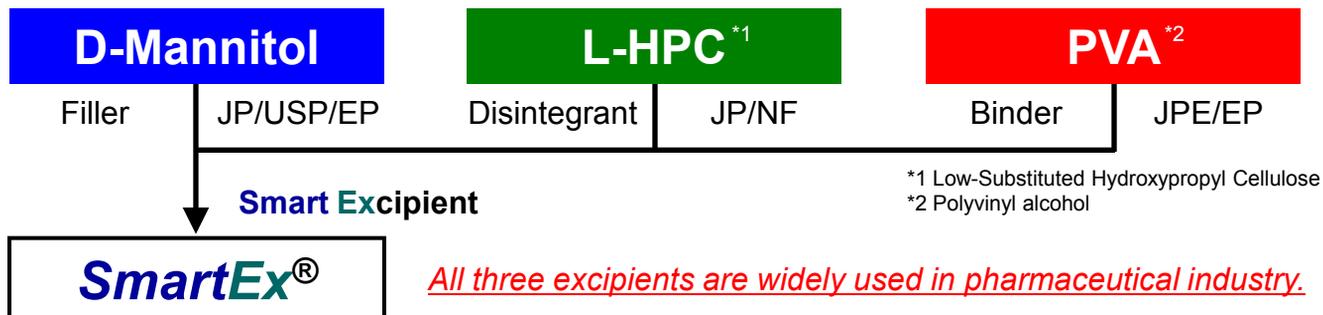


SmartEx[®]

Direct compressible excipient
for fast disintegrating tablets

【About SmartEx[®]】

SmartEx[®] is a co-processed excipient containing three pharmaceutical excipients, is suitable for direct compression manufacturing orally disintegrating tablets and immediate release tablets. Two grades of SmartEx[®] with different particle size are available.



- SmartEx[®] QD-50 : Small particle size grade, for faster disintegration
- SmartEx[®] QD-100 : Large particle size grade, for higher compressibility

【Benefits of SmartEx[®]】

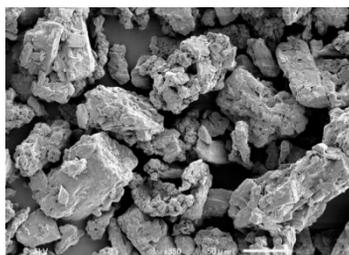
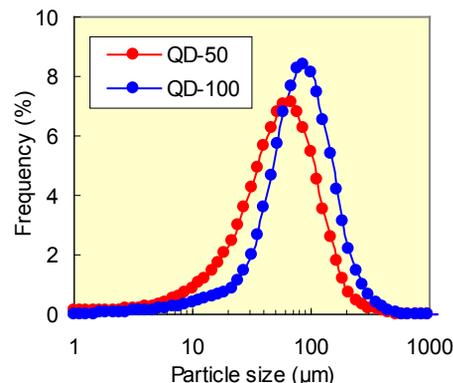
- ✓ High compressibility : Applicable for low compressible APIs
- ✓ Fast disintegration : Disintegrate in less than 30 seconds
- ✓ Good mouth feeling : Smooth mouth feel and good taste
- ✓ Good flowability : Possible to produce low deviation tablets
- ✓ Excellent stability : No change in hardness under high humidity condition

【Physical properties of SmartEx[®]】

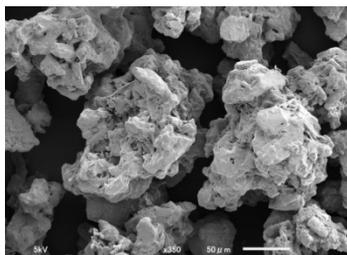
	QD-50	QD-100
Mean particle size (μm) -D ₅₀ ^{*3}	57	86
90% cumulated particle size (μm) -D ₉₀	133	182
Bulk density (g/mL)	0.45	0.44
Tapped density (g/mL)	0.61	0.55
Angle of repose (°)	38	37

*3 laser diffraction method

(The data is typical value and not specification)



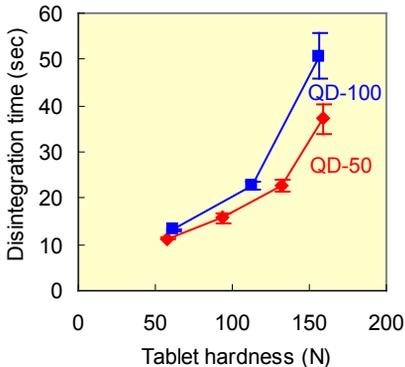
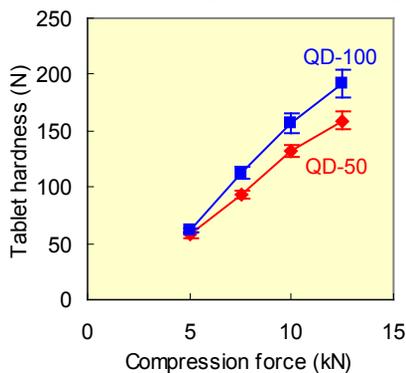
SmartEx[®] QD-50



SmartEx[®] QD-100

Manufacturer: FREUND CORPORATION
Supplier: Shin-Etsu Chemical Co.,Ltd.

