

Mannogem® Mannitol

Improved Formulations, Better Tablets

www.spipharma.com



Increased Productivity



Your team works hard to create a product that patients want to take. Selecting an excipient that makes their job easier and the patient experience better can be a challenge. Improve the patient experience and benefit from efficient manufacturing operations by formulating with **Mannogem Mannitol**.

Efficient Operations

Higher production rates are possible with Mannogem Mannitol direct compression grades because tablet robustness is not compromised with increased press speeds. Mannogem has low sensitivity to press speed and can be tableted over a wide range of dwell times. Its compaction mechanism, based on the increased surface area resulting from brittle fracture deformation,

reduces sensitivity to lubricant levels and extended blending times. The high binding capacity of Mannogem makes it an excellent tablet binder, capable of producing quality, robust tablets at lower compression forces. These attributes yield low friability that can withstand the stresses associated with film coating, printing and packaging.

Improved Formulations, Better Tablets

Safeguard the chemical and physical stability of the API and excipients within a formulation. Low hygroscopicity adds protection against moisture, and Mannogem Mannitol does not promote acid-base reactions, oxidation, or react with primary amines.

Mannitol dissolves rapidly while retaining porosity, making it the excipient of choice in lyophilized and directly compressible orodispersible formulations. More of the API can be available because it does not become entrained with insoluble binders. This can allow less API to be used, leading to fewer side effects for the patient and reduced cost for the manufacturer.

Improved Patient Experience



Excellent Mouthfeel

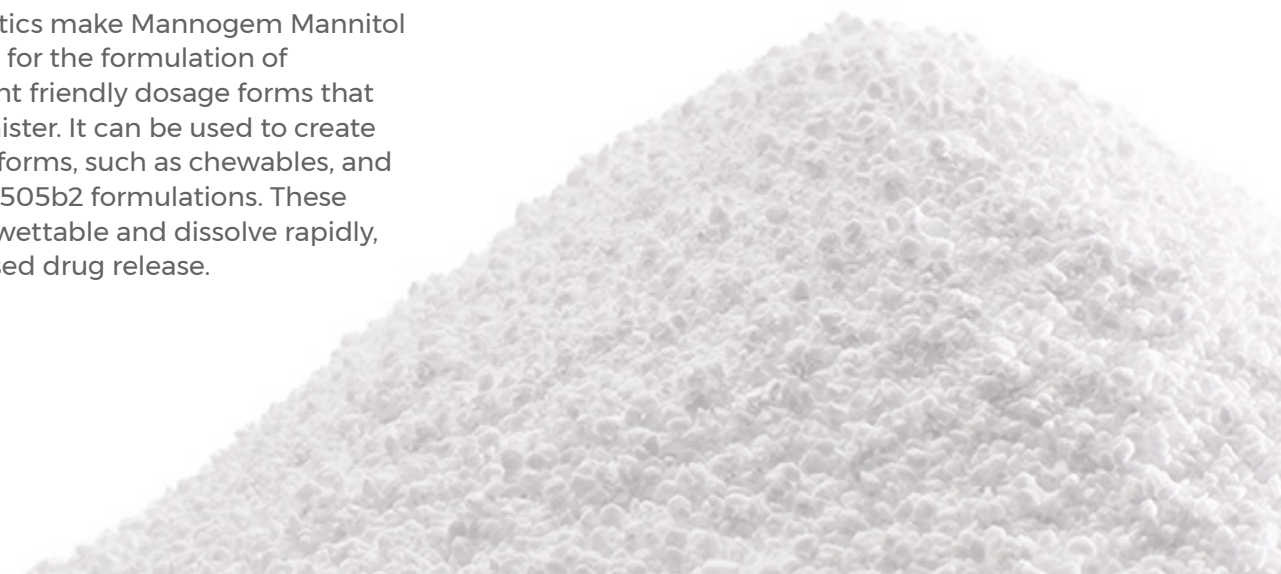
Mannitol has a negative heat of solution which imparts a cooling sensation. It dissolves quickly, delivering excellent palatability through a creamy texture and a mild sweetness.

Compliance

Mannogem Mannitol helps improve the palatability of tablet formulations, and can enable formulators to create dosage forms which are easier to take, and more portable. Mannogem can help drive compliance, particularly with sensitive populations such as children and the elderly.

Innovation

These characteristics make Mannogem Mannitol an ideal excipient for the formulation of convenient, patient friendly dosage forms that are easy to administer. It can be used to create alternate dosage forms, such as chewables, and has been used in 505b2 formulations. These grades are easily wettable and dissolve rapidly, leading to increased drug release.



