THE ADVANTAGE IS EASY TO SWALLOW

LustreClear

MICROCRYSTALLINE CELLULOSE/CARRAGEENAN BASED AESTHETIC COATING SYSTEMS
The LustreClear advantage

Achieve flexibility and commercial advantage in clear coatings with LustreClear, FMC BioPolymer’s novel high-efficiency all-in-one coating system.

Unlike current conventional coating products, this unique aqueous film coating technology combines microcrystalline cellulose (MCC) and carrageenan to provide a distinctive, smooth satin finish on solid dosage forms. The combination of taste-masking and unparalleled ease of swallowing gives clear advantage in consumer preference and patient compliance.

LustreClear can be used to coat a wide variety of substrates, including waxy matrices and difficult to coat actives, such as ibuprofen. It allows for a lower temperature of operation, enabling the coating of thermosensitive drugs. And LustreClear’s ease of drying reduces susceptibility to overwetting.

The short preparation time, lack of foaming, low spraying viscosity, reduced clogging and ease of cleaning streamlines your coating operation, saving time and money.

Product reliability assurances

FMC BioPolymer is the global pharmaceutical market leader in microcrystalline cellulose and carrageenan.

Our manufacturing processes ensure consistent product quality. Global presence and sensible purchasing practices enable us to offer security of product supply. And LustreClear applications support is strongly reinforced by FMC’s wealth of technical expertise.

There is no logo bridging with LustreClear.

With LustreClear, there is minimal clogging or bearding of spray nozzles. This allows easier coating operation with less downtime.
The advantages of LustreClear begin with the coating preparation and extend through to the finished product. They include:

Coating preparation
- Easy to disperse
- No foaming

Coating process and time
- Easy to apply
- Faster drying time
- Wide processing temperature range

Superior sensory attributes
- Enhanced organoleptics
- Easier to swallow
- Unique taste masking

Robust film coat
- Coats both waxy matrices or actives
- Reduced logo-bridging
- Smooth, satin-like finish

Preparation of the LustreClear coating is completed in four easy steps.
LUSTRECLEAR
The innovative all-in-one aesthetic coating

• An aqueous film coating for tablets and other solid-dosage forms

• A novel technology based on the unique combination of carrageenan and microcrystalline cellulose (MCC)

• Greater flexibility in processing for a wide variety of products

• User-friendly process is easy to disperse and apply

• Saves both time and money

• Produces elegant coated dosage forms that are easier to swallow

• Provides unique taste masking
A film coating for pharmaceutical applications

Product specifications

**Specification**
- Identification, IR: Passes
- Loss on drying, %: NMT*6
- Residue on ignition, %: NMT 7
- Heavy metals, %: NMT 0.001

**Microbiological analysis**
- Total aerobic microbial count/gm: NMT 1000
- Total yeast and mold count/gm: NMT 100
- *Pseudomonas aeruginosa*: Absent in a 10g sample
- *Escherichia coli*: Absent in a 10g sample
- *Staphylococcus aureus*: Absent in a 10g sample

*NMT – Not More Than

**Typical properties**
- pH (4% solids): 5 – 8
- Loose bulk density (g/mL): 0.4 – 0.5
- Tap density (g/mL): 0.6 – 0.8
- Viscosity (10% w/w solids), cps: NMT 2000 (Brookfield #4, 20 rpm)
- Solubility – in water: partially soluble, dispersible

**Coating preparation**
- Use a propeller mixer of sufficient power and blade size to maintain a vortex as viscosity increases during dispersion. The dispersion is extremely shear thinning with low pumping and spraying viscosities.
- Slowly add LustreClear to the vortex of deionized water to form a 10% suspension, and continue mixing for approximately 1-3 hours, depending on the batch size, after which the dispersion is ready for spraying.
- Hot water may be used to lower the viscosity and facilitate dispersion.
- Film coat dispersion will be ready within 1-2 hours of mixing, depending on the water temperature.
## Suggested coating parameters

<table>
<thead>
<tr>
<th>Process condition</th>
<th>Ibuprofen</th>
<th>Acetaminophen</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAN</td>
<td>12&quot; Vector® LDCS equipped with 4 mixing baffles</td>
<td>48&quot; Accela-Cota® with 4 mixing baffles</td>
</tr>
<tr>
<td>RPM</td>
<td>12–16</td>
<td>3–6</td>
</tr>
<tr>
<td>Spray apparatus:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Guns</td>
<td>#1 Jet spray</td>
<td>4 Binks #95 air guns</td>
</tr>
<tr>
<td>• Fluid nozzle</td>
<td>1.0 mm</td>
<td>63BSS, 1.2 mm</td>
</tr>
<tr>
<td>• Air cap</td>
<td>134255-45-SS</td>
<td>66SD</td>
</tr>
<tr>
<td>• Atomizing air pressure</td>
<td>25 psi (1.7 bar)</td>
<td>60 psi (4.1 bar)</td>
</tr>
<tr>
<td>• Tubing</td>
<td>MasterFlex® #16</td>
<td>3/16&quot; ID x 3/8&quot; OD x 3/32&quot; WT</td>
</tr>
<tr>
<td>Delivery system</td>
<td>MasterFlex pump, digital console drive model 7523-30, fitted with #1 MasterFlex standard pump head</td>
<td>#2 MasterFlex pump Digi-Static model 75 with #2 MasterFlex standard pump heads/pump</td>
</tr>
<tr>
<td>Delivery rate</td>
<td>10–15 ml/min/gun</td>
<td>100–150 ml/min/gun</td>
</tr>
<tr>
<td>Exhaust air</td>
<td>Range 35°C – 45°C</td>
<td>Range 50°C – 65°C</td>
</tr>
<tr>
<td>Product temperature</td>
<td>Actual 37°C</td>
<td>Actual 38 – 43°C</td>
</tr>
<tr>
<td>Inlet air</td>
<td>Range 55°C – 60°C</td>
<td>Range 60°C – 79°C</td>
</tr>
<tr>
<td>Caplet charge</td>
<td>1.0 kg</td>
<td>120.0 kg</td>
</tr>
<tr>
<td>Coating weight gain</td>
<td>3%</td>
<td>3%</td>
</tr>
</tbody>
</table>

**Coating formulation**

<table>
<thead>
<tr>
<th></th>
<th>Gms</th>
<th>Wt%</th>
<th>Kg</th>
<th>Wt%</th>
</tr>
</thead>
<tbody>
<tr>
<td>LustreClear</td>
<td>30.0</td>
<td>10.0</td>
<td>3.6</td>
<td>10.0</td>
</tr>
<tr>
<td>Purified water</td>
<td>270.0</td>
<td>90.0</td>
<td>32.4</td>
<td>90.0</td>
</tr>
<tr>
<td>Total</td>
<td>300.0</td>
<td>100.0</td>
<td>36.0</td>
<td>100.0</td>
</tr>
</tbody>
</table>

The ingredients used in LustreClear products are chosen to meet the appropriate regulations and compendial standards of the United States, Europe and Japan as applicable to the specific LustreClear product's use as a coating on dietary supplements or as a coating on pharmaceutical products in these countries.
PRODUCT CHARACTERISTICS

LustreClear

microcrystalline cellulose/carrageenan-based coating system

Moisture barrier

LustreClear provides a moisture barrier similar to HPMC.

![Figure 1. 74% RH, moisture uptake of tablets - 3% coating.](image1)

Low viscosity

LustreClear has lower spraying viscosities than the pseudo-Newtonian HPMC, due to shear thinning. Viscosities are comparable at low shear rates.

![Figure 2. Apparent viscosity of 10% dispersion.](image2)
Stable viscosity
No substantial change in the viscosity profile after standing for 24 hours.

Temperature profile
HPMC undergoes thermal gelation above 50°C, which could lead to blockage in static lines at high temperatures. In contrast, LustreClear not only exhibits the typical thermal thinning of polymer solutions, but also sharply decreases in viscosity above 30°C.

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PRODUCT ATTRIBUTES

LustreClear
microcrystalline cellulose/carrageenan-based coating systems

Clearly the innovative cost-effective aesthetic coating system

LustreClear opens new possibilities in aqueous film coating for a wide variety of tablets and other solid-dosage forms. This advanced technology platform, based on the unique combination of microcrystalline cellulose and carrageenan, makes processing easier and offers distinctive sensory attributes.

