

Dear Readers,

This issue we are focusing on our new product SmartEX which now has a DMF (Drug Master File) number since early this year. We have received some very good feedback with this product since we launched it in 2014. We would also like to highlight that we are organising a technical seminar in Cambridge, Massachusetts. Please take a look at the programme as the main focus of the seminar will be solubility enhancement.

SmartEx



SmartEX was launched in 2014 and this year the DMF was registered in U.S.FDA.

With growing number of pediatrics and geriatrics oral disintegration tablets are more popular than ever before. With the continuous growth and usage of Oral Disintegration Tablets (ODT) in the Pharma industry, Shin-Etsu has developed a new co-processed excipient specifically designed for ODT, and also immediate release tablet formulations by direct compression. The concept of the SmartEx is that it speeds up the formulation development of the product. The co-processed SmartEx includes a filler (D-Mannitol), binder (PVA / Polyvinyl alcohol) and disintegrant (L-HPC / Low-Substituted Hydroxypropyl Cellulose) all in the one product. All three excipients are widely used in pharmaceutical industry. One of the main advantages over other co-processed products is that the SmartEx contains L-HPC and therefore gives you excellent stability and harder tablets.

ODT application example

We made a similar formulation that was based on the ODT tablet that contained Ibuprofen in the market and checked the stability disintegration time and hardness over four weeks.

SmartEx formulation

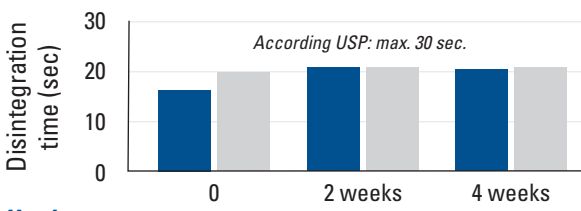
Ingredient (SmartEx)	w/w %
Ibuprofen	30%
SmartEx QD-50	68,5%
Colloidal silicon dioxide	0,5%
Magnesium stearate	1,0%

Process conditions: IMA Kilian Pressima (Rotary tablet press) / Tablet size round, biplan, 16 mm, 660 mg.

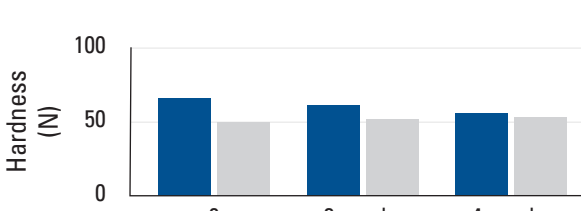
Storage conditions

- 40°C / 75% RH
- 4 weeks in open bottles

Disintegration



Hardness



Legend: ■ SmartEx formulation, □ ODT marketed product based on Ibuprofen

Comparison after 4 weeks on stability



SmartEx formulation

ODT marketed product

Summary

SmartEx tablets have similar behavior in terms of disintegration as the commercial product, however the advantage of using SmartEx in the formulation is that you can produce harder tablets and better stability i.e. no color change.

New Shin-Etsu office in South America for the pharma division

Shin-Etsu do Brasil Representações de Produtos Químicos Ltda, was founded in 2012, starting with the Silicon Division and after with the Tylose Division (Civil construction and coatings). The Pharma business at South America started with local distributors, that was covering the hole market. In January of this year, Mr. Max Ferrari (Regional Sales Manager South America) started the Pharma division directly activities in Brazil, following the Global strategy of Shin-Etsu to be closer from the Global accounts and consolidate the presence at South America.

Located in São Paulo, the financial hearth of Brazil, the directly presence of Pharma division will bring more than closer contact with the customers, but more presence at the market and easier access to the Shin-Etsu Pharma products, that can be translated in technical support, using the Wiesbaden team and faster answers to the customers enquires.

Very soon the region will have a local website, in local language to make easier the access to the products application and brochures, besides the corporate and local information.

If you want to have more information from Shin-Etsu at the South America region, please contact us at max.ferrari@shinetsu.com.br



27th April 2016

Baltimore Maryland, USA

Shin-Etsu's subsidiary in North America is pleased to announce that our joint poster accepted for presentation at the 2016 Excipient meeting won first place in the Academic category. The poster is a joint effort between the University of Maryland School of Pharmacy and Shin-Etsu. The poster is titled Co-Plasticizer: "A Potential Stabilizing Agent for Aqueous Coating with Hydroxypropyl Methylcellulose Acetate Succinate". The winning authors are Tanvi M. Deshpande and Stephen Hoag (Univ.

of Maryland) and Anisul Quadir and Sakae Obara (Shin-Etsu/SE Tylose USA). The poster describes the successful use of an aqueous coating system for enteric coating of tablets using Hydroxypropyl Methylcellulose Acetate Succinate (HPMC).

Copies of the poster can be obtained by contacting: steve.oneill@setyloseusa.com

Technical seminar

14th September 2016

Cambridge, Massachusetts, USA – 2nd Annual Scientific Seminar

Shin-Etsu's subsidiary in North America is excited to announce our Second Annual Scientific Seminar, scheduled for September 14, 2016 in Cambridge Massachusetts at the beautiful Hyatt Regency. The seminar, titled CRecent Advances in Drug Delivery and Solubility Enhancement Based on Cellulosic Polymers," will feature expert speakers from the pharma industry (Merck, Novartis, Bend Research, Kashiv), academia (St. John's University), polymer process experts (Foster Delivery Science), and polymer science experts (Shin-Etsu) The focus again in 2016 is on the science behind the use of cellulosic polymers to increase solubility/bioavailability and drug delivery.

This seminar is ideal for scientists and engineers involved in pharmaceutical development, formulation, preformulation, pharmaceuticals, drug delivery, and chemical engineering. Please join us for this cutting edge event and get the latest scientific updates in this critical area of pharmaceutical development.

Please visit our North America homepage at www.shinetsupharmausa.com or directly to the registration page at www.shinetsupharmaseminar.com for more details and to register. For any questions, please contact steve.oneill@setyloseusa.com. Space is limited so register early. We hope to see you there!

Technical Information

Shin-Etsu is continuously striving to deliver new technical data for your formulation development. Please take a look at this month's

new technical information sheets that are available from your local Shin-Etsu representative.

New

H-015
Stability of HPMCP Coated Tablets

A-049
Aqueous based enteric formulation of Shin-Etsu AQQAT[®] containing amino acid as a stabilizer

A-048 / H-014
Taste Masking of Coated Fine Particles by Aqueous and Solvent Coating

Conferences

Please come and visit us at the following conferences. We will have technical teams available who will be happy to answer any questions and we can also book private or confidential meetings.



17th – 20th July 2016
Controlled Release Society Annual Meeting
Seattle, WA USA



13th – 17th November 2016
AAPS Annual Meeting
Denver, CO USA
Booth Number 749



4th-6th October, 2016
CPhI Worldwide
Fira de Barcelona Gran Via, Barcelona, Spain

Booth number 4H46

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