Direct Compression Grades

Mannogem XL Technology

Mannogem XL is an innovative way to create mannitol for direct compression. The technology is designed to improve the formulation experience as well as to enhance formulation performance. It creates multifunctional, compendial grades of DC spray dried mannitol that provides superior binding and quick disintegration, resulting in superior tabletability.

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.

Products created with Mannogem XL technology retain the positive qualities of compendial mannitol while boasting enhancements over standard competitive mannitol:

25% Higher Tablet Hardness

38% Quicker Disintegration per Tablet

50% Higher Drug Loading Capability

200% Friability Improvement at Low Compression Force

Spray-Dried Mannogem

The proprietary spray dry process used to manufacture Mannogem yields a porous material with lower disintegration times, a narrow particle size distribution, enhanced flow, and compression properties. It is due to these properties that Mannogem is excellent in ODT formulations.

It produces tablets with higher hardness than other excipients at comparable compression forces, and its higher surface area allows Mannogem to work well as a base for ordered mixing with micronized APIs and low dose formulations.

SPI Pharma has innovated spray dried mannitol to provide even higher compactability. Mannogem XL technology creates a mannitol designed to improve the formulation experience and enhance formulation performance. The result is a multifunctional, compendial grades that provides superior binding and quick disintegration.

Mannogem Granular Grades

Granular Mannogem Grades are manufactured through a wet granulation process and have a larger particle size than our Mannogem spray dried material. They exhibit excellent flow, disintegration and compression properties. These products are ideal for formulating tablets with taste masked APIs, which often have a larger particle size due to the taste making process.

Mannogem Granular has a larger particle size that has shown to contribute to a softer texture for chewable tablets. The larger particle size allows it to match specific particle size and density constraints to minimize segregation during transport and manufacturing.

Mannogem 2080 has a smaller average particle size and a tighter overall particle size range. This lower particle size produces higher surface area relative to Mannogem Granular, making it an effective API carrier system.

Mannogem Powder

Mannogem Mannitol Powder is an excellent excipient for use in wet granulation and lyophilization. It dries rapidly, resulting in shorter processing time and increased productivity.

Mannitol is also a good excipient for hot melt extrusion applications. It melts without decomposition at a temperature of approximately 165° C. Its rapid recrystallization upon cooling make it an attractive carrier to improve solubility of poorly soluble APIs.

User Guides



Application Guide for Operations

Mannogem Mannitol allows for higher production rates, reduced sensitivity to lubricants, low friability, and high binding capacity. Your team will want to work with Mannogem because it makes your operation run more efficiently.

Reference the chart to the right/below to find your process of choice. There, you will be able to see which grade of Mannogem best suits your needs.

Once you have determined the grade that works for you, contact us for a sample. Our technical team is available to answer questions and discuss best practices.

Mannogem XL			
Mannogem EZ			
Mannogem Granular and 2080		Mannogem Powder	
✓	✓		Dry blending of micronized and low dose actives
		✓	Dry blending
✓	✓	✓	Direct compression
✓	✓	✓	Roller compaction
		✓	Wet granulation
		✓	Lyophilization
		✓	Hot melt extrusion

Use-Based Formulation Guide

Development of dose forms that are age-appropriate and acceptable to patients is a clear trend with regulators. The excellent organoleptics of Mannogem, together with its high compatibility and improved tableability of our XL Grade over standard mannitol, mean that it can be used by formulators in projects to cover a wide range of dose form concepts and dosage strengths.

The chart below illustrates dosage form options and which grade of Mannogem Mannitol works best for the desired product.

Our regionally-based technical experts are available to come and work with your team to optimize the formulation and delivery method of your choice. Contact us to request a sample and get started.

Mannogem XL				
Mannogem EZ			Mannogem Granular and 2080	
		Mannogem Powder		
				Swallow tablets
				Orally disintegrating tablets
				Chewable tablets and lozenges
				Tablets with taste masked APIs
				Sachets and stickpacks
				Liquid suspensions/syrups
				Effervescent tablets



Excipients for Swallow Tablets



Taste Masked Actives



ODTs/ODPs



Effervescent Tablets



Vaccine Adjuvants



Soft Gel Capsules



Antacid & Laxative Ingredients



Chewable Tablets & Lozenges



Nutraceutical Applications

Improve the patient experience and benefit from efficient manufacturing operations by formulating with Mannogem Mannitol.

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