

# Mannogem<sup>®</sup> Mannitol

Product Selection Guide



# Select with Confidence



## The Mannogem<sup>®</sup> Advantage

Your team works hard to create a product that patients want to take. Selecting an excipient that makes your job easier, and the patient experience better, can be a challenge. Mannitol is a popular choice for its stability, solubility, hygroscopicity and crystalline properties. SPI Pharma's highly functional line of Mannogem Mannitol products, paired with unparalleled technical expertise, can help you to overcome issues with complex formulations. Reference the chart below to determine which Mannogem grade best suits your formulation 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 Grade	PSD (D50 μm)	Properties		Dosage Form					Process							
		Compressibility	Flowability	Swallow	ODTs	Chewables	Capsules	ODPs •	Direct Compression	Dry Granulation	Wet Granulation	Hot Melt Extrusion	Semi- Solids	Liquids	Freeze Drying	Formulation Usage
Spray-Dried	Mannitol															
XL Opal	160	****	****	~	$\checkmark$	$\checkmark$			~	*						† Ideal for challenging DC formulations for tablets, chewables, and ODTs
XL	140	****	****	1	~	√			✓	~						† Ideal for challenging DC formulations for tablets, chewables, and ODTs
EZ	140	****	***	~	~	~	~	~	~	~						Good general PSD for mixing with APIs and other ingredients for tablets, chewables, and ODTs. Can be used if finer material than the granular grades are required for stick-pack and sachet applications
Granular Ma	<b>nnitol</b> 300	***	****	V	v	✓		~	~	✓						† Most compressible, granular grade for use in tablets, chewables and ODTs. Can also carry larger particle sized, taste-masked APIs and MUPs to ensure good content uniformity. Excellent for stick-packs and sachets
Granular	480	**	****	¥	¥	¥	¥	*	1	4						For best flowability and soft chewable experience. Can carry larger particle sized, taste- masked APIs and MUPs, ensuring good content uniformity. Excellent for stick packs and sachets
2080	320	**	***	~	~	~	~	~	~	1						For good flow, and soft chewable experience. Can carry larger particle sized taste-masked APIs, and MUPs to ensure good content uniformity. Excellent for stick-packs and sachets
Powder Man	nitol															
Emerald	25			~							✓	√	✓	√	√	Fine mannitol for granulation, freeze drying, hot melt extrusion and liquids
Onyx	50			~							✓	✓	~	✓	✓	Mannitol for granulation, freeze drying, hot melt extrusion and liquids

Stick-packs/Sachets

+ Grades utlizing our proprietary Mannogem XL technology produce compendial mannitol with enhanced compressibility and disintegration performance.

# Innovating For Good





# Level Up With Mannogem XL Technology

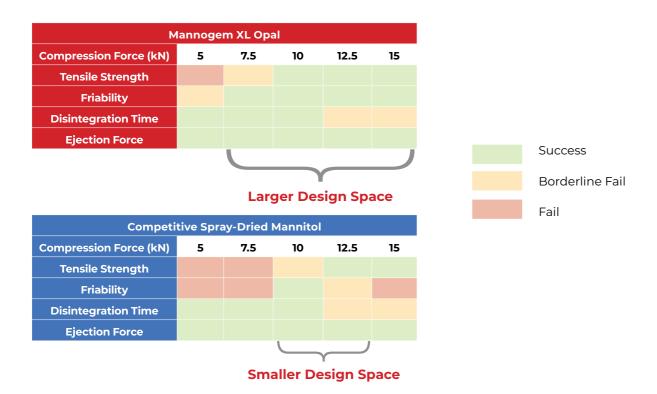
Mannogem XL is a proprietary technology from SPI Pharma engineered to overcome mannitol's poor compactability properties, producing multifunctional, compendial grades of mannitol with superior binding properties, rapid disintegration, greater compressibility and tight particle size ranges. Products created with Mannogem XL technology retain the positive qualities of compendial mannitol while boasting enhancements over standard competitive mannitol. XL simplifies the formulation of orally-disintegrating tablets (ODTs) and other patient-centric oral dosage forms to promote better adherence and administration. Improve your manufacturing operations, product performance and the patient experience. Formulate with XL technology.

# **The Precious Gem Collection**

Our Precious Gem Collection of Mannogem Mannitol grades are ideal for the formulation of convenient, patient-centric dosage forms, such as ODTs and chewables, with smaller tablet sizes and faster disintegration times further enhancing patient adherence. They broaden the options for overcoming issues with challenging formulations, such as content uniformity, poor API compressibility, and improved organoleptics.

#### Mannogem XL Opal

Mannogem XL Opal is a 160 µm spray-dried mannitol engineered to enhance functionality in direct compression formulations. Experience increased speed of development, enhanced manufacturing efficiency, improved product performance and patient satisfaction with Opal. The principles of quality by design require formulations to have a wide design space to minimize development time. Opal is uniquely designed to optimize key attributes to deliver robust tablets and wide design space. Such formulations will transfer to production quickly and enable high yields and fast production speeds. Accelerate success with Opal.



#### Mannogem XL Ruby

Compared to traditional 300 µm granular products, Mannogem XL Ruby exhibits superior tabletability and overall performance, translating to simpler formulation processes, accelerated development timelines and greater manufacturing efficiency for pharmaceutical formulators. Ruby addresses content uniformity issues and is ideal for use with pressure-sensitive, taste-masked APIs. Raise the bar with Ruby, deliver sophisticated and innovative medicines to the patients who need them.

#### Mannogem Emerald & Onyx

With Mannogem Emerald and Onyx, pharmaceutical formulators now have an alternative source for industry-standard 25 µm and 50 µm mannitol powders for granulation applications. These specialized mannitol powders provide the same productivity and performance-enhancing qualities of compendial mannitol powders, while expanding the number of global supply options for pharmaceutical formulators. Secure your supply chain and formulate with confidence using Emerald and Onyx.

### **Regulatory Expertise**

SPI Pharma's quality and regulatory experts help ensure Mannogem Mannitol products are of the highest quality and conform to global regulations. All Mannogem Mannitol products are made to current excipient GMP standards to conform to USP and/or USP/ EP Ph.EUR, JP and IP monograph requirements. We maintain a comprehensive Product Regulatory Datasheet which includes statements and certifications of conformance for many additional quality and safety regulations for Food and Pharma uses.





### **Improved Formulations, Better Tablets**

Development of dose forms that are age-appropriate and acceptable to patients is a clear trend with regulators. Improve the patient experience and benefit from efficient manufacturing operations by formulating with Mannogem Mannitol grades. With our depth and breadth of formulation and development experience, speed up your time to market by avoiding potential problems that can delay your progress.

Our regionally-based technical experts are available to come and work with your team to optimize the formulation and delivery method of your choice. Premium formulation service offerings are also available. Reduce trial and error. Get to market faster. Contact us to request a sample and get started.

**Request Samples** 



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