



SPI Pharma Expands Mannogem® Mannitol Product Portfolio to support the development, manufacture and administration of oral dosage forms.

WILMINGTON, Del – March 16, 2020: SPI Pharma has announced an expansion of its line of Mannogem Mannitol products for use in multiple patient-friendly oral dosage forms to now include: Mannogem XL Opal, Mannogem XL Ruby, Mannogem Emerald, and Mannogem Onyx.

SPI Pharma has applied its proprietary manufacturing technology to address mannitol's inherently poor compressibility, producing new multifunctional, compendial grades of mannitol with superior binding and quick disintegration properties, greater compressibility, and tight particle size ranges.

SPI Pharma's new compendial mannitol grades are ideal for the formulation of convenient, patient-friendly dosage forms, such as orally-disintegrating tablets (ODTs) and chewables, with smaller tablet sizes and faster disintegration times further enhancing patient compliance. They broaden the options for overcoming issues with challenging formulations, such as content uniformity, poor API compressibility, and improved organoleptics.

Mannogem XL Opal and Mannogem XL Ruby

Mannogem XL Opal and Ruby enable formulators to efficiently develop sophisticated dosage forms, such as multiple unit particle systems (MUPS) and controlled-release (CR) ODTs. These products maintain the same properties as standard compendial mannitol, with the added benefits of SPI Pharma's proprietary technology.

Tablets formulated and produced using Mannogem XL Opal and Mannogem XL Ruby exhibit higher hardness, faster disintegration per tablet hardness, higher drug-loading capability, and significant improvement in friability. They also require less binder and can be made at lower compression forces.

"The extension of our Mannogem Mannitol product line reflects SPI Pharma's commitment to go beyond what our customers are seeking by assessing the market and anticipating their needs, as well as the needs of their customers," said President and Chief Executive Officer Jeanne Thoma.

Mannogem XL Opal enables higher production rates, as press speeds can be increased without compromising tablet robustness. The product's compaction mechanism reduces sensitivity to lubricant levels and extended blending times. With its high binding capacity, Mannogem XL Opal Mannitol can function not only as a filler but also as tablet binder. The result is high-quality, low-friability tablets equipped to withstand the stresses associated with film coating, printing, and packaging. Mannogem XL Ruby provides, for the first time, similar improvements in compressibility in a granular mannitol.

"Formulation is always challenging, and the advantages of mannitol have always been offset by the extra complications that it poses during formulation. These new products provide our customers with a solution that leverages the patient-centric benefits of mannitol while avoiding common formulation problems and simplifying manufacturing," added Sarath Chandar, Chief Scientific Officer in SPI Pharma's Applied Innovation Group.

Mannogem Emerald and Mannogem Onyx

The complete line expansion also includes Mannogem Emerald and Onyx — 25 µm and 50 µm mannitol powders. By broadening their portfolio with these two popular mannitol powders, SPI Pharma will enable customers to formulate with the confidence of a secure supply chain. When this confidence is combined with the expert technical service available through its dedicated pharmaceutical formulation staff, customers working with SPI Pharma are propelled to successful commercial launches.



An ABF Ingredients Company

About SPI Pharma

SPI Pharma, headquartered in Wilmington, Delaware, provides innovative solutions to global pharmaceutical and nutritional customers. Product lines include Antacid Actives, Excipients, Drug Delivery Systems, Taste-Masking, and Vaccine Adjuvants. SPI Pharma specializes in drug development services, having participated in over 60 commercially launched and marketed drugs globally. Leveraging the backing of its parent company, Associated British Foods plc, and its sites in the United States, France, and India, the company solves the most challenging formulation problems — efficiently, cost-effectively, and with a focus on service. For further information on SPI Pharma, please visit www.spipharma.com.

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