

Directly Compressible Mannitol

GRANUTOL

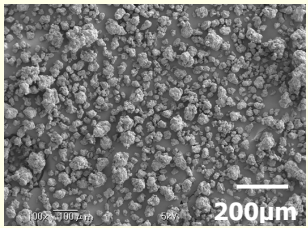
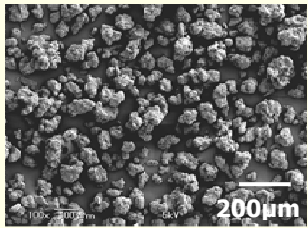
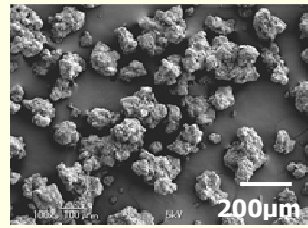
GRANUTOL was developed by applying a unique manufacturing technique, also applied to DILACTOSE (lactose for direct compression).

GRANUTOL is made of D-mannitol and for specifically direct compression.

This excipient is suitable as filler for ODT and chewable tablets compared to lactose because of an overall better mouthfeel result.

《Product Lineup》

Three types available in different particle sizes.

Type		GRANUTOL F	GRANUTOL S	GRANUTOL R	
Compendial		JP "D-mannitol" USP, Ph.Eur. "Mannitol" conformity			
Internal Specification	Particle size specification	250 µm on : not more than 2% 250-45 µm : 40-80% 45 µm pass : 20-60%	500 µm on : not more than 2% 500-75 µm : not less than 50% 75 µm pass : 20-50%	500 µm on : not more than 2% 500-75 µm : not less than 80% 75 µm pass : not more than 20%	
	Repose angle	not more than 42°	not more than 40°	not more than 40°	
Physical properties	Particle size distribution	D ₁₀	30 µm	41 µm	78 µm
		D ₅₀	65 µm	83 µm	154 µm
		D ₉₀	137 µm	147 µm	253 µm
	Bulk density	0.49 g/mL	0.55 g/mL	0.53 g/mL	
	Repose angle	39°	33°	34°	
SEM					

*Physical properties are representative values only, not specifications.

《Features》

- ✚ GRANUTOL consists of the most stable β type D-mannitol crystal**

Three types of α , β and δ D-Mannitol crystals are known.
Among them, β type crystals are the most stable.
- ✚ GRANUTOL is useful for water-unstable and Maillard reaction-prone API**

D-mannitol has almost no free-water and is chemically stable,
therefore, useful for reactive API.
- ✚ Excels in flowability and compression formability, thus effective for direct compression**

With high compression formability, no capping is seen even with high compression force.
The flowability is high, making GRANUTOL optimum for direct compression.
- ✚ Pleasant mouthfeel is suitable for ODT and chewable tablet.**

Mannitol has a moderately sweet, cool taste and easy to take.
By the addition of the appropriate amount of disintegrator to Granutol,
smooth disintegrating tablets can be obtained. Notably, Granutol F type is superior
for Oral Disintegrating Tablets because of excellence in formability and disintegration.

《Tablet property》

Formulation	S, R ... GRANUTOL: Magnesium Stearate = 100:1.0 F ... GRANUTOL: Magnesium Stearate = 100:1.2
Compression Condition	Rotary tableting machine (12 stations) Dosage form : 8 ϕ -10R, 200 mg/Tab, Rotation speed : 50rpm

