Introduction

J.T.Baker® PanExcea™ performance excipient from Avantor™ Performance Materials consists of a binder, filler and disintegrant and is designed for use in direct compression manufacturing processes of Immediate Release (IR) drugs. Using a novel, water-based process, the patent pending PanExcea MHC300G performance excipient yields engineered spherical particles that provide excellent multifunctional characteristics, including increased flowability and compressibility. Enhanced applications performance is demonstrated by the improved variable Active Pharmaceutical Ingredient (API) loading capability mixing and compatibility, as well as the excellent content uniformity and consistent tablet disintegration.

The following tables represent a comparison between an Ibuprofen IR formulation containing PanExcea MHC300G performance excipient and an Ibuprofen IR formulation containing conventional excipients. The elimination of the use of multiple excipients is one of the key benefits of PanExcea MHC300G performance excipient.

### TABLE 1 IR Tablet Formulation Using PanExcea MHC300G Performance Excipient

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>% w/w</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ibuprofen</td>
<td>62.5</td>
</tr>
<tr>
<td>PanExcea MHC300G</td>
<td>36.5</td>
</tr>
<tr>
<td>Glidant</td>
<td>0.5</td>
</tr>
<tr>
<td>Lubricant</td>
<td>0.5</td>
</tr>
</tbody>
</table>

### TABLE 2 IR Tablet Formulation Using Conventional Excipients

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>% w/w</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ibuprofen</td>
<td>62.5</td>
</tr>
<tr>
<td>Binder — MCC</td>
<td>32.5</td>
</tr>
<tr>
<td>Disintegrant — CPVD</td>
<td>3.3</td>
</tr>
<tr>
<td>Diluent — HPMC</td>
<td>0.7</td>
</tr>
<tr>
<td>Glidant</td>
<td>0.5</td>
</tr>
<tr>
<td>Lubricant</td>
<td>0.5</td>
</tr>
</tbody>
</table>

Auxiliary excipients can be used along with PanExcea MHC300G to optimize tablet properties such as disintegration/dissolution. Excipients can be selected from any of the following:

- **Diluents:** Microcrystalline Cellulose, Lactose, Xylitol, Mannitol, Starch, Dicalcium Phosphate
- **Disintegrants:** Sodium Starch Glycolate, Crosscarmelose Sodium, Crospovidone, Starch 1500
- **Other Excipients:** Flavors, Colors, Stabilizers, etc.
- **Lubricants:** Magnesium Stearate, Talc, Colloidal Silicon Dioxide, Sodium Stearyl Fumarate

A few alternative processing methods for the preparation of select formulations using PanExcea MHC300G performance excipients for IR tableting applications are presented on the reverse.
Application Guidelines and Recommended Processing Methods for PanExcea MHC300G Performance Excipient

Method 1 — for Slightly to Moderately Cohesive APIs

• Coarse screen the API, PanExcea MHC300G performance excipient and other ingredients.
• Load the screened API and PanExcea MHC300G performance excipient into the suitable blender.
• Load other excipients (Glidant, Solubilizer, Stabilizer, etc.) and blend as required.
• Lubricate the blend and discharge for Tableting.

Method 2 — for Highly Cohesive or Lumpy APIs

• Pre-blend the API and PanExcea MHC300G performance excipient in suitable blender with Agitator bar on.
• Discharge the blend and pass through a mill equipped with a screen whose effective opening is larger than 200 micron (US Standard Sieve # 40 or lower).
• Load the milled material back into the blender.
• Add screened or milled flow agents (silica) and other ingredients and blend as required.
• Lubricate the blend and discharge the blend for Tableting.

Alternative Method for Highly Cohesive or Lumpy APIs

• Pass API through a mill, occasionally adding a few scoops of PanExcea MHC300G performance excipient to the mill. (This allows moderate dispersion and prevents API to form lumps after milling.)
• Load the milled material into the blender and blend as required with Agitator bar on.
• Add screened or milled flow agents (silica, etc.) and other ingredients and blend as required.
• Lubricate the blend and discharge for Tableting.

About Avantor™ Performance Materials

Avantor Performance Materials manufactures and markets high-performance chemistries and materials around the world under several respected brand names, including the J.T.Baker®, Macron Fine Chemicals™, Rankem™, Diagnova™, BeneSphera™, and POCH™ brands.

Avantor products are used in a wide range of industries. Our biomedical and life science solutions are used in academic, industry and quality control laboratories for research, pharmaceutical production and medical lab testing, while our electronics solutions are used in the manufacturing of semiconductors and flat panel displays. Based in Center Valley, Pennsylvania (USA), Avantor is owned by an affiliate of New Mountain Capital, LLC.

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