AAPS 2014 Presentation Guide

Tuesday, November 4th

Novel Lipophilic Salts of Atazanavir for Improved Drug Loading in Lipid Vehicles: A Joint Presentation with Capsugel and BMS

PRESENTING AUTHOR: SUBMISSION AUTHORS: POSTER NUMBER: TIME

Xue-Qing Chen Xue-Qing Chen, Mike Morgen, Warren Miller, Gajendra Chowan, Anoop T2065 9:30AM - 12:30PM

Kumar, Ajay Saxena, Sheelendra Singh, Sridhar Desikan, Sandhya

Mandlekar, Ching Su, Roy Haskell, Olafur Gudmundsson, Michael Hageman

Capsules for Dry Powder Inhalation – Performance Evaluation of Different Capsules with Various Inhalation Devices

PRESENTING AUTHOR: SUBMISSION AUTHORS: POSTER NUMBER: TIME:

Dominque Cadé Claire Tardy, Magali Baudoin, Dominique Cadé T3174 1:30PM - 5:00PM

Development of Taste-Masking Fexofenadine Lipid Multiparticulate for Pediatric Use

PRESENTING AUTHOR: SUBMISSION AUTHORS: TIME.

Hassan Benameur Aurélien Sivert, Chloe Labeye, Diane Ertel, Hywel Williams, T3224 1:30PM - 5:00PM

Jan Vertommen, Hassan Benameure

Synthesis of Spray-Dried Nanocrystals by a Single Step Flash Precipitation Spray Drying Process

PRESENTING AUTHOR: SUBMISSION AUTHORS: POSTER NUMBER: TIME:

Aaron Goodwin Vikram Pansare, Aaron Goodwin, Ron Beyerinck, David Vodak, T3108 1:30PM - 5:00PM

Dwayne Friesen, Robert Prud'homme

Wednesday, November 5th

Alcohol Dose Dumping for Controlled Release Formulations: Is DRcaps® Acid Resistant Capsule an Option?

PRESENTING AUTHOR: SUBMISSION AUTHORS: POSTER NUMBER: TIME:

Dominque Cadé Dominique Cadé, Elisabeth Groshens, Xiongwei He W4029 9:30AM - 12:30PM

Drug Substance Containment Approaches for New Processes on Legacy Equipment

PRESENTING AUTHOR: SUBMISSION AUTHORS: POSTER NUMBER: TIME:

Alyn McNaughton Alyn McNaughton, Jose Mosquera, James Johnston, W4370 9:30AM - 12:30PM

Massoud Bakhshaee

Dry Coating Based Surface Modification of Amorphous Spray Dried Dispersions to Improve Powder Flowability through Densification and Particle Cohesion Reduction

PRESENTING AUTHOR: SUBMISSION AUTHORS: POSTER NUMBER: TIME:

Aaron Goodwin Aaron Goodwin, Charlie McLaughlin, William Steinhauff, Randy Wald W4333 9:30AM - 12:30PM

Use of Flory-Huggins (FH) Theory to Predict Effect of Drug Load on Thermodynamic Stability of Binary Systems

PRESENTING AUTHOR: SUBMISSION AUTHORS: POSTER NUMBER: TIME:

Piero Piccinni Piero Piccinni, Jane Fraser, David Jones, Stephen Brown, W4128 9:30AM - 12:30PM

Gavin Andrews

Validating the Commercial Performance of an Innovative New Sprinkle Capsule Design for Pediatric and Geriatric Use

PRESENTING AUTHOR: SUBMISSION AUTHORS: TIME: POSTER NUMBER: TIME:

Missy Lowery Stef Vanquickenborne, Missy Lowery, Catherine Lehmann, Martha Cope W4362 9:30AM - 12:30PM

DRcaps® Capsules Banding for Improved Acid Resistance

PRESENTING AUTHOR: SUBMISSION AUTHORS: POSTER NUMBER: TIME:

Dominque Cadé Xiongwei He, Isabelle Remondiere, Dominique Cadé W5132 1:30PM - 4:30PM



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Multi-compartment Hard Capsule and Potential Applications

PRESENTING AUTHOR: SUBMISSION AUTHORS: TIME: TIME:

Dominique Cadé Xiongwei He, Isabelle Remondiere, Dominique Cadé W5133 1:30PM - 4:30PM

Novel HPMC Capsules Display Acid Resistance Behaviour – A Scintigraphic Imaging Study: A Joint Presentation with Capsugel and Bio-Images

PRESENTING AUTHOR: SