

Mannogem[®] XL Opal

Tech Bulletin

Increased Productivity and Improved Formulations

Mannogem XL Opal is a 160µm spray-dried, highly compressible, self-disintegrating excipient engineered to enhance mannitol's functionality in direct compression formulations and meeting NF, EP, and JP requirements. Opal combines SPI Pharma's mannitol material science with the patient-centric properties of spray-dried mannitol. Compared to industry-standard 160µm spray-dried mannitols, Opal offers superior tabletability, and can be used as an effective binder in a wide array of oral solid dosage forms to drive enhanced stability and manufacturing productivity.

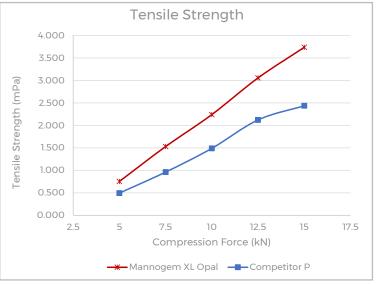
Opal helps pharmaceutical formulators overcome many of the common challenges of working with mannitol. Increased speed of development, enhanced manufacturing efficiency, improved product performance and patient satisfaction are just a few of the benefits formulators are realizing with Opal. It opens new ways to incorporate mannitol's stability and organoleptic profile into drug formulations. Opal allows the development of new and alternative dosage forms that satisfy the needs and preferences of patients.

Mannogem XL Opal and competitive 160µm spray dried mannitol were blended with 2.5% sodium stearyl fumarate to create placebo tablets of 500mg. Tablets were compressed under multiple compression forces and evaluated for robustness. Results are summarized in Figures 1 and 2. Mannogem XL Opal exhibits significantly improved compressibility compared to the competition.



Create robust tablets over a range of compression forces. Opal allows the development of new & alternative dosage forms that satisfy the needs and preferences of patients.

Figure 1: Mannogem XL Opal Shows Better Tensile Strength Than Competition for Multiple Compression Forces



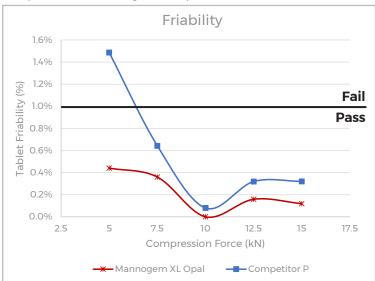


Figure 2: Mannogem XL Ruby Shows Lower Friability Than Competition Over a Range of Compression Forces



Opal is part of SPI Pharma's Mannogem XL suite of mannitol products. Beyond the performance advantages, Mannogem XL Opal was designed to be simple to use and easy to formulate. Its particle size distribution matches other standard spray dried materials, allowing for easier incorporation in new or existing formulations.

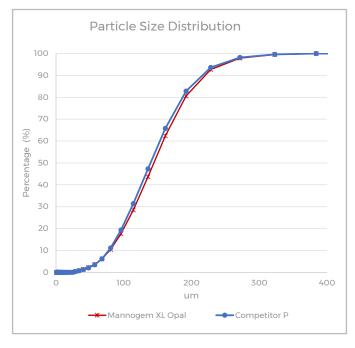


Figure 3: Mannogem XL Opal's Particle Size Distribution Matches Currently Available Standard Products



Our technical team is available to answer questions and discuss best practices. Contact us today for a sample.



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