



Mannogem[®] XL Ruby

Enhanced Formulations and Improved Patient Experience

Mannogem XL Ruby is a 300µm granular-grade mannitol meeting NF, EP, and JP requirements. Compared to traditional 300µm granular products, it exhibits superior tabletability combined with the soft texture organoleptic profile unique to granular mannitol. Mannogem XL Ruby is the latest innovation in granular mannitol from SPI Pharma. Due to its larger particle size, it helps to solve many of the formulation challenges associated with the development of chewable and orally disintegrating tablets.

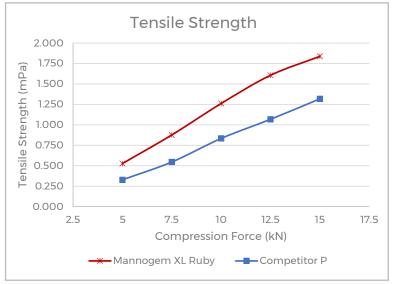
Mannogem XL Ruby is a product that can help to improve the patient experience and facilitate drug administration. For example, development of more pleasing chewable tablets incorporating large particle taste-masked APIs with enhanced mouthfeel has been limited because of difficulties creating robust tablets. For the first time, Mannogem XL Ruby enables development of these types of patient-centric formulations.

Mannogem XL Ruby and competitive 300µm granular mannitol were blended with 2.5% sodium stearyl fumarate to create placebo tablets of 500mg. Tablets were compressed under multiple compression forces and were evaluated for robustness. Results are summarized in Figures 2 and 3 below. Mannogem XL Ruby enables robust tablets to be formed with good tensile strength and friability across a range of compression forces. The competitive material was unable to provide consistent robust tablets.

Mannogem XL Ruby was designed to help simplify the formulation process. Ruby is compendial mannitol and has a particle size distribution similar to currently available mannitol excipients. This reduces the complexity of incorporating these compendial materials into existing and new formulations.

Ruby enables the creation of pleasing, robust chewable tablets incorporating large particle tastemasked APIs.

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



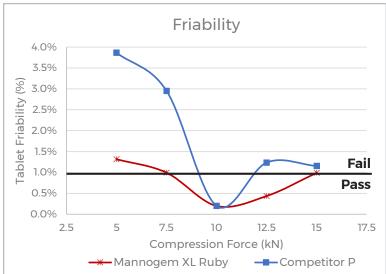


Figure 2: Mannogem XL Ruby Shows Lower Friability Than Competition Over a Range of Compression Forces

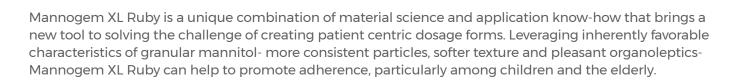
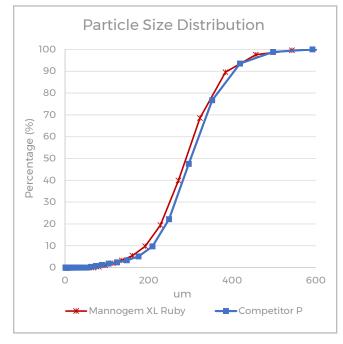


Figure 3: Mannogem XL Ruby's Particle Size Distribution Matches That of Currently Available Standard Products





Pleasant Organoleptics

SPI Pharma^{*} An ABF Ingredients Company

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Increased Operational Efficiency & Speed



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