GAZETTE

1st European Conference on Pharmaceutics: Drug Delivery

Reims, France, 13-14 April 2015

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2014

N°30

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APGI Thesis Award 2014

The "APGI YOUNG INVESTIGATOR AWARD" sponsored by Sanofi and delivered jointly by SANOFI and APGI, awards each year the most outstanding PhD thesis in the field of Drug Delivery Sciences and Technology. If you have defended your PhD thesis between 1 October 2013 and 30 September 2014, you may be a candidate for APGI Thesis Award 2014. Please send three copies of your thesis (paper version only) and a brief curriculum vitae to the secretariat of APGI: 5 rue Jean-Baptiste Clément, FR-92296Chatenay-Malabry Cedex, France, before 22 November 2014. The awardee will be recognized at the 1st European Conference on Pharmaceutics: Drug Delivery 13-14 April 2015 in Reims, France (http://www.apgi.org/Reims2015.htm).

Editorial

Dear Colleagues,

A new series of major scientific congresses will start in April 2015: The **European Conferences on Pharmaceutics**. They will be jointly organized by the APGI, our Italian friends - the ADRITELF, and our German friends - the APV. The meetings' structure will be similar to that of the World Meetings on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology: There will be parallel sessions of invited talks and short talks selected from submitted abstracts, poster presentations and an industrial exhibition. But the European Conferences on Pharmaceutics will be shorter than the World Meetings: only 2 days (instead of 3.5 days). These new international scientific meetings will be held every 2 years: in all uneven years (2015, 2017, 2019 etc.). Thus, they will fill the gaps between the World Meetings, which will continue to be held every 2 years: in the even years (2016, 2018, 2020 etc.). So, in the future, there will be one major scientific meeting in our field every year in Europe. The **1st European Conference on Pharmaceutics** will be held in **Reims**, France, on **13-14 April 2015**. Professor **Patrick Couvreur** (Paris, France) and Professor **Hartmut Derendorf** (Gainesville, USA) will give plenary lectures on "Drug Targeting - Where are we?" and "Advances in Pulmonary Drug Delivery". The **deadline for abstract submission is 15 November 2014**!

The official journal of our society: the "**Journal of Drug Delivery Science and Technology**" (JDDST) **has been transferred** from the publisher "Editions de Santé" **to** "**Elsevier**". Since Elsevier has a large portfolio of international scientific journals, it can be expected that the accessibility of the articles published in JDDST will substantially increase. Very unfortunately, Professor **Dominique Duchêne**, who acted for numerous years as highly efficient and enthusiastic Editor-in-Chief of the journal, decided to step down. Thanks to her very fruitful efforts and her continuous engagement, JDDST (formerly STP Pharma Sciences) has become one of the leading journals in the field. In the name of our society **I sincerely thank Dominique for all her work and energy!** I have the honor to succeed her and will do my very best to continue the journal's success story.

Prof. Juergen Siepmann
President of APGI

1st European Conference on Pharmaceutics: Drug Delivery

Reims, France, 13-14 April 2015

The APGI, ADRITELF and APV decided to create a new series of international scientific meetings, the:

European Conferences on Pharmaceutics

which will be held every two years, starting in 2015.

Thus, in the future there will be a major scientific meeting every year in our field in Europe: The *European Conferences on Pharmaceutics* in the *uneven years*, and the *World Meetings on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology* in the *even years*. Both congresses will generally be held in March/April.

The **1st European Conference on Pharmaceutics will be held in Reims**, France, on **13-14 April 2015**.

The aim is to help bridging the gap between fundamental academic research and industrial applications, offering the opportunity to initiate fruitful exchange and cooperation between university and industry.

The general structure of the European Conferences on Pharmaceutics will be similar to that of the World Meetings on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, but the events will be shorter: 2 days instead of 3.5 days.

Monday 13 April

9:00 - 9:15	Opening		Posters	Exhibition
9:15 - 10:15	Plenary lecture			
10:15 - 10:45	Coffee			
10:45 - 12:45	Invited talks	Short talks		
12:45 – 15:00	Lunch			
15:00 – 17:00	Invited talks	Short talks		
17:00 – 20:00	Welcome reception			

Tuesday 14 April

9:00 - 11:00	Invited talks	Short talks	Posters	Exhibition
11:00 - 11:30	Coffee			
11:30 - 12:30	Plenary lecture			
12:30 – 15:00	Lunch			
15:00 – 17:00	Invited talks	Short talks		

International News

World-wide leading experts in the field will give plenary lectures and invited talks on hot topics. They will give overviews on the current state of the art in the respective domains and outlooks on future perspectives. In Reims, this includes:

- Prof. Patrick Couvreur, Paris, France-Plenary Lecture "Drug Targeting-Where are we?"

- Prof. Hartmut Derendorf, Gainesville, FL, USA - Plenary Lecture "Advances in Pulmonary Drug Delivery"

- Prof. David Brayden, University of Dublin, Dublin, Ireland "Therapeutic Index Issues around Oral Peptide Permeation Enhancers"
- Dr. Paul Gellert, AstraZeneca, Macclesfield, United Kingdom "Smart Drug Delivery from an Industrial Perspective"
- Prof. Richard Guy, University of Bath, Bath, United Kingdom "Transdermal Drug Delivery: A Mature and Evolving Technology"
- Derek O Hagan, Novartis Vaccines and Diagnostics, Inc. (US-Cambridge) "Challenges and Advances in Vaccine Delivery"
- Prof. Wim Hennink, University of Utrecht, Utrecht, The Netherlands "Protein and Peptide Delivery: Current State of the Art"
- Sean Jones, Medicine and Healthcare Products Regulatory Agency, United Kingdom

"The New Guideline on Quality of Transdermal Patches: New Requirements in Development"

- Dr. Martin Lueck, Gruenenthal, Aachen, Germany "Recent Challenges in Oral Controlled-Release Drug Delivery"
- Prof. Gianfranco Pasut, University of Padova, Padova, Italy "Progresses in Anticancer Drug Delivery by Polymer Conjugation"
- Prof. Clive Roberts, University of Nottingham, Nottingham, United Kingdom

"3D Printing"

- Dr. Peter Serno, Bayer, Berlin, Germany

"Orodispersible Dosage Forms"

- Dr. Michel Sournac, Pierre Fabre, Toulouse, France

"Transdermal Drug Delivery: An Industrial Viewpoint"

- Dr. Heiko Spilgies, LTS Lohmann Therapie-System AG, Andernach, Germany

"Novel Application Systems for Transdermal Vaccine Delivery".

In addition, latest research findings will be presented in the form of short talks, selected from submitted abstracts. Furthermore, poster presentations will give the opportunity to get an update on the most recent research in Pharmaceutics and to personally exchange with the authors.

Also, an industrial exhibition will accompany the Conference and allow learning about the latest trends and newest products in the area of pharmaceutical ingredients, developing & processing equipment, analytical technologies, medicinal products, medical devices, contract manufacturing and many other fields.

The Conference will, thus, be a perfect occasion for young as well as for established scientists from academia and industry from all over the world to present their work, network, discuss newest scientific findings and to share their experience with colleagues on a broad range of topics related to Drug Delivery.

All coffee and lunch breaks as well as the welcome reception (including a choice of selected champagnes) will be included in the registration fees and be held in the industrial exhibition and poster presentation area in order to facilitate discussions between participants, exhibitors and presenters.

Reims is world-wide famous for its Champagne, Cathedral and Coronations. It has also become a modern and lively regional capital thanks to its location, at the crossroad of several European routes. You can easily reach Reims by car or by train (e.g. 40 min from Paris), and there are direct trains (30 min) to Charles-de-Gaule (CDG) Paris International Airport.

We are looking forward to seeing you at the 1st European Conference on Pharmaceutics in Reims in 2015!

Please note:
The deadline for abstract submission is 15 November 2015!

http://www.europeanmeeting.org/home/
info@europeanmeeting.org
Contact Sponsoring & Exhibition: apgi.asso@u-psud.fr

Main sponsor

Platinum sponsors

JDDST transferred to Elsevier

The "**Journal of Drug Delivery Science and Technology**" (JDDST) is the official journal of our society (as well as of the ADRITELF and the Japanese Society for Pharmaceutical Technology). It was formerly entitled "STP Pharma Sciences" and belonged to the publisher "Editions de Santé".

JDDST has now been transferred to the publisher "**Elsevier**", who provides a large portfolio of international scientific journals (including for instance Journal of Controlled Release and European Journal of Pharmaceutics and Biopharmaceutics). Thus, it can be expected that the accessibility of the articles published in JDDST will substantially increase in the future.

Very unfortunately, Professor **Dominique Duchêne**, who acted for numerous years as highly efficient and enthusiastic Editor-in-Chief of the journal, decided to step down. She was the **"heart and soul" of JDDST**. Thanks to her substantial and very fruitful efforts and her never ending engagement, JDDST has become one of the leading international journals in our field. This standing and the very high scientific quality of the articles is clearly attributable to the exceptional work of Professor Dominique Duchêne!

The **APGI sincerely thanks ominique for all her energy and all the time she spent for the journal!**

Professor Juergen Siepmann, the president of APGI, has the honor to succeed her as Editor-in-Chief.

APGI Young Investigator Award 2013

Dr Amrit Paudel

University of Leuven
Group Biomedical Sciences
Faculty of Pharmaceutical and Pharmacological Sciences
Drug Delivery and Disposition

Promoter: Prof. Dr. G. Van den Mooter

has been awarded for her Ph.D. thesis entitled:

"Formulation and Process Considerations in Manufacturing Spray-Dried Amorphous Solid Dispersions: A Case Study with Naproxen-Polyvinylpyrrolidone"

PhD summary

The oral route is a convenient and most often used route of drug administration to patients. Adequate aqueous solubility and gastrointestinal permeability are prerequisites for a drug to be formulated into a solid oral dosage form. However, this necessity is continually confronted by the increasing number of drug candidates possessing poor aqueous solubility. Amorphous solid dispersion is a potential solubilisation strategy and spray -drying is an efficient manufacturing process for the same. Unfortunately, there is limited number of marketed amorphous dispersion formulations owing to poor physicochemical stability, manufacturability and downstream processability. Moreover, the inadequate current understanding on the physical chemistry of amorphous solid dispersions has limited to the iterative and empirically driven formulation approach. To rationalize the current trial and error practice of manufacturing amorphous solid dispersions, the influence of key formulation and process variables on the physical structure and stability of amorphous solid dispersions prepared by cospray-drying a model poorly water soluble drug, naproxen and a model carrier, polyvinylpyrrolidone was elucidated in the framework of this doctoral dissertation. The drug-polymer binary phase behaviour and intermolecular interaction were investigated using existing thermodynamic models and compared with the experimentally obtained kinetic miscibility. The results revealed that the spray-dried amorphous dispersions are highly supersaturated in comparison to the estimated solid solubility of the drug in the polymer. Also, the currently used mixing models lacking the accounts of hydrogen-bonding were unable to discriminate the polymer chain length effect on the phase behaviour of interacting systems. Spray-drying solvent composition was shown to be another contributor for the particular phase structure of the end product. Moreover, addition of an anti-solvent for the polymer resulted in amorphous dispersions with the best miscibility and physical stability. Next, the phase behaviour and intermolecular interactions between naproxen-PVP K 25 were compared and contrasted in solid dispersions prepared by slow solvent evaporation and those prepared by quench cooling. A persuasive difference was evidenced in the composition-dependent miscibility and in the intermolecular interactions. In addition, the spray drying temperature and atomizing conditions proved to be the key process parameters influencing the miscibility, stability and in vitro performance of the spray-dried dispersions. Faster evaporating conditions viz, higher inlet temperature and/or higher atomization airflow rate resulted into heterogeneous amorphous dispersions of the selected systems which, in contrary, possessed higher physical stability against moisture-induced phase separation and recrystallization.

10th World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology

Glasgow, UK, 4-7 April 2016

In continuation of the very successful past scientific meetings in Budapest, Paris, Berlin, Florence, Geneva, Barcelona, Malta, Istanbul, and Lisbon the APGI, ADRITELF and APV will jointly organise the 10th World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology in Glasgow, UK, on 4-7 April 2016. The World Meetings have become the largest scientific meetings in our field in Europe, with about 1000 submitted abstracts and 1400 participants from all over the world. In Lisbon, the accompanying industrial exhibition ResearchPharm was fully booked.

The 10th World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology will continue providing a cross-disciplinary platform for pharmaceutical scientists working in all fields of drug product development: in industry, academia and regulatory bodies.

In addition to two parallel sessions on industry-related topics presented by distinguished invited speakers, the 10th World Meeting (like its recent predecessors) will have two more parallel tracks, providing ample room for a number of oral presentations given by young or established scientists from all over the world. In these contributions (selected by the Programme committee from many hundreds submitted abstracts) most recent scientific findings and experiences will be presented on a broad range of topics related to Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology. Along with the poster presentations of the submitted papers the exhibition ResearchPharm will take place presenting the newest trends and novel products in the area of pharmaceutical ingredients, developing and processing equipment, analytical technologies, medicinal products, medical devices, contract manufacturing and recent publications.

The meeting is intended to bring together people working in fundamental and applied academic research, chemical and pharmaceutical industry and the regulatory field offering the opportunity to initiate fruitful discussions and collaborations.

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A.D.R.I.T.E.L.F.

APV MAKING SCIENCE WORK

Programme committee

- Dr. Rainer Alex
- Prof. Franco Alhaique
- Prof. Joerg Breitkreutz
- Dr. Lea Ann Dailey
- Prof. Elias Fattal
- Prof. Massimo Fresta
- Dr. Marco Gentile
- Dr. Joel Richard

International News

In Memoriam notice

Marcus Eli Brewster III

14 October 1957 – 15 September 2014

Dr. Marcus Eli Brewster passed unexpectedly away at his home in Beerse, Belgium, on September 15th 2014. At his death Marcus was the Vice President and Scientific Fellow for the Pharmaceutical Development and Manufacturing Sciences group at Janssen R&D (a Johnson & Johnson company), and the President Elect of the Controlled Release Society. Marcus was a great scientist, colleague and friend and is sadly missed by everyone that knew him.

Marcus was born (October 14th 1957) and raised in Jacksonville, Florida. After receiving his BS degree in Chemistry from Mercer University in Georgia he moved to University of Florida in Gainesville where he studied under the guidance of Professor Nicholas Bodor. Marcus received his Ph.D. degree with honors in August 1982 at the age of 24. His thesis was entitled "Application of a Dihydropyridine↔Pyridinium Salt Redox System to Drug Delivery to the Brain". The dihydropyridine↔pyridinium drug delivery system was then developed further and became the basis of Dr. Bodor's company Pharmatec Inc., which was located at the University of Florida's industrial park in Alachua, Florida. Marcus became the Director of Research of Pharmatec and later Senior Director of its follow up company Pharmos Corp. in Alachua. In September 1997 Marcus moved to Belgium to become a Director of Drug Delivery Research at Janssen Pharmaceutica in Beerse.

The dihydropyridine↔pyridinium drug delivery systems were very lipophilic, practically insoluble and chemically unstable in aqueous solutions and, thus, needed to be both solubilized and stabilized before they could be properly tested in animal models. This was a challenging quest. Various approaches were explored, including numerous complexing agents. Small sample of the newly developed complexing agent 2-hydroxyproyl-β-cyclodextrin was obtained from Dr. Josef Pitha at NIH. Complexation of the novel delivery systems with 2-hydroxyproyl-β-cyclodextrin both solubilized and stabilized the systems in aqueous solutions. It was like miracle that had profound effect on Marcus and his research endeavors. The synthetic chemist soon became a formulation scientist and one of the world leaders in cyclodextrin technology. His first of about 60 peer-reviewed papers on cyclodextrins, entitled "Brain-Enhanced Delivery of Testosterone with a Chemical Delivery System complexed with 2-Hydroxypropyl-β-cyclodextrin", was published in the journal *Drug Design & Delivery* in 1988. Marcus had, however, a broad and general interest in drug delivery and published altogether about 270 peer-reviewed papers, in addition to a large number of other scientific publications, on as diverse topics as prodrugs, soft drugs, drug solubilization and bioavailability, polymeric micelles, non-viral vectors, topical drug delivery, supersaturation, complexes and nanotechnology. Marcus is named as inventor or co-inventor on approximately 75 patents. He delivered approximately 80 plenary or invited lectures at various scientific meetings and more than 60 other oral presentations. He was an editor of the Journal of Pharmaceutical Sciences as well as on the editorial boards of couple of other journals. He received several honors for his work including prizes from PARC, FACCS, the European Journal of Pharmaceutical Sciences as well as numerous J&J distinctions.

It was in the summer of 1980 that I first met Marcus when we both worked in Dr. Bodor's group in Florida. In those days Marcus was a synthetic chemist working on novel prodrugs or drug delivery systems for the brain. He was so enthusiastic about his research that he sometimes slept in the lab; worked for 24 hours for days. He worked hard but also enjoyed the good life, good food, beer and wine, and frequently visited American steak houses and Japanese restaurants. He learned Japanese and could apparently without effort place an order in Japanese when we went to restaurants, not only in Florida but also later in Japan when we travelled together to attend scientific events. Learning new languages were one of his many passions. At meetings Marcus always spent good time at the poster sections where he could be in close contact with the presenters. His curiosity and passion for science as well as his charm and good sense of humor attracted young scientists who loved to be around him. He asked interesting questions and with his sharp scientific mind he could always explain confusing experimental results or come up with new ideas to explore. When Marcus gave a presentation everyone in the audience was inspired. Marcus travelled the world on company business or to give lectures on drug delivery sciences. He loved to travel to meet new people, make new friends and explore new cultures.

But most of all Marcus was a good friend of exceptional intelligence that loved to share his wisdom and passion for science with everyone around him. Marcus Eli Brewster is deeply missed by his friends and fellow scientists all over the world.

Thorsteinn Loftsson

9th World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology

Lisbon, Portugal, 30 March–3 April, 2014

After the great success of the previous World Meetings on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology (Budapest, Paris, Berlin, Florence, Geneva, Barcelona, Malta and Istanbul) the 9th edition of the congress was held from the 30th March to 3rd April 2014 in the Congress Center of Lisbon, Portugal. More than 1300 participants from 56 countries attended the meeting, that was jointly organized by the APV (German "International Association for Pharmaceutical Technology"), A.D.R.I.T.E.L.F. (Italian "Associazione Docenti Ricercatori Italiani di Tecnologie e Legislazione Farmaceutiche") and APGI.

During the opening ceremony Prof. João Pinto (University of Lisbon, Portugal), the chair of the meeting, as well as Prof. Joerg Breitkreutz (University of Duesseldorf, Germany), Prof. Franco Alhaique (University of Rome, Italy) and Prof. Juergen Siepmann (University of Lille, France) welcomed the participants from all over the world. Maria da Graca Carvalho from the European Commission gave an outlook on the European research program 2015-2020, followed by an overview about the pharmaceutical Industry in Portugal given by Guy Villax (Hovione). Dr. Jean René Authelin from Sanofi (Global Head of Pharmaceutical Engineering, France) presented an overview on the role of pharmaceutical engineering in the development of industrial processes and addressed the future challenges of Pharmaceutical Engineering. The Welcome Reception in the evening allowed for networking with participants from academia, industry and regulatory authorities from over 50 countries.

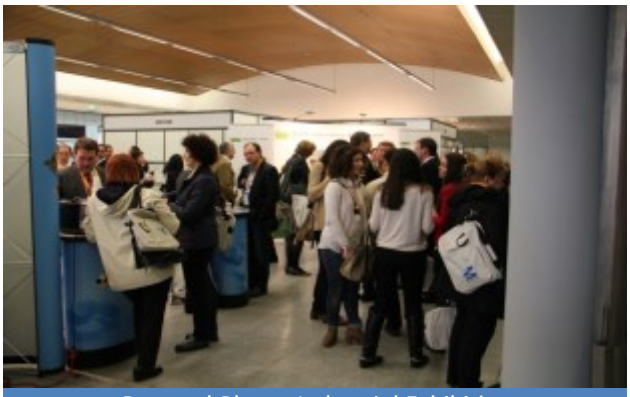
On Tuesday, the lectures started with invited talks on Solid

Congress Center of Lisbon

Dosage Forms, Protein and Nucleotide Formulations, Advanced Analytics as well as Dermal and Transdermal Delivery. Dr. Alexander Kabanov from the University of North Carolina (USA) gave an excellent presentation about challenges and opportunities in Nanomedicines.

In the afternoon Dr. Adrian Funke (Bayer) presented a case study dealing with the introduction of QbD and PAT tools in the development of an active film coating. In this study, Design of Experiments was used to optimize the formulation parameters, Raman spectroscopy allowing for determining the endpoint of the coating process. Following this lecture, Prof. Abdul Basit from the University of London (UK) presented new developments in GIT drug delivery. He pointed out different aspects of IVIVC and how to overcome major hurdles in this field.

During the fully booked industrial exhibition "ResearchPharm" and the poster sessions, the participants had the opportunity to discuss new achievements in development and production of new medicinal products and medical devices.



