J.T.Baker® PanExcea™ MHC300G Performance Excipients for Immediate Release Applications

Introduction

J.T.Baker® PanExcea™ performance excipients from Avantor™ Performance Materials are manufactured using novel particle engineering technology and provide multifunctional performance, which enables fast and efficient drug development and manufacturing. The PanExcea family of performance excipients features homogeneous particles engineered to enable your Quality by Design (QbD) drug formulation initiatives, while reducing formulation complexities. All products in the PanExcea performance excipients product line are comprised of highly characterized, widely used Generally Recognized As Safe (GRAS) pharmaceutical materials. Full regulatory support is provided for customer applications.

Increased Revenues and Shortened Time to Market

PanExcea performance excipients improve supply chain, manufacturing, and regulatory efficiencies—speeding your product to market, while reducing your ownership costs and increasing your revenues.

- Implementation of direct compression will eliminate wasteful wet or dry granulation steps and reduce complexity
- Simplified manufacturing processes minimize regulatory costs and quality issues
- Reduced supply chain complexity eliminates costs associated with distribution, materials handling, quality control, and regulatory compliance

Increased Formulation Flexibility with Rapid Formulation Development

PanExcea performance excipients for immediate release applications have been designed with filler, binder, and disintegrant to provide increased excipient functionality or “all in one” excipients that enable robust and simplified formulation development processes.

- Variable Active Pharmaceutical Ingredient (API) loading capability of five percent to 75%
- Extensive API compatibility
  - Accommodates addition of auxiliary excipients
- Simplified drug formulations
- Potential to reduce tablet size and volume of excipients used
Enhanced Applications Performance

These ready-to-use PanExcea™ performance excipients are manufactured to assure consistency from lot-to-lot as well as homogeneity throughout the lot, assuring you of tablet content uniformity and robust tableting processes.

- Increases drug loading capability as a result of the novel particle morphology
- Optimized powder flow characteristics enable direct compression with high speed tableting to enhance productivity
- Delivers high compressibility for robust tableting of all Biopharmaceutical Classification System (BCS) API categories
- Provides desired disintegration times with exceptional tablet hardness

PanExcea performance excipients are optimized to drug formulations using direct compression. The products may be directly formulated with all classifications of APIs and accommodate dilution with, or addition of, auxiliary excipients as needed.

PanExcea Performance Excipients for Immediate Release (IR) Overview

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Product Number</th>
<th>Product Container/Size</th>
<th>Product Functionality</th>
<th>Product Composition*</th>
</tr>
</thead>
<tbody>
<tr>
<td>MHC300G</td>
<td>4489-08</td>
<td>25kg fiber drum</td>
<td>Filler, binder and disintegrant</td>
<td>Compendial grades of MCC, HPMC and CPVD</td>
</tr>
</tbody>
</table>

* MCC = microcrystalline cellulose; HPMC = hydroxypropylmethylcellulose; CPVD = crospovidone.

All raw materials are cGMP-manufactured, compendial grades and are currently listed in the FDA Inactive Ingredient Guide (IG List).

For your regulatory convenience and product safety, PanExcea MHC300G performance excipient is residual solvent and Bovine Spongiform Encephalopathy (BSE) free.

PanExcea MHC300G Typical Properties

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Results</th>
<th>Characteristic</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>True Density</td>
<td>1.54 g/cc</td>
<td>Compressibility</td>
<td>Less than 20%</td>
</tr>
<tr>
<td>Angle of Repose</td>
<td>Less than 35 degrees</td>
<td>Hausner Ratio</td>
<td>Less than 1.25</td>
</tr>
<tr>
<td>Flowability Index*</td>
<td>Greater than 85</td>
<td>D50</td>
<td>115µm</td>
</tr>
</tbody>
</table>


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.

For additional information please visit www.avantormaterials.com or follow www.twitter.com/avantor_news