

Mannogem[®] Mannitol

The perfect formulation tool.



Mannogem[®] Mannitol

Mannogem Mannitols are a set of versatile excipients from a reliable supplier. We customize to your needs one formulation at a time. Stable. Soluble. Compactible. Mannogem.

SPI Pharma[™]

www.spipharma.com



Mannogem[®] Mannitol

The Versatile Excipient

SPI Pharma is a leading manufacturer of mannitol based products for the pharmaceutical industry with over 75 years of experience in polyol chemistry, enabling us to offer a wide range of mannitol options for any and all formulation requirements. SPI's technical expertise in mannitol makes us the preferred formulation partner.

Product Name	Target Application	Particle Size	Key Features
Mannogem Powder	Wet granulation tableting and suspension	30-150 μ	Ideal for wet granulation and lyophilization. Specially designed for making PPI pellets.
Mannogem Granular	Direct compression tableting and sachets	170-1190 μ	Ideal for chewable / swallow tablets.
Mannogem Granular 2080	Free flowing, directly compressible	300-590 μ	Major use is in API protection and dissolution enhancement in swallow tablets.
Mannogem EZ Spray Dried	Direct compression and wet granulation	75-150 μ	Its high porosity and narrow particle size make it an ideal choice for triturating with low dose micronized actives.

The Mannogem Mannitol product line provides an option for multiple pharmaceutical applications. Figures 1 & 2 show how different the morphology can be from one grade to another, providing formulators with maximum flexibility with regard to applications.

Figure 1: Mannogem Granular 2080

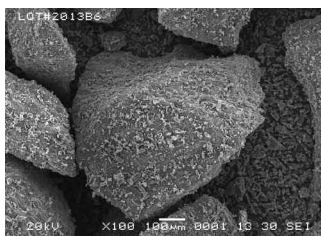
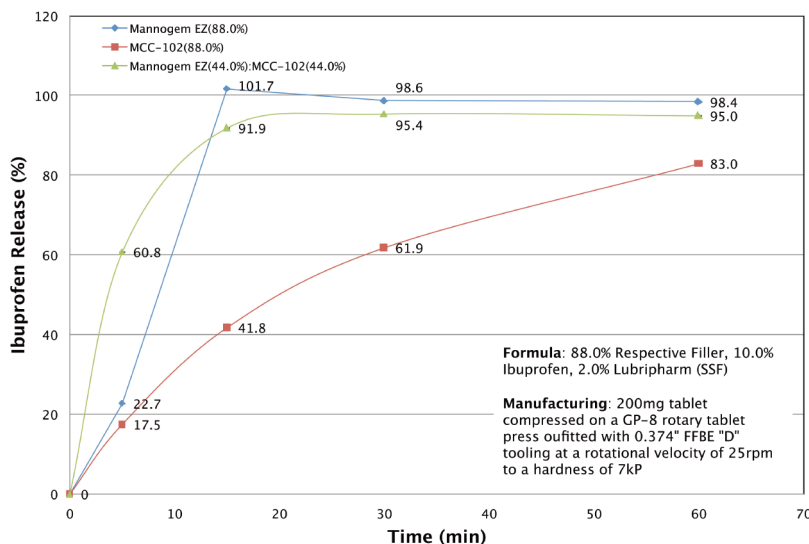
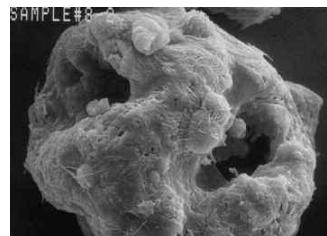


Figure 2: Mannogem EZ



Solubility

Mannogem improves the solubility of APIs by allowing rapid contact with dissolution media.

Figure 3: A blend of Mannogem EZ and MCC-102 synergistically increases the early phase dissolution rate of Ibuprofen from direct-compression, immediate-release tablets.