Advantages of LustreClear

| Ease of use saves time and money | • Easy to disperse  
|                                 | • No foaming, de-aeration not required  
|                                 | • Coating can be completed the same day  
|                                 | • Minimal spray gun clogging or bearding  
|                                 | • Does not require stirring during use  
|                                 | • Product temperature can be maintained as low as 30°C  
|                                 | • Faster drying time  
|                                 | • Easy to clean  
| Elegant finished-product benefits | • Superior organoleptics  
|                                 | • Easier to swallow  
|                                 | • Reduced logo bridging  
|                                 | • Smooth finish  
|                                 | • Satin sheen  
|                                 | • Taste masking  
| An innovative aesthetic coating | • Lower spraying viscosities  
|                                 | • High spray rates  
|                                 | • Novel rheologies  
|                                 | • Coats waxy substrates  
| Regulatory advantages | • Global regulatory acceptability  
|                                  | • Tricompendial ingredients (U.S., Europe, Japan)  
| Comprehensive technical support | • Expert advice via phone or internet  
|                                 | • Face-to-face and web-based training  
|                                 | • Feasibility and applications development  
|                                 | • Equipment and process development  
|                                 | • Scale-up and technology transfer  
|                                 | • Manufacturing support and troubleshooting  

For technical support, call:  
United States: 800-526-3649  
Europe: 32-2-775-8311

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**PRODUCT STABILITY**

**LustreClear**

microcrystalline cellulose/carrageenan-based coating systems

### Shelf-life

Three years for all LustreClear grades when stored in original packaging under dry conditions.

### Stability programs

All LustreClear grades are set down for a minimum of three years in accordance with ICH stability guidelines, under the following storage conditions:
- Three years 25°C/60%
- Six months 40°C/75%

Stability programs include both:
- LustreClear raw material in commercial packaging
- Acetaminophen (Paracetamol) tablets coated with 3% LustreClear, in HDPE bottles

Results:
- No significant change in raw material rheology, pH or appearance
- No significant change in coated tablet properties
- Functionality of raw material unchanged after storage

### Physical properties of coated tablets (3% LC-103):

<table>
<thead>
<tr>
<th>Stability temperature condition</th>
<th>Time (months)</th>
<th>Hardness (kp)</th>
<th>Friability (%)</th>
<th>Disintegration time (min)</th>
<th>% Dissolved at 10 mins</th>
<th>% Dissolved at 30 mins</th>
</tr>
</thead>
<tbody>
<tr>
<td>25°C/60%RH</td>
<td>0</td>
<td>11.6</td>
<td>0.00%</td>
<td>2.0</td>
<td>82</td>
<td>99</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>11.1</td>
<td>0.03%</td>
<td>2.8</td>
<td>82</td>
<td>101</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>10.9</td>
<td>0.01%</td>
<td>2.8</td>
<td>86</td>
<td>100</td>
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<tr>
<td></td>
<td>12</td>
<td>11.1</td>
<td>0.05%</td>
<td>2.1</td>
<td>87</td>
<td>100</td>
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<tr>
<td></td>
<td>24</td>
<td>12.1</td>
<td>0.05%</td>
<td>2.1</td>
<td>83</td>
<td>98</td>
</tr>
<tr>
<td>40°C/75%RH</td>
<td>3</td>
<td>10.4</td>
<td>0.00%</td>
<td>2.6</td>
<td>85</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>9.9</td>
<td>0.03%</td>
<td>3.8</td>
<td>88</td>
<td>100</td>
</tr>
</tbody>
</table>

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SENSORY CHARACTERISTICS
LustreClear
microcrystalline cellulose/carrageenan-based coating systems

Innovative coatings for superior organoleptics

Today’s pharmaceutical market demands not only therapeutic efficacy, but also aesthetically appealing products with superior sensory characteristics. Significant benefits of enhanced sensory attributes include:

- Higher customer satisfaction
- Better patient acceptance and compliance
- Market differentiation and branding
- Greater product loyalty

Clearly easier to swallow

Tablets coated with LustreClear are easier to swallow. This can improve patient compliance, especially in pediatric and geriatric applications.

Clearly a better taste

LustreClear does not have the undesirable bitter or animal/protein related overtones of HPMC.
Clearly a better mouthfeel

The unique properties of LustreClear provide a clean and pleasant mouthfeel, reducing the perception of:

- Premature disintegration in the mouth
- Coating residue in oral cavity
- Sticking to the roof of the mouth

![Mouthfeel Comparison Graph]

Clearly the best choice

Tablets coated with LustreClear are easier to swallow, taste better and have a superior mouthfeel, when compared to HPMC.

Sensory analysis methodology

Independent expert panel testing of LustreClear coated tablets*:

- Uncoated tablets vs. tablets coated with HPMC or LustreClear (LC-103)
- Evaluation criteria: Taste, mouthfeel, and ease of swallow
- Rating by panel of six organoleptic experts
- 0 – 15 point universal scale, with 0 = none and 15 = very strong

*Source: Sensory Spectrum

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