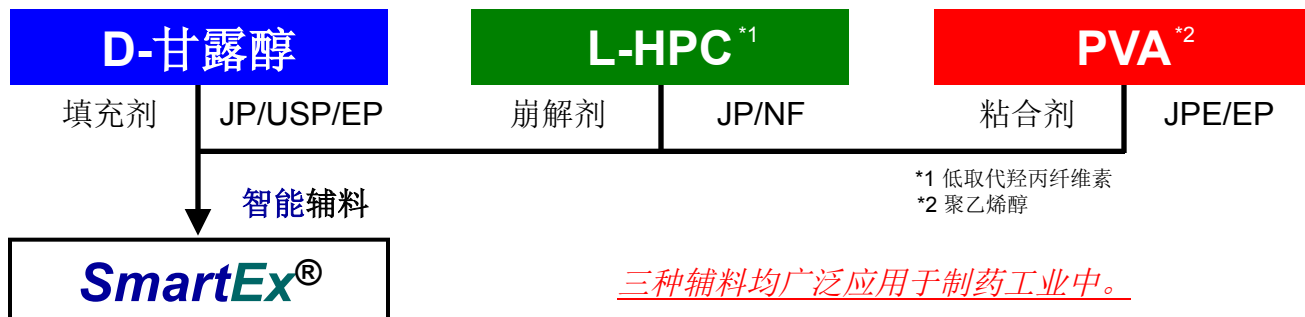


SmartEx®

应用于速崩片的直压辅料

【关于 SmartEx®】

SmartEx®是一种含有三种药用辅料的共加工辅料，适用于直接压片制备口腔崩解片和速释片。有两种不同粒径型号的SmartEx®可供选择。



- SmartEx® QD-50 : 小粒径型号，应用于快速崩解
- SmartEx® QD-100 : 大粒径型号，应用于更高的可压性

【SmartEx®优势】

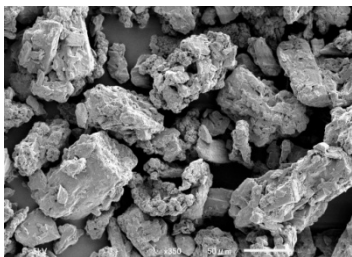
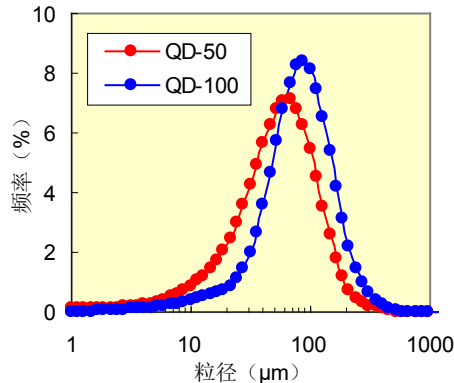
- ✓ **高可压性** : 适用于可压性差的API
- ✓ **快速崩解** : 崩解时间小于30秒
- ✓ **良好的口感** : 顺滑的口感和良好的味道
- ✓ **良好的流动性** : 制备片剂差异小的片剂
- ✓ **卓越的稳定性** : 高湿条件下硬度不变

【SmartEx®物理性质】

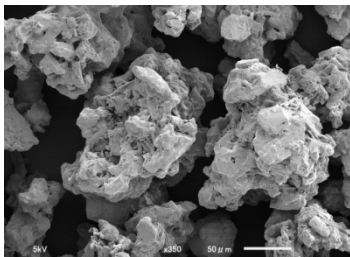
	QD-50	QD-100
平均粒径 (μm) -D ₅₀ ^{*3}	57	86
90%累积粒径 (μm) -D ₉₀	133	182
堆密度 (g/mL)	0.45	0.44
轻敲密度 (g/mL)	0.61	0.55
休止角 (°)	38	37

*3 激光衍射法

(数据为典型值而非标准值。)



