

Directly Compressible Excipients for Orally Disintegrating Tablets

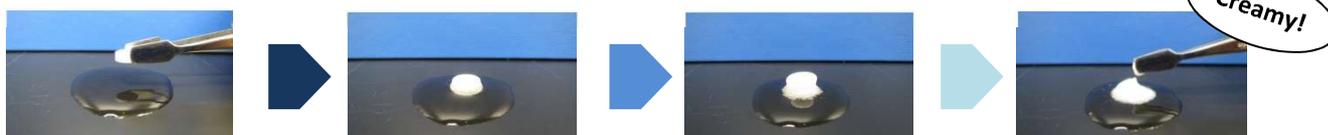
GRANFILLER-D™

GNF-D211
GNF-D215

Product Features

- GRANFILLER-D is a co-processed excipient intended for preparing Orally Disintegrating Tablets (ODTs).
- It is designed to achieve rapid disintegration while maintaining high tablet hardness.
- Composed of four compendial grade excipients, D-Mannitol, Microcrystalline Cellulose, Carmellose and Crospovidone.
- Regulatory status: Listed in JPE2018, US-DMF filed.

Tablet containing GRANFILLER-D disintegrates rapidly when contacting with water.

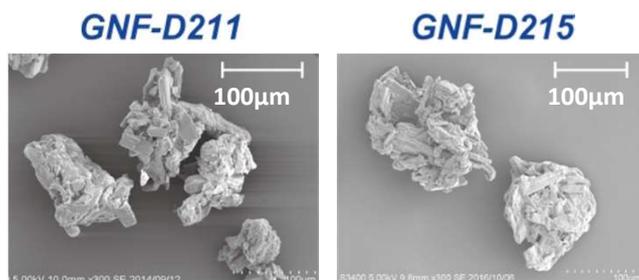


Characteristics

- Well-balanced tablet property between OD time and hardness
- Excellent content uniformity
- High API loading capacity
- Compatible with various excipients

Powder Properties

	GNF-D211	GNF-D215
Mean Particle Size*	100 μm	140 μm
Bulk Density	0.30 g/cm ³	0.31 g/cm ³
Tapped Density	0.44 g/cm ³	0.43 g/cm ³
Water Content	3.8 wt%	3.7 wt%
Angle of Repose	40°	39°
Orifice Diameter	6.3 mm	4.0 mm

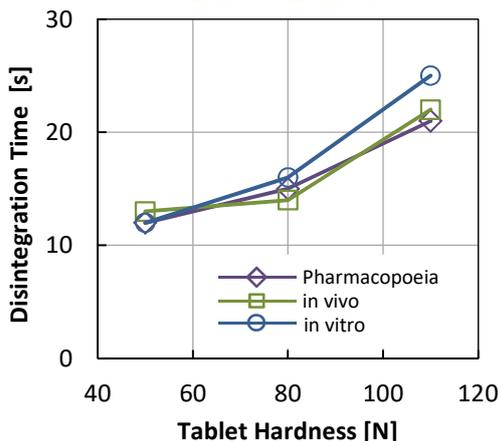


*Measured by dry laser diffraction / light scattering particle counter.

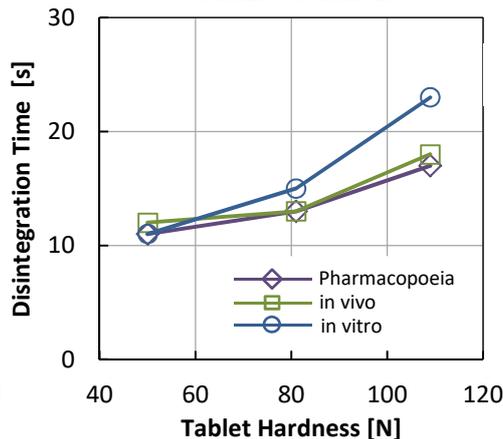
Tablet Properties (Placebo)

Tablets using GRANFILLER-D achieve “100 N tablet hardness” and “20 seconds oral disintegration time.”

GNF-D211



GNF-D215



Components of ODT:

GNF-D211/GNF-D215 (99.5%) + Mg Stearate (0.5%)

Tablet Shape:

250 mg, φ 8 mm, Flat bevelled edge

Tableting Condition:

Rotary-press, 20 rpm

Tablet Hardness:

Measured by electronic hardness tester (Avg. of n=10)

Disintegration Time:

Measured by JP general test method (Avg. of n=6)

Oral Disintegration Time (in vivo):

