Regulatory Status Overview

J.T.Baker® PanExcea™ Performance Excipients from Avantor™ Performance Materials

US FDA cGMP
- FDA registered and WHO certified cGMP site
- Q7A Quality System Design
  - Management of Change (MOC) assurance
  - Quality systems follow Q7 cGMP guidance
- IPEC Good Manufacturing and Distribution Practices
- Raw materials
  - USP grade and listed in FDA Inactive Ingredient List (IIG)
  - Robust Supplier Management Program

Regulatory
- DMF
  - PanExcea MHC300G registered as DMF Type IV, # 23071
  - PanExcea MC200G registered as DMF Type IV, # 24079
  - Stability, impurity profile and other relevant data included
- Inclusion in IIG list
  - Individual components and amount on list
- Can be quantified and shown within limits for specific formulation

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

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