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Technical Bulletin

Mannogem® XL Mannitol USP/EP/JP

Superior Tabletability

Mannogem XL is an innovation in directly compressible spray-dried mannitol. XL is designed to deliver a higher level of performance during formulation, manufacture, and patient use; simply a step-change in DC mannitol performance.

Introduction

Tabletability can be defined as the ability of a powder to form a tablet of adequate strength when force is applied to that powder[1] and is generally assessed by means of testing the resultant tablet hardness, tensile strength, and friability. For conventional swallow tablets, a tensile strength of > 1.7MPa[2] is generally seen as the minimum requirement to show adequate tablet robustness.

Background

Studies were undertaken comparing the tabletability of Mannogem XL to a standard spray dried mannitol competitor product. Tablets were formulated with non-direct compressible APAP chosen as a difficult-to-tablet model compound and compressed using 0.551" FFBE tooling to a tablet weight of 500 mg. Samples were taken at the various compression forces and tested to evaluate tensile strength and friability. The data are presented in Figures 1 and 2 below.

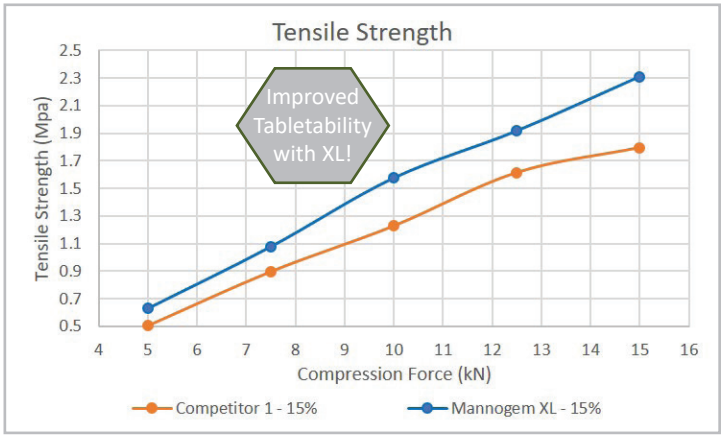

Figure 1: Tablet tensile strength (MPa) versus compression force (kN) for Mannogem XL and a competitor spray dried mannitol at 15% drug loading.

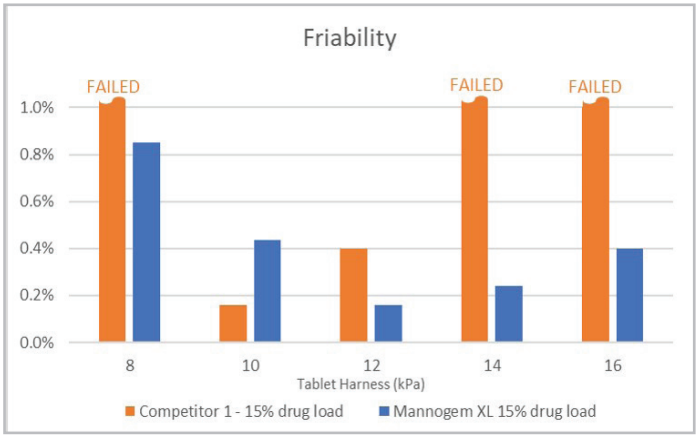

Figure 2: Tablet friability (%) versus tablet hardness (kP) for Mannogem XL and a competitor spray dried mannitol at 15% drug loading.

Results

Data show a 25% increase in the tabletability of the formulation when using Mannogem XL at 15% drug loading. A completely linear profile for tensile strength versus compression force indicates a robust formulation that is not prone to tablet problems such as capping.

Tablet robustness is a key Critical Quality Attribute for any formulation and is assessed in terms of both tensile strength as above but also in terms of friability. An ideal formulation will have a requisite high tensile strength and associated low friability at a range of compression forces. Formulations based on Mannogem XL achieve the requisite target for swallow tablets of 1.7MPa TS at lower compression forces than for other mannitols and retain low friability. Data in Figure 2 show good friability over a range of tablet hardness when using XL vs competitive product. Such formulations can be considered robust and therefore less prone to scale-up issues or failures during manufacture.

Mannogem XL has superior tabletability to other conventional spray dried mannitols, leading to the possibility of higher drug loadings in more robust tablets. This has multiple benefits:
Patients
Smaller, less friable tablets
Formulators
Simpler and quicker development that is less prone to scale up issues
Manufacturers
Faster speeds, at lower compression forces and less failures improve productivity, cost efficiency, and reduced tooling wear and tear

References

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2. Developing Solid Oral Dosage Forms 2nd Edition, Pharmaceutical Theory and Practice, p905 Edited by Qiu Y, Chen Y, Zhang G, Yu L and Mantri R.U 2017.Carino, G. and Mathiowitz, E. Oral insulin delivery, Adv. Drug Del. Rev. 35, 249-257 (1999).

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