

# Product Safety

**BIOGRUND encourages and expects you to read and understand the entire Material Safety Data Sheet, as it contains important information – especially the first-aid, fire-fighting and toxic information.**

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<b>HAZARDS IDENTIFICATION</b>	Classification of the substance/preparation: This product is not classified as dangerous, according to EC criteria.
<b>PERSONAL PROTECTION</b>	<p>Protective gloves are needed when handling this material. Consistent with general hygienic practice for any material, skin contact should be minimized.</p> <p>Use safety glasses. Safety glasses should be consistent with EN 166 or equivalent.</p> <p>Wash hands before smoking or eating.</p>
<b>HANDLING AND STORAGE</b>	<p>Good housekeeping with respect to dust is necessary for safe handling of product. Avoid dust formation. Provide exhaust ventilation if dust forms.</p> <p>Keep away from heat, sparks and flame. No smoking open flames or sources of ignition in handling and storage area.</p> <p>Store in a dry and cool place. Keep container well closed.</p>
<b>DISPOSAL</b>	<p>Any disposal practice must be in compliance with all local and national laws and regulations. Do not dump into any sewers or on the ground or in the water.</p> <p>According to local regulations, empty drums or containers can be washed out for recycling. Do not allow washing water to enter inter watercourses.</p> <p>Packing must be recycled in accordance with national and local regulations for environmental protection.</p>

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