ResearchPharm Industrial Exhibition

On Wednesday, many topics such as Drug Nanoparticles & Vesicles, Tissue Engineering & ATMP, Continuous Manufacturing, Performulation & Physical Pharmaceutics, Patient-cented Medicines, Green & Sustainable Pharma, Controlled Drug Delivery, and Advanced Analytics were presented as short lectures.

In the morning session, Prof. Roberta Cavalli from the University of Turin- Department of drug science and technology (Italy) gave an overview on nanosuspensions, emphasizing the most frequently used methods for their preparation and characterization. Also, Dr. Herbert Kasowski (Executive Advisor, Vaeocon Management Consulting) presented Energy and resource saving

Poster Exhibition

Pharmaceutical Manufacturing and gave an example from Pfizer. Prof. David J. Mooney from the School of Engineering and Applied Sciences & Wyss Institute (Cambridge) gave an update on Biomaterials used as therapeutic cancer vaccines as well as the development of sustained biomaterials for localized immunomodulatory factor delivery.

The gala dinner in the Convento do Beato gave the opportunity to get in contact with former and new collaborators. One highlight was the show of the Fado group of the University of Lisbon

Dinner Event at the Convento do Beato

presenting a unique mixture of traditional music and dance.

On Thursday, short lectures on different topics (Nanoparticles, Oral drug delivery, Site-specific drug delivery, Pharmaceutical Engineering & Green manufacturing, Generics & Biosimilars, Skin- nose & lung delivery, Pharmaceutical Engineering and Poorly soluble drugs) were presented and enjoyed by the participants who intensively interacted during the discussions of the different topics.

The Marie Janot Award Plenary lecture was given by Prof María José Alonso from University of Santiago de Compostela (Spain).

She presented an overview nanocarriers used to overcome biological barriers from cell membrane to the mucosa.
She addressed a variety of different polymers used for the development of nanoparticules, confronting the biological barriers limiting their access to the target cells.
Prof. Alonso was recognized for her outstanding achievements in this field.

Prof. Maria José Alonso

Moreover, Prof. Richard H. Guy from the University of Bath (United Kingdom) focused on drug delivery methodologies into and through the skin. He explained the use of various techniques to extend the range of applicable drugs and to quantify drug delivery to specific areas.

Furthermore, Prof. Thorsteinn Loftsson from the University of Iceland presented efficient approaches for increasing oral bioavailability using cyclodextrins. He reviewed the physicochemical and biological properties of these molecules, including their tendency to form aggregates and their pharmacokinetics. Finally, he showed examples on different practical applications of cyclodextrins in pharmaceutical formulations.

Plenary lecture

2nd Poorly Soluble Drugs Workshop

College of Pharmacy, University of Lille, Lille, France, 2 July 2014

Following the success of the 1st APGI "Poorly Soluble Drugs Workshop" in 2011, the 2nd workshop in this series was held at the College of Pharmacy, University of Lille, on 2nd July.

The one day event was attended by more than 150 participants.

A variety of lectures was given by academic and industrial speakers, pointing out the challenges encountered with poorly water-soluble drugs as well as potential strategies to address them. Special highlights included the invited lectures of Prof. M. Descamps from the University of Lille (France) and Prof. T. Rades from the University of Copenhagen (Denmark) on drugs in the amorphous state and emerging trends for their stabilization. Prof. G. van den Mooter from the University of Leuven (Belgium) and Prof. D. Craig from the UCL School Pharmacy (UK) presented formulation and process considerations for the manufacturing of solid dispersions. Special emphasis was placed on spray drying techniques and recent physical characterization tools for solid dispersions. Prof. A. Müllertz from the University of Copenhagen (Denmark) described how to develop lipid based drug delivery systems for optimal performance, in particular self-nanoemulsifying drug delivery systems (SNEDDS). Dr. M. Brewster from Johnson & Johnson (Belgium), Dr. A. Rajabi-Siahboomi from Colorcon (USA), Dr. A. Gryczke from BASF (Germany), Dr. C. Popescu from Roquette (USA), Dr. J. Moeschwitzer from NetxPharma (Germany), and Dr. D. Gabriel from Apidel SA (Switzerland) presented novel excipients and innovative applications for poorly water-soluble drugs in vitro as well as in vivo.

It was also a special moment to commemorate the 50th APGI's anniversary: The APGI's former presidents, Prof. D. Duchêne and Prof. E. Fattal, presented an overview on the history of the APGI society and major aims and scopes. Then, the current president, Prof. J. Siepmann, presented the perspectives and new challenges to be addressed in the future.

Furthermore, an industrial exhibition was organized in the poster-lunch/coffee break area, which allowed for intensive exchange between the participants, poster presenters and exhibitors. The exhibition offered an overview on the most recent advances and novel trends in this field.

In addition, practical demonstrations in small groups were held on hot-melt extrusion (by Thermo Fisher), spray-drying (by ProCepT), solubility measurements (by Sirius Analytical), particle size measurements (by Malvern), thermal analysis (by TA Instruments) and milling (by Netzsch).

There

8th Annual PSSRC Symposium

Ljubljana and Portorož , Slovenia, 16-18 September, 2014

The 8th annual PSSRC (Pharmaceutical Solid State Research Cluster) symposium "Advanced Characterization Techniques for Solid Pharmaceutical Dosage Forms" was held during three days: 16-18 September 2014 at the College of Pharmacy in Ljubljana (closed days) and in the Grand Hotel Bernardin in Portorož (Open Day), Slovenia. Research cluster counts 11 academic laboratories, located at the Universities of Cambridge (United Kingdom), Copenhagen (Denmark), Düsseldorf (Germany), Ghent (Belgium), Graz (Austria), Helsinki (Finland), Leuven (Belgium), Lille (France), Lisbon (Portugal), Ljubljana (Slovenia) and Otago (New Zealand) (www.pssrc.org). The aim of this consortium is to overcome current limitations in the

formulation of solid pharmaceutical dosage forms: Novel systems and strategies are developed, ensuring the quality of medicines.

The Annual PSSRC Meeting was dedicated to the next generation of pharmaceutical scientists (doctoral students and post-docs). The 3 days meeting gave the **Young Scientists** the unique opportunity to network and share professional experiences: They presented posters and lectures and discussed their latest research findings.

One of the 3 days was the **"Open PSSRC Day"**, during which internationally highly recognized experts in the field present overviews on the current state of the art of "hot topics". During the two closed days, PhD students gave short talks on their research works. Five sessions were organized (Solid state challenges, Process understanding and monitoring methods, Applications in analytical science, Particle engineering and Drug product design) during which 49 talks have been presented by PhD students. This was the opportunity for PhD students to share their results and experiences among themselves and also with assistant professors and professors. They received a lot of advices, supports and recommendations from other scientists that can be very helpful for their PhD thesis. At the end of the closed days, a tour was organized to discover Ljubljana city .