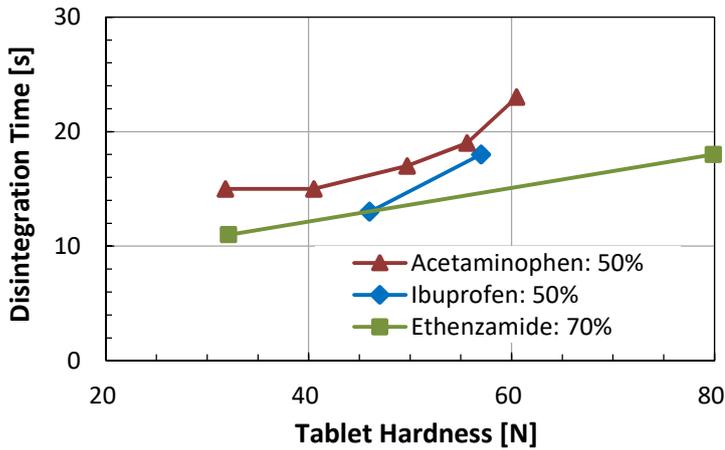
3 times at a time measured by 3 adults (Avg. of n=9)

Oral Disintegration Time (in vitro):

Measured by Tricorp tester (Okada Seiko Co., Ltd. Japan)

Tablet Properties (Containing API)

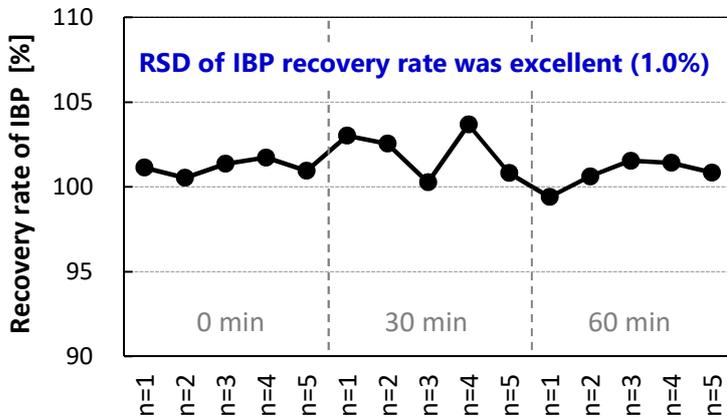
GRANFILLER-D enables high content of API while maintaining high tablet hardness and rapid disintegration.



Composition: GNF-D211 + API + Mg Stearate (0.5% -1.5%) + LASA (1.0%)
 Tablet Shape: 250 mg, φ8 mm, Flat-bevelled edge
 Tableting Condition: Rotary-press, 20 rpm
 Tablet Hardness: Measured by electronic hardness tester (Ave. of n = 10)
 Disintegration Time: Measured by JP general test method (Ave. of n = 6)

Content Uniformity

Content uniformity of API turned out to be excellent for ODTs with GRANFILLER-D.



Recovery rate of Ibuprofen (IBP) in each tablet was measured at 0, 30, 60 minutes during tableting by rotary-press.

Composition: GNF-D211 (98.5%)+IBP*(1%)+Mg Stearate (0.5%)
 *Mean particle size of 57μm
 Tableting Method: 200 mg, φ8 mm, Flat bevelled edge
 Tableting Condition: Rotary-press, 30 rpm

Preparation of Various Tablets

GRANFILLER-D can be applied to various tablet shapes, such as mini-tablets and Coin-shaped tablets which show ultra rapid disintegration.

	Normal Tablet (*1)			Coin-shaped Tablet (*2)			Mini Tablet (*3)		
Tablet Weight [mg]	250			150			15		
Tablet Diameter, Thickness [mm]	Φ8, 3.8 - 4.4			Φ14, 0.8			Φ2.5, 2.5		
Ethenzamide [%]	70	-	-	30	-	-	-		
Acetaminophen [%]	-	50	-	-	10	-	9.8		
Ascorbic Acid [%]	-	-	30	-	-	10	-		
Tablet Hardness [N]	80	61	50	16	13	13	14		
Disintegration Time [s]	18	23	26	5.8	5.5	6.2	2.2		
Oral Disintegration Time [s]	-	-	-	5.7	6.1	3.6	2.4		
Friability [%]	0.30	0.30	0.29	0.98	0.63	0.96	0.14		

Components of Tablet: *1 GNF-D211 + API + LASA (1.0%) + Mg Stearate (0.5 -1.5%)
 *2 GNF-D211 + API + LASA (1.0%) + Mg Stearate (0.3 - 0.7%)
 *3 GNF-D211 (88.2%) + Acetaminophen (9.8%) + SSF (2.0%)

Tableting Condition: Rotary-press, 10-20 rpm
 Tablet hardness: Measured by electronic hardness tester (Ave. of n = 10)
 Disintegration time: Measured by JP general test method (Ave. of n = 6)

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GRANFILLER-D was jointly developed by DAICEL Group and NICHIRIN CHEMICAL INDUSTRIES, LTD.

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