

Freund Excipients Report No.DL-E-1511

Directly Compressible Lactose **DILACTOSE**

DILACTOSE is JP Lactose Hydrate (granulated powder) developed by a unique fluid bed granulation method. Works well as an effective excipient for direct compression.

《Product Lineup》

Three types available in different particle sizes.



Туре			DILACTOSE F	DILACTOSE S	DILACTOSE R
Compendial			JP "Lactose Hydrate" USP/NF Ph.Eur. confirmity		JP "Lactose Hydrate"
Internal Specification	Particle Size Specification		180 µm on : not more than 2%	355 µm on : not more than 2%	500 µm on : not more than 2%
			180-53 µm : 50-80%	355-75 μm : 50-70%	500-70 μm : not less than 80%
			53 µm pass : 20-50%	75 µm pass : 30-50%	75 μm pass : not more than 20%
	Repose Angle		not more than 42°	not more than 40°	not more than 38°
Physical properties	Particle Size Distribution	D ₁₀	33 µm	51 µm	84 µm
		D ₅₀	64 µm	94 µm	171 µm
		D ₉₀	124 µm	169 µm	254 µm
	Bulk Density		0.47 g/mL	0.55 g/mL	0.56 g/mL
	Repose Angle		39°	38°	37°
	SEM		мал понт тури таки	200µm.	200µm

*Physical properties are representative values only, not specifications.



《Features》



Well-balanced between compressive formulation and disintegration

There are three manufacturing methods for direct compression lactose: high-shear granulation, spray drying and fluid bed granulation.

Our DILACTOSE is manufactured by the fluid bed granulation method.

Granulated lactose manufactured by high-shear granulation is generally inferior in compressive formulation. Although spray drying excels in compressive formulation, it is inferior in disintegration.

DILACTOSE is superior both in compressive formulation and disintegration. With these superior qualities, DILACTOSE enables the production of a higher level of hardness and tablets that disintegrate quickly..



[Formulation] Each excipient: Magnesium Stearate = 100:1[Compression condition]Dosage form: 8ϕ -10R, 200mg/tab, Rotation speed: 50rpm, Compression pressure: 6, 8, 10, 12kN

(crystallized lactose : 6, 8, 10kN, high-sheared granules : 8, 10, 12kN)



Better miscibility and fluidity

Despite the fine particle size of DILACTOSE S AND F, excellent fluidity is insured. Our exquisite granulating method succeeded in granulating fine crystals of lactose while maintaining excellent fluidity.



Well-stabile in storage

As the hygroscopicity of DILACTOSE is not as high as spray-dried lactose, there is a lower possibility of caking over time making for more stability in storage.