

Stability of IR Tablets

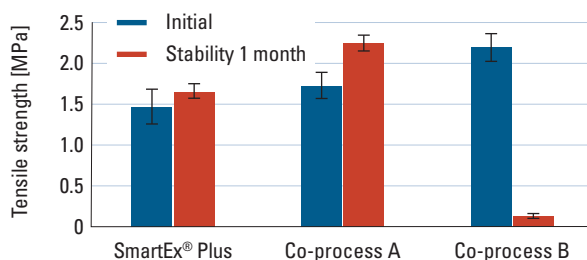
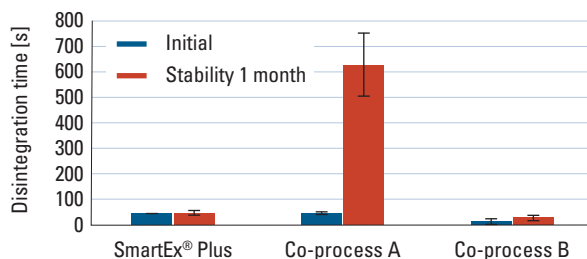
Example Stability of IR Tablets

- Fast disintegrating ibuprofen tablets (diameter 8 mm) were produced
- Tensile strength and disintegration (USP disintegration test, water) were analysed before and after one month storage (40°C/75% relative humidity)

Material	w/w [%]
Ibuprofen	25.0
SmartEx® Plus or other co-processed excipients	74.0
Silicon dioxide	0.5
Magnesium stearate	0.5

Result

Tablets with SmartEx® Plus showed improved stability in terms of disintegration and hardness compared to other co-processed excipients.



Contact

Europe

SE Tylose GmbH & Co. KG

Kasterstr. 45, 65203 Wiesbaden, Germany
Phone: +49 611 962-6345 Fax: +49 611 962-9777
contact@setylose.com
www.setylose.com

Japan / Asia

Shin-Etsu Chemical Co., Ltd.

Cellulose Technical Support Center,
YBP Technical center, 134, Godo-cho,
Hodogaya-ku, Yokohama, 240-0005, Japan
Phone +81 45 459-5415 Fax +81 45 459-5416
www.metolose.jp

North America

SE Tylose USA, Inc.

Pharmaceutical Application Laboratory
140 Commerce Way, Suite H,
Totowa, NJ 07512-1185, USA
Phone: +1 973-837-8001 Fax: +1 973-339-9094
contact-pharma@setyloseusa.com
www.shinetsupharmausa.com

India

Shin-Etsu Chemical Tylose India Pvt. Ltd.

Office no. B, 7th Floor, D Building, MBC Park,
Ghodbunder Road, Kasarwadavali
Thane West- 400615, India
Mobile: +91 9819469899

South America

Shin-Etsu do Brasil Representação de Produtos Químicos Ltda.

Rua Coronel Oscar Porto, 736,
11º Andar - Sala 114, Bairro Paraíso
CEP: 04003-003 – São Paulo, Brazil
Phone: +55 (11) 3939-0695 Fax: +55 (11) 3052-3904
Mobile: +55 (11) 99743-7557
max.ferrari@shinetsu.com.br
www.setylose.com

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SmartEx® Plus

Explore SmartEx® Plus in
Direct Compression of Tablets



IR Tablets and ODT

Shin-Etsu

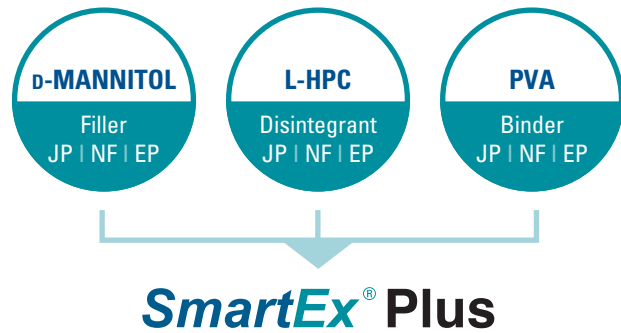
Introduction

SmartEx® Plus is a co-processed excipient based on only three components:

