SPI Pharma™
An ABF Ingredients Company

NEW PRODUCT!

Mannogem® XL Mannitol USP/EP

Highly Compressible | Self Disintegrating | Engineered Excipient

Introducing Mannogem XL, an innovative approach to mannitol designed to improve the formulation experience as well as to enhance formulation performance. It is a multifunctional, compendial grade of DC spray dried mannitol that provides superior binding and quick disintegration.

XL provides greater manufacturing consistencies through its performance and its tight particle size range. Using XL it is possible to increase patient compliance through tablet size reduction and faster disintegration times.

Mannogem XL retains the positive qualities of compendial mannitol while boasting enhancements:

- 25% higher tablet hardness
- 38% quicker disintegration per tablet hardness
- 50% higher drug loading capability
- 200% improvement in friability at a low compression force

XL is uniquely engineered to provide productivity improvements from development to manufacture, resulting in major gains in final dosage form consistency.

SPI Pharma's extensive knowledge of polyol chemistry and singular focus on the pharmaceutical industry allows us to provide solutions for our customers' processing needs. We know formulation can be challenging.

We develop and manufacture excipients of the highest quality to help formulators do their job better and to enable greater profitability for our customers. Please check with your sales rep or distributor to request a sample, or to order commercial/pilot quantities.

What is important to your formulation?
Superior compactibility
Simplified formulations
Speed development at lower costs
How?
Going beyond a standard diluent (filler) and performing as a binder with excellent disintegration, Mannogem XL enables production of difficult to compress and problematic formulations

What is important to your manufacturing process?
Experience fewer failures Create higher yields and tableting rates
How?
Advanced process control and design

What is important to caregivers?
Increase patient compliance
How?
Faster disintegration, ability to reduce tablet size, and formulation simplification

What is important to patients?
A positive experience when taking medication
How?
Utilize the qualities of mannitol including positive organoleptics, useful in formulation of chewable, fast melts and orally disintegrating tablets

Typical Property*	Mannogem XL
Average particle size d(50)	≈ 140µ
Bulk density (g/mL)	0.47
Tap density (g/mL)	0.55
Carr's Index	15
LOD (%)	< 0.3
*typical values for reference, not to be interpreted as specifications	

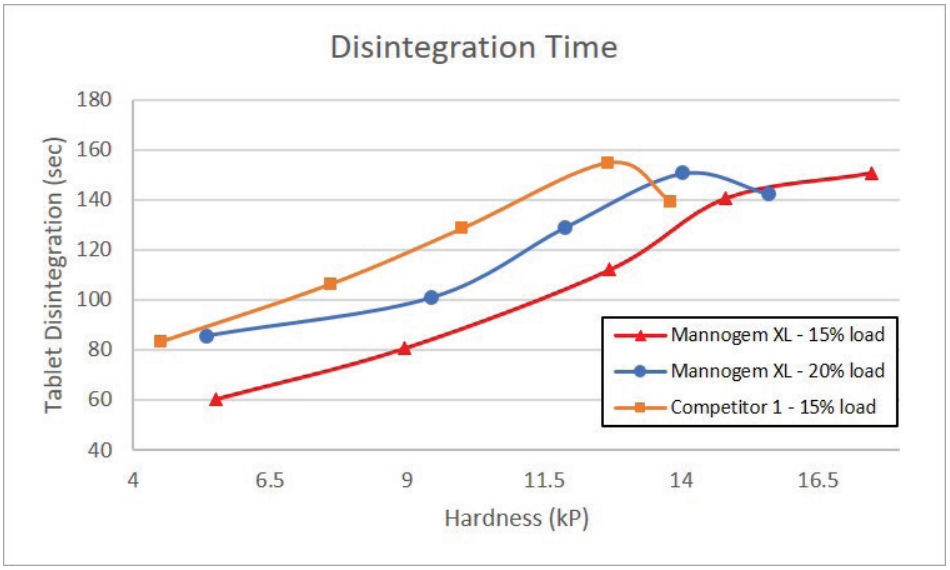

Figure 1. Disintegration time vs. hardness for various drug load of non-DC APAP.

Case Study 1: Comparison of Mannogem XL vs. leading competitor using non-DC APAP. 500mg FFBE tablets with 11 mm diameter were made with 15 and 20%. Tablets run at a 20 ms dwell time.

Mannogem XL is a multifunctional excipient, giving excellent compactibility and a faster disintegration time. Mannogem XL provides better disintegration time per hardness even under higher drug loads when compared to the leading spray dried mannitol (Figure 1).

Its more efficient binding function enables improved formualations and higher drug loading for difficult to compress actives.

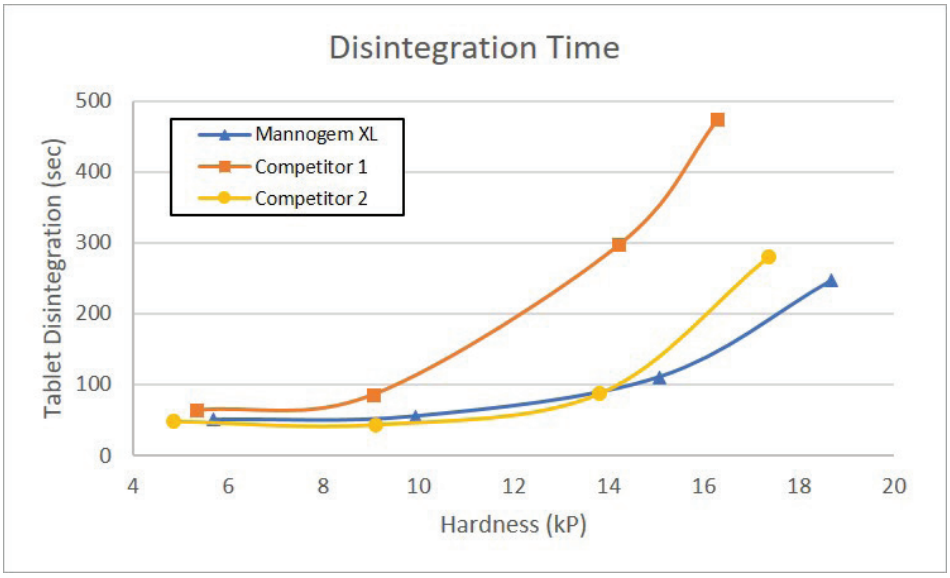

Figure 2: Tablet disintegration vs hardness for 1245 mg FFBE tablets with a diameter of 16 mm.

Case Study 2: Formulation made to mimic 160 mg Children's APAP chewable. 1245 mg FFBE tablets with a diameter of 16 mm. Tablets normalized to hardness at a 20 ms dwell time and set to recover for 24 hrs.

Mannogem XL's tight particle size control and process optimization is essential to speed up and simplify development. Compared to other spray dried mannitols, Mannogem XL enables the production of superior tablets (Figure 2).

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