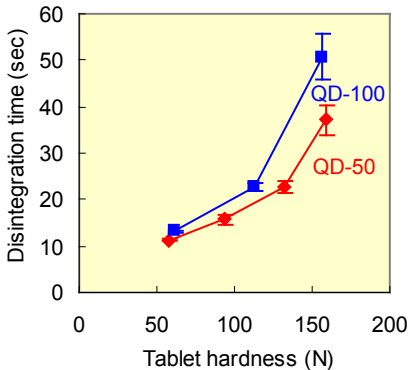
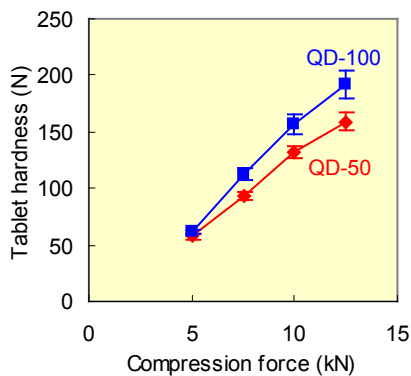
SmartEx® QD-50



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

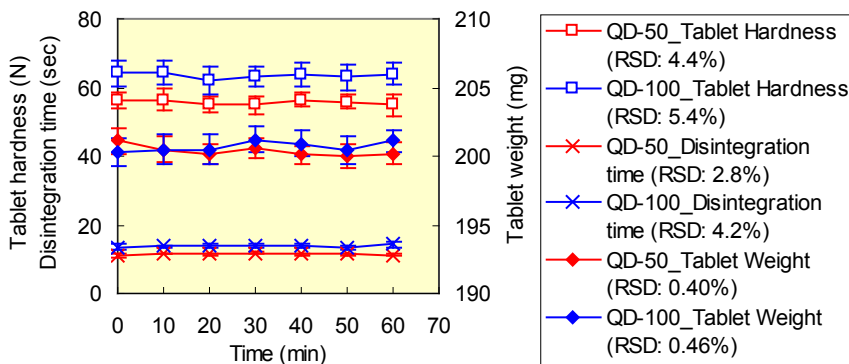
■ SmartEx® QD-50 showed faster disintegration, and SmartEx® QD-100 showed higher compressibility.

【 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

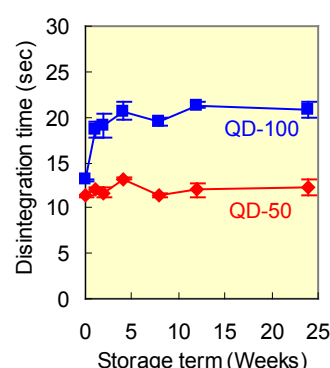
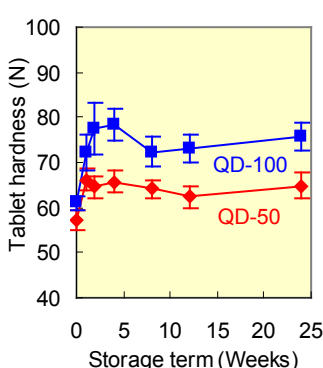
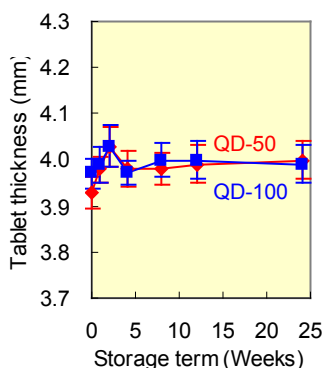
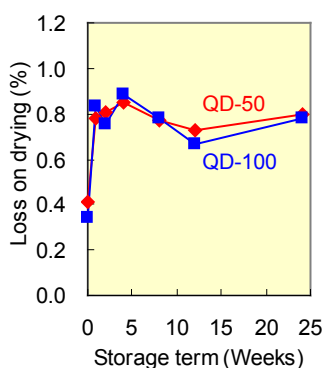
Machine:	VIRGO® (12 punches)
Compression force:	pre 3kN, main 5kN
Tablet size:	8mm-D, 12mm-R, 200mg/T
Tableting speed:	40rpm
Powder supply:	Open feed shoe



■ 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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