【 Compressibility and Disintegration Properties of SmartEx® 】



Tablet formulation

SmartEx® QD -50 or QD-100	100 (parts)
Magnesium Stearate	1.0

Tableting conditions

Machine:	Rotary tableting machine (VIRGO®, Kikusui, Japan)
Tablet size:	8mm-D, 12mm-R, 200mg/T
Tableting speed:	20rpm

Disintegration test: JP disintegration method, Test fluid: purified water, n=6

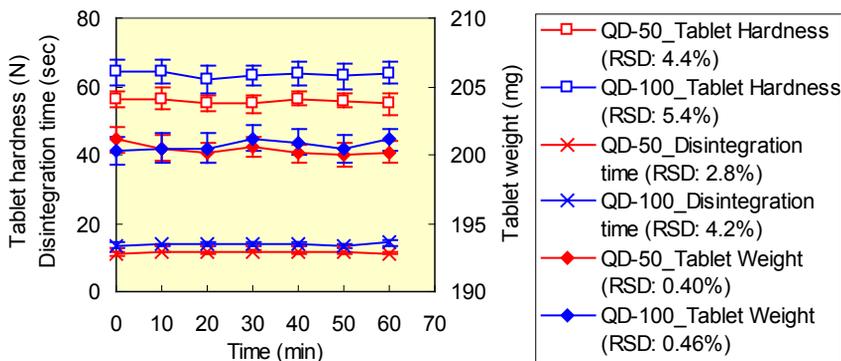
■ SmartEx® QD-50 showed faster disintegration, and SmartEx® QD-100 showed higher compressibility.

【 Deviation of tablet properties in Direct Compression 】

Continuous tablet compression was conducted with above placebo formulation. Variation of tablet weight and hardness was evaluated (n=20).

Tableting conditions

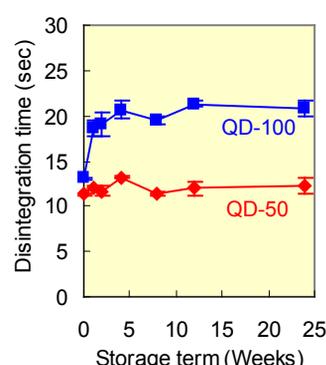
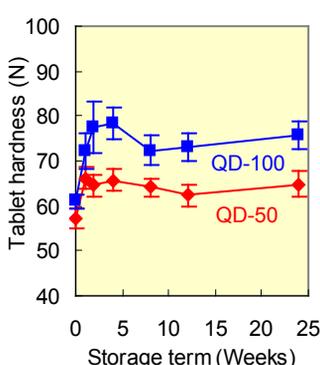
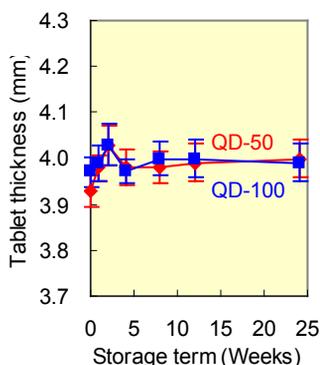
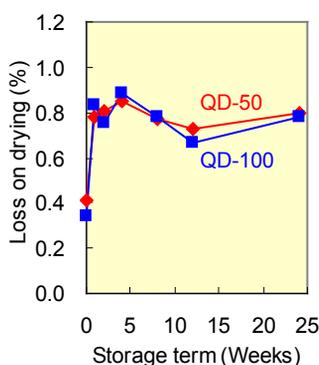
Machine:	VIRGO® (12 punches)
Compression force:	pre 3kN, main 5kN
Tablet size:	8mm-D, 12mm-R, 200mg/T
Tableting speed:	40rpm
Powder supply:	Open feed shoe



■ SmartEx® showed good flowability therefore deviation of tablet properties were low.

【 Stability of SmartEx® placebo tablets 】

Storage condition: 40°C75%RH, opened bottle, 6 months (24 weeks)



■ SmartEx® placebo tablets showed excellent stability under high humidity condition.

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