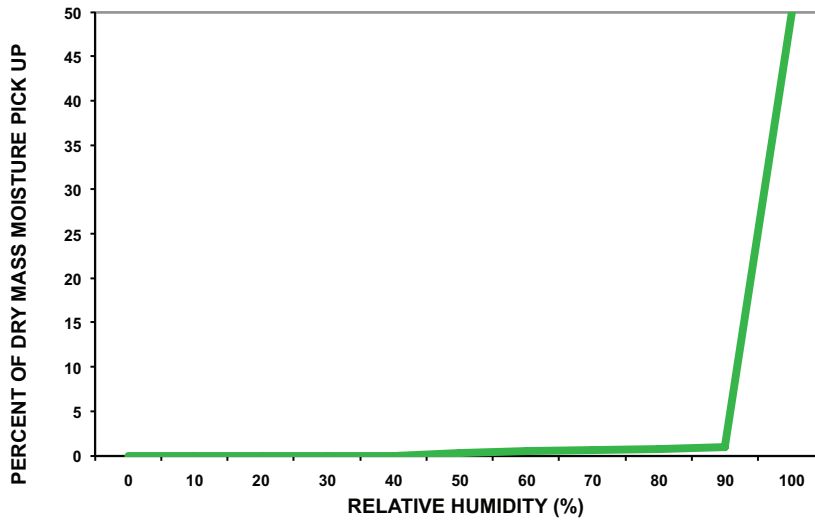
Stability

Mannogem does not undergo the Maillard reaction with free amines, making it a preferred alternative to lactose and other carbohydrate fillers.

Low Hygroscopicity

Mannogem reduces the potential for pH-based degradations, protects amorphous material from crystallization and protects moisture sensitive APIs from hydrolysis.

Figure 4: Dynamic Vapor Sorption For Mannitol



Applications

Please contact your salesperson or visit our website, www.spipharma.com, for these applications and more:

- Lubrication Sensitivity Analysis
- Compaction Diagrams
- Dilution Curves
- White Papers
- Formulary

MANNOGEM® Mannitol, USP/EP Directly Compressible Mannitol



CRITICAL PROPERTIES:	EZ	GRANULAR/2080	POWDER
Assay, % (Dry Basis EP)	98.0 - 102.0	98.0 - 102.0	98.0 - 102.0
Assay, % (Dry Basis USP)	96.0 - 101.5	96.0 - 101.5	96.0 - 101.5
Loss on Drying, %	NMT 0.3	NMT 0.3	NMT 0.3
Water by KF, %	NMT 0.5	NMT 0.5	NMT 0.5
Reducing Sugars*, mL	NLT 12.8	NLT 12.8	NLT 12.8
Chlorides, ppm*	NMT 70	NMT 70	NMT 70
Sulfates, ppm*	NMT 100	NMT 100	NMT 100
Arsenic, ppm*	NMT 1	NMT 1	NMT 1
Acidity, mLs	NMT 0.3	NMT 0.3	NMT 0.3
Melting Range, °C	165 - 169	165 - 169	165 - 169
Nickel, ppm*	NMT 1	NMT 1	NMT 1
Lead, ppm*	NMT 0.5	NMT 0.5	NMT 0.5
Conductivity, uS	NMT 20	NMT 20	NMT 20
Specific Rotation*	+137° to +145°	+137° to +145°	+137° to +145°
OTHER SPECIFICATIONS/TARGETS:			
Total Aerobic Plate Count*, cfu/g	NMT 1000	NMT 1000	NMT 1000
Total Yeast and Mold*, cfu/g	NMT 100	NMT 100	NMT 100
<i>E.coli</i> Test Method	Negative	Negative	Negative
<i>Salmonella</i> Test Method	Negative	Negative	Negative
<i>Staphylococcus Aureus</i> Test Method	Negative	Negative	Negative

Product conforms to USP/EP monograph.

STANDARD PACKAGING: 100kg for Powder and Granular/2080; 50kg for EZ.

* Meets USP/EP requirements based on statistical testing.

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