The "Open Day" was open to the public and it mainly consisted

of oral presentations of experts in their research fields. This year, the Open Day was at the same time the Satellite Symposium of the Central European Symposium on Pharmaceutical technology (CESPT), entitled "Functionality related characteristics of materials for controlled release". 8 presentations were given. Among them, Prof. Peter Kleinebudde from the Heinrich Heine University (Germany) talked about the excipients and their functionality related characteristics. Prof. Anette Müllertz from the University of Copenhagen (Denmark) talked about optimizing in vitro models in order to predict oral drug performance. An interesting presentation was given by Fred Monsuur from the Grace Company about Silicon Dioxides for drug delivery technologies. Other speakers included: Dr. Korbinian Löbmann from the University of Copenhagen (Denmark), Dr. Biljana Janković from the University of Ljubljana (Slovenia), Dr. Matej Horvat from Lek Pharmaceuticals, a PhD student of Elena Boldyreva from the Novosibirsk State University (Russia) and Dr Leena Peltonen from the University of Helsinki (Finland).

At the end of these three days, Prof. Peter Kleinebudde who served as Director of the PSSRC Cluster during the last 2 years handed over to Dr. Axel Zeitler (Cambridge). The 9th PSSRC Meeting will be held in 2015 in Ghent (Belgium).

IMS2015 Boston

20th International Symposium on Microencapsulation
October 1-3, 2015 • Northeastern University • northeastern.edu/ims2015

Co-hosted by: International Microencapsulation Society · Northeastern University College of Engineering · CPBN Northeastern University Center for Pharmaceutical Biotechnology and Nanomedicine

Welcome to the 20th International Symposium on Microencapsulation!

Dear Friends and Colleagues,

I am pleased to announce that the 20th International Symposium on Microencapsulation will be held at Northeastern University in Boston October 1st to 3rd, 2015.

The Symposium will include plenary talks, invited presentations, and posters sessions. The meeting will cover the most important aspects of microencapsulation and will include scientific sessions on new materials for microencapsulation, layer-by-layer technology, targeted and stimuli-sensitive systems, lipid-based microencapsulation, translational and clinical aspects of microencapsulated preparations, and consumer products.

The Advisory Board for the Symposium is currently working on the final program, while the local Organizing Committee is finalizing the logistics of the meeting, including registration, accommodations, abstract submission and reception. So, please check back soon for updates, plan your trip to Boston, and spread the word about Mirco2015.

Registration fees for the Symposium (to include Symposium materials, coffee breaks, and Conference Dinner) will be: US$ 300 (late US$400) for students and postdocs; US$ 600 (late US$750) for academia, and US$800 (late US$1,000) for industry.

The information about the program as well as registration and abstract submission opportunities will soon appear at the Symposium's website: http://www.northeastern.edu/ims2015/

Vladimir P. Torchilin

16èmes JOURNEES de FORMULATION

Groupe Formulation - Société Chimique de France

Villeneuve d'Ascq
Les 9 et 10 Décembre 2014

Objectifs du Colloque

L'ambition d'un développement durable et les réglementations de plus en plus contraignantes conduisent les formulateurs à utiliser des matières premières dérivées de ressources renouvelables, sans danger pour l'homme et l'environnement, et des procédés plus sûrs, utilisant moins d'énergie et moins polluants. Chercheurs, industriels et étudiants venez nombreux communiquer et échanger lors de ces 16èmes journées de Formulation !

Conférenciers invités

Mardi 9 Déc 2014
Spécialités chimiques

Xavier Fernandez (Univ. Nice-Sophia Antipolis, France) : Biodiversité végétale - Nouveaux conservateurs naturels : développements, formulation et difficultés

Cosima Stubenrauch (Univ. Stuttgart, Allemagne) : Novel hybrid carbohydrate/ Oligoethylene oxide surfactants

André Laschewsky (Fraunhofer Institute – Potsdam, Allemagne) : Polymères dérivés de sucres pour les formulations aqueuses

Tony Bartolini (Novozyme, France) : Enzymes et micro-organismes en détergence

Ronald Hage (Catexel, Pays-Bas) : Bleach catalysts for laundry, raw cotton treatment, pulp bleaching and paint drying

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Benoît Hénault (Dow Corning, Belgique) : Silicones: technologies, formulations et développement durable

Yoann Lefeuvre (Formulaction, France) : Influence des biopolymères sur la stabilité et la rhéologie des formulations actuelles

Mercredi 10 Déc 2014
Produits Formulés

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Martin Mosquet (Lafarge, France) : Formulation des matériaux de construction

Thierry Vidal (Solvay, Belgique) : New solvents for sustainable solutions

Sylvain Gressier (LUM GmbH, Allemagne): Stabilités accélérées et caractérisation des interactions particulaires

Appel à Communications

Des posters et des communications orales flash (5 min) seront présentées (les détails seront donnés prochainement sur le site web). Un prix du meilleur poster de 500 € sera offert par la société Formulaction.

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DuraLac® H: A new, alternative source of anhydrous lactose

Franz K. Penz*
Meggle E & T, Megglestr. 6-12, D 83512 Wasserburg; Germany
www.meggle-pharma.de

Introduction:

Anhydrous lactose was developed and patented in the United States of America in the early 1940s and this product quickly found its way into pharmaceutical applications. Most notably, the initial use of anhydrous lactose was preferentially focused in the Anglo-American hemisphere, perhaps due to academic, economic and political circumstances. Asia and Europe have traditionally favored α-lactose monohydrate grades.
Globalization has occurred in all industry categories. Fundamental changes have also been observed within the pharmaceutical landscape and consequently, this has had as well an impact on the excipient industry. Worldwide migration of production sites and their accompanied products, the development of new, diverse formulations, and a variety of manufacturing techniques has necessitated the constant supply of robust, ubiquitous and reliably sourced excipients. *Meggle* has accepted this challenge and introduced an alternative source for anhydrous lactose, DuraLac® H.

Material and methods:

Angle of repose, compressibility-related indices, Hausner ratio (rt/rb), and Carr's Index ([rt-rb]/rt x100) were evaluated by compendial methods. FlowRatex® operation was conducted per the manufacturer recommended protocols. Blends comprising 0.5 % lubricant (Mg-stearate, Merck; Germany) and a glidant (hydrophilic fumed silica, Aerosil® 200, Evonik; Germany) were mixed in a Turbula® mixer (Bachofen; Switzerland) at 45 rpm for 5 min. Compaction trials were performed on a STYL'One® tablet press (Medelpharm; France). ANALIS® software was utilized for documentation acquisition. Punch diameter was 11.28 mm, round, flat-faced, with 22 mm high die walls. Tablet hardness was evaluated, using an Erweka hardness tester, Type TBH® 30. Disintegration was handled by an Erweka ZT® 3-2 apparatus, according to compendial requirements (Ph.Eur. 2.9.1). For active pharmaceutical ingredients (APIs) Theophylline (anhydrous, BASF), Paracetamol (Salutas), and Diprophylline (fine powder, BASF) were selected for their solubility profiles (tablet hardness ca. 70 N). An USP 35 dissolution paddle apparatus was used for dissolution trials (Sotax; Switzerland). Hydrophilic fumed silica and Mg-stearate were preferred in a concentration of 1 %, and congruence of release profiles was analysed by similarity factor f2, according to Moore and Flanner. Particle size distribution (PSD) was investigated by Sympatec®/Helos & Rodos particle size analyzer. Scanning electron microscopy (SEM) was used to scan the material at a beam voltage of 5 kV (Ultra 55® FESEM, ZEISS).

Production process, regulatory and quality information:

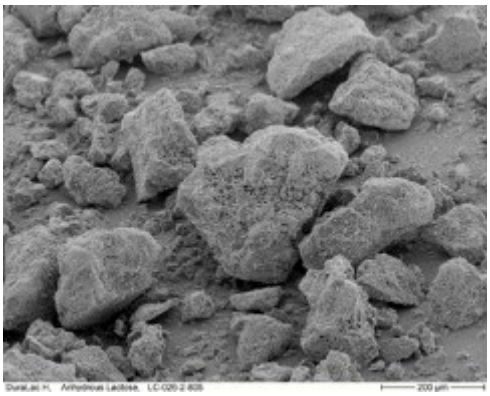
Meggle offers dual sourcing, and DuraLac® H is produced in Le Sueur, MN; USA. This state of the art, pharma-dedicated production site complies with cGMP-standards according to the Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients and USP NF General Information Chapter <1078>. Starting material is an USP NF-compendial α-lactose monohydrate grade, dissolved in water and sprayed on two counter rotating drums at elevated temperatures. Anhydrous lactose spontaneously crystallizes on hot surfaces and is subsequently scraped off (picture 1).

Picture 1: Anhydrous lactose production: Scrape-off and fall into a chute of white DuraLac® H crystals from a rotating drum after spontaneous crystallization on the hot surface.

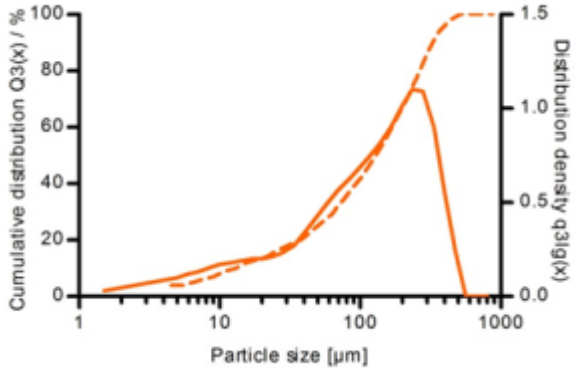
The white crystals fall into a chute and are transported by a screw-conveyor to a final milling and sieving step, assuring the defined PSD. Finally, pharmaceutical anhydrous lactose grade DuraLac® H is packed either into 25 kg carton boxes or 50 kg fiber drums, both containing aluminium laminated inliners. The shelf life is 24 months, according to ICH Q1A stability guidelines. Further detailed information on high batch-to-batch consistency, specifications and regulatory documents can be downloaded from www.meggle-pharma.com. DuraLac® H complies with lactose anhydrous monographs in JP, Ph.Eur., USP NF, and is GRAS listed.

Physico-chemical characterisitics:

Anhydrous lactose, appearing as a white to off-white, crystalline, odorless powder heap, has a slightly sweet taste. Morphology of anhydrous particles is different to monoclinic sphenoidal crystals of α-lactose monohydrate. Anhydrous lactose granules are remarkably dense, representing agglomerates of microcrystals exhibiting a wide irregularity in shape and breaking edges due to its production process (picture 2).



Picture 2: SEM of anhydrous lactose DuraLac® H crystals. The particles represent agglomerates of microcrystals and exhibit a wide irregularity in shape due to its production process.



Picture 3: Typical cumulative PSD and distribution density of Meggle's anhydrous lactose grade DuraLac® H. Analyzed by Sympatec® /Helos & Rodos particle size analyzer.

A typical laser diffraction PSD exhibits a d_{50} value of 135 µm (d_{10} 15 µm, d_{90} 310 µm; see picture 3), and a specific BET-surface area is found in the range between 0.3 and 0.4 m^2/g. Additional basic powder technological data may be taken from table 1.

DuraLac® H*

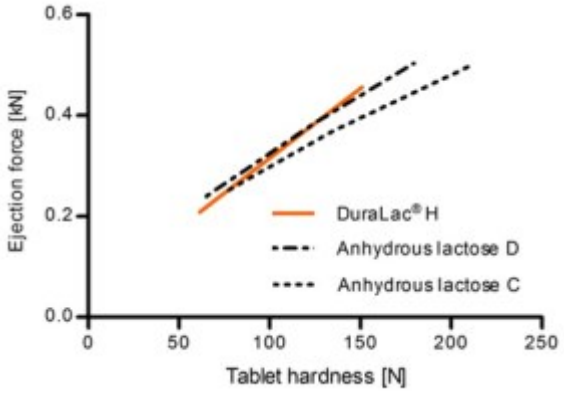
Parameter	Value	Unit
Water (KF)	0.6	[%]
Loss on drying	0.1	[%]
Bulk density	670	[g/ml]
Tapped density	880	[g/ml]
Carr-Index	1.31	[%]
Hausner-ratio	23.86	[1]
Angle of repose	42	[^{0}]

*typical values, only

Table 1: Typical powder technological parameters for anhydrous lactose grade DuraLac® H.

Lactose appears as α- and β-anomer, and in anhydrous lactose, a typical ratio of 20% α- and 80% ß-modification, containing no water of crystallization is evident. The ß-anomer exhibits higher water solubility, respectively.
DuraLac® H is largely moisture stable, showing very low hygroscopicity. It starts to absorb significant amounts of moisture not before a relative humidity of 70 % at 25°C, as indicated by differential vapor sorption (DVS). Passing through conditions of higher humidity anhydrous lactose demonstrates hysteresis behavior, caused by the conversion of lactose from anhydrous to monohydrate form.

DuraLac® H demonstrates excellent compaction properties and low lubricant sensitivity, which may be attributed to the brittle nature of anhydrous lactose. This leads to large, new bonding surface during compaction. It also facilitates the necessary functionality required by direct compression processes to produce robust tablets at high speed, and defined granules in roller compaction. A typical tensile strength of 2.5 N/mm^2 for DuraLac® H placebos may be seen at a corresponding compaction pressure of 180 MPa. Ejection forces up to 400 N are common and may be observed at a tablet hardness of 130 N for neat anyhydrous lactose grades (see picture 4).



Picture 4: Typical ejection forces of various anhydrous lactose grades (DuraLac® H, Anhydrous Lactose C and D), showing similar PSD (1% Mg-stearate; STYL'One® tablet press (Medelpharm; France)).

Flowability is a result of various powder properties, and amongst them PSD and morphology seem to have the utmost impact. With its rough surface, neat anhydrous lactose is generally defined by modest flow due to particle structure prone to cohesive effects and an elevated fraction of fines. However, this reflects reality in limited common formulation practices as the strong majority of formulations is lubricated. Anhydrous lactose drastically enhances its flow properties upon lubrication.

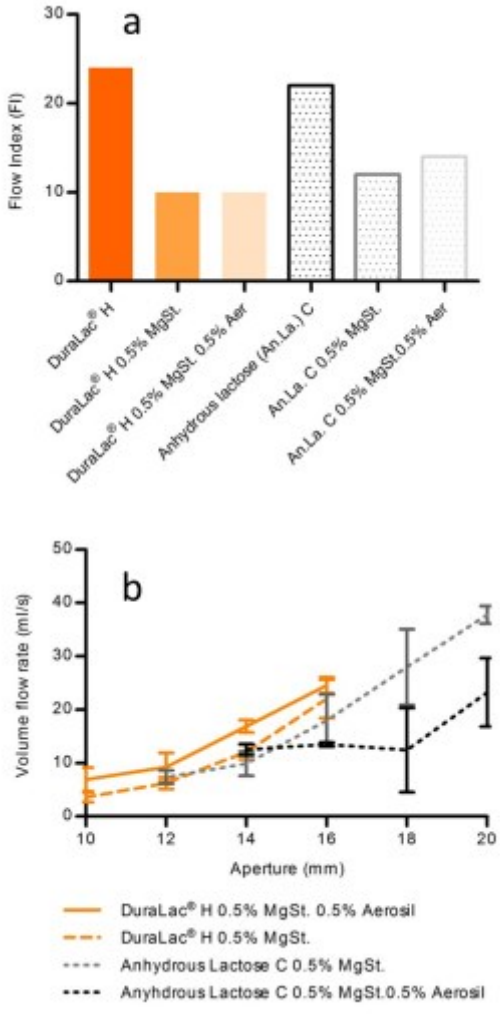
With the introduction of lubricants and glidants, anhydrous lactose flowability was evaluated using a FlowRatex®, a robust and simple device to mimic a tableting or device filling process, allowing a substantial increase in flowability to be quantified.

Aperture diameters of 22 mm (equivalent to a Flowability Index (FI) of 22) and larger are required to insure consistent powder flow of two commercially available, neat anhydrous lactose grades (DuraLac® H and Anhydrous Lactose C).

Adding 0.5 % Mg-stearate to this system cuts the FI almost in half, indicating a dramatic improvement in flow properties. For DuraLac® H, the FI drops from 24 to 10. For the second investigated lactose grade (Anhydrous Lactose C) the FI changes from 22 to 12. In general a smaller FI stands for better flow.

An additional concentration of 0.5 % fumed silica to the system seems to have a positive impact on DuraLac® H only, as indicated by a subsequent increase in volume flow (see picture 5b, orange dotted versus orange continuous line), and the FI value of 10 for DuraLac® H does not change.

However, with the additional fumed silica, the FI for Anhydrous Lactose C increases from 12 to 14, and a decrease in volume flow is observed (see picture 5b, grey dotted versus black dotted line). This gives evidence that the further addition of a glidant may not be successful in all cases.

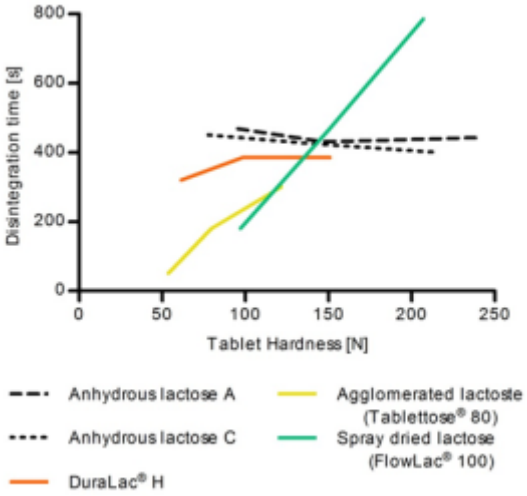


Pictures 5a, b: Powder flow of neat and lubricated anhydrous lactose compared by flow index (FI) and volume flow rate. Adding 0.5 % Mg-stearate to the system cuts numbers of FI almost in half, indicating a dramatic improve in flow properties (5a).

Extra lubrication by 0.5 % fumed silica seems to have an impact on DuraLac® H only, as indicated by an increase in volume flow rate (5b: compare orange dotted versus orange continuous line). FlowRatex® operation was conducted as per the manufacturer recommended protocols.

Disintegration of anhydrous lactose-based tablets is less hardness dependent compared to α-lactose monohydrate compacts, and at moderate to high compression forces disintegration is also faster. This phenomenon is due to the presence of ca. 80% ß-lactose anhydrous, which shows increased water solubility in comparison to α-anomer anhydrous and hydrous. α -lactose anhydrous is known to block water imbibition by its small pore diameter and precipitation of dissolved anhydrous α -lactose into hydrous α-lactose. At low compression force porosity seems to be the crucial factor.
If several commercially available anhydrous lactose grades are investigated, little difference may be seen (picture 6, dashed and dotted black lines, orange continuous line). Neat, anhydrous lactose grades comprising comparable PSD are roughly defined by disintegration times between 300 and 450 sec at a broad range of tablet hardness between 50 and 200 N. Hardness dependent disintegration performance may not be assumed.
On the contrary, α-lactose monohydrate-based grades, like agglomerated Tablettose® 80 or spray-dried FlowLac® 100 are highly hardness dependent (picture 6, yellow and green continuous lines). For spray-dried lactose, an increase in disintegration time is most distinct, from 200 to 800 sec at 100 to 200 N tablet hardness, respectively. Tablettose® 80 performs within the range of 50 to 300 sec disintegration time at 50 to 125 N tablet hardness.

Aside from the solubility exhibited by the α- and ß-anomers, a more plastic compaction process, leading to different pore forming may be taken into consideration with spray-dried lactose as well. Higher plasticity is a result of the presence of amorphous lactose.



Picture 6: Disintegration of anhydrous lactose-based tablets (DuraLac® H, Lactose A and C; orange continuous line, dashed and dotted black lines) is less hardness dependent compared to α-lactose monohydrate compacts (agglomerated Tablettose® 80, FlowLac® 100; yellow and green continuous lines) at moderate to high tablet hardness. Disintegration testing was performed by an Erweka ZT® 3-2 apparatus, according to compendial requirements.

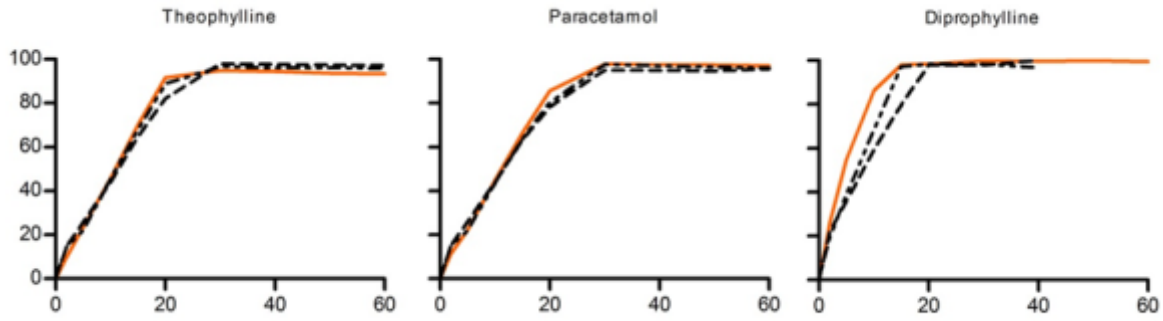
Drug dissolution and release profiles are routinely used to monitor product quality and even predict in vivo performance. Whereas drug dissolution may be seen as a relatively simple operation, drug release can involve quite complex steps as tablet disintegration is influenced by penetration of water, drug diffusion through pores or even change of the water-filled network by precipitation. As a result of good water solubility and surface wetting anhydrous lactose favors immediate release.
To prove robustness and exchangeability of various commercially available anhydrous lactose grades in a formulation, a rational approach was chosen by taking different solubilities of drug substances in water into account. Three diverse APIs, showing poor to excellent water solubility had been consulted as model systems: Theophylline (7.4 g/l), Paracetamol (14 g/l) and Diprophylline (330 g/l), defined by highest water solubility, at 25 °C in each case.

An overall low API load of 10 % was chosen to slow down drug release and observe the primary effects of the "lactose matrix" being present in a disproportionally high ratio. Subsequently, no disintegrants or superdisintegrants were applied. All investigated anhydrous lactose grades showed similar PSD, represented by a d_{50} of 139 ± 9 µm. Drug release profiles of a formulation using different lactose matrices had been compared quantitatively by using the similarity factor f2 according to Moore and Flanner[i], whereas values of f2 ≥ 50 -100 are indicating equivalence of two curves. The release kinetics of 3 different commercially available anhydrous lactose grades as a matrix were compared (DuraLac® H as reference, and Anhydrous Lactose grades A and B for comparison) by using the three selected APIs. In all cases, the results demonstrated similar factors of f2 ≥ 50, indicating product equivalence. Only in one example was a divergence investigated (table 2). These results give a strong indication that a simple mutual substitution of anhydrous lactose as an excipient matrix within a formulation may be achieved.

Conclusion:

DuraLac® H, disclosing complete regulatory documentation opens a new, alternative source for anhydrous lactose in pharmaceutical tableting operations and manufacture. Chemical-, physical-, and functionality related powder parameters are found within a range comparable to other commercially available anhydrous lactose grades. DuraLac® H is an equivalent alternative in anhydrous lactose formulations.

API		Theophyllin	Paracetamol	Diprophyllin	
Lactose	Anh. Lact. A - - - -	66,06	73,74	41,83	f2
	Anh. Lact. B - • • -	71,45	83,66	50,78	
	DuraLac®H - - - -	reference	reference	reference	



Drug release kinetics; x-axis: time (0 - 60 min) and y-axis: rel. drug release

Table 2: Comparison of drug release kinetics using 3 different commercially available anhydrous lactose grades (DuraLac® H as reference, Anhydrous Lactose A and B for comparison) in a formulation containing either Theophylline, Paracetamol or Diprophylline. By using similarity factor f2 ≥50 as an indicator of product equivalence a simple mutual substitution of anhydrous lactose within a formulation may be achieved.

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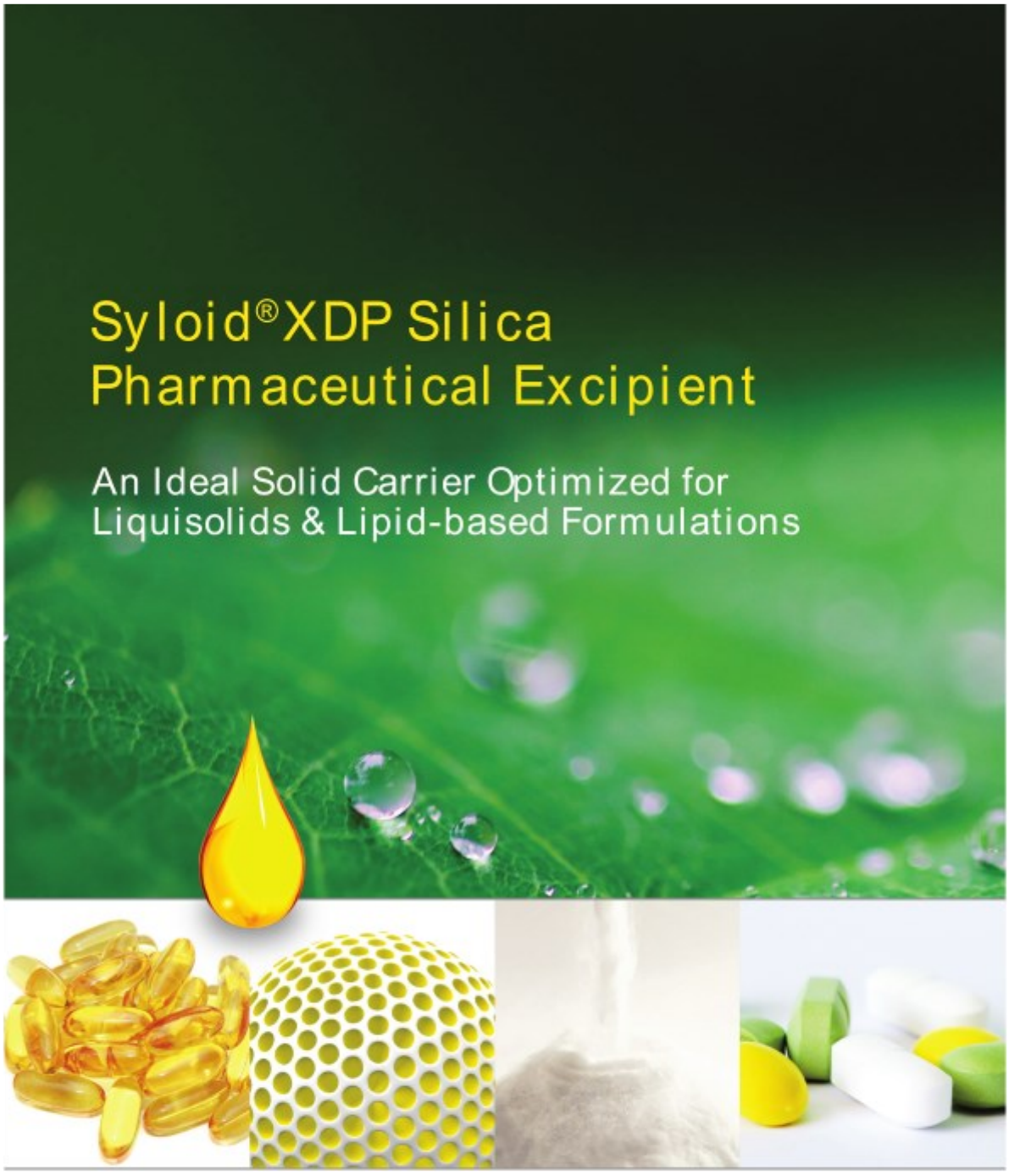

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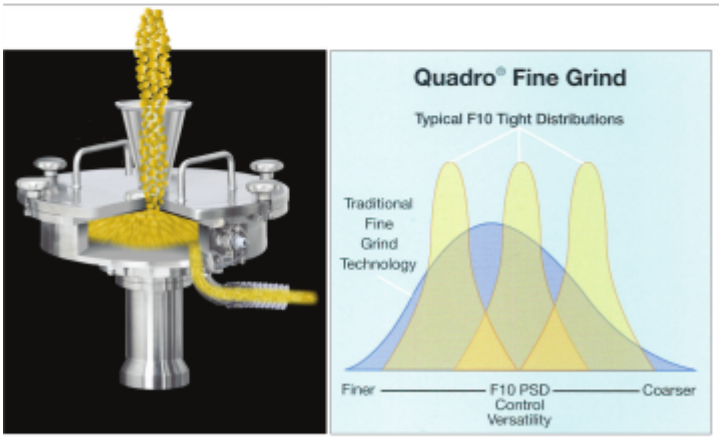

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