- D-Mannitol
- Polyvinylalcohol (PVA)
- Low substituted hydroxypropylcellulose (L-HPC)

It is used for:

- Direct compression of immediate release tablets (IR)
- Oral dispersible tablets (ODT)
- Dispersible tablets
- Tablets produced by continuous manufacturing

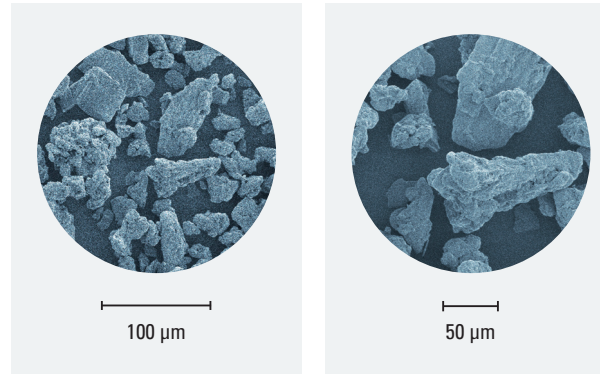


Benefits

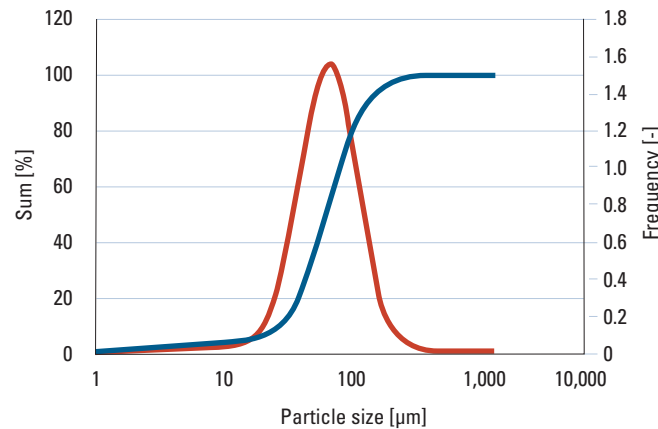
- Improved stability
- High compressibility
- Free flowing particles
- Fast disintegration and good mouth feeling
- Multi compendial

General Information

Particle morphology



Particle size distribution



ODT Formulation

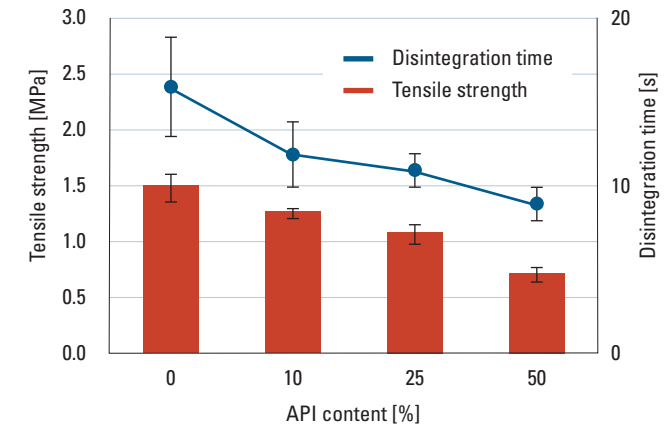
Example for ODT Formulation

- Acetaminophen ODT (diameter 8 mm) were produced
- Tensile strength and disintegration (USP disintegration test, water) were analysed

Material	w/w [%]
Acetaminophen	0.0 to 50.0
SmartEx® Plus	99.5 to 49.5
Magnesium stearate	0.5

Result

Sufficient tensile strength obtained. The disintegration time is complying to the USP (< 30 s) and EP (< 180 s) requirements for ODTs.



SmartEx® is manufactured by Freund Corporation and supplied by Shin-Etsu. 1 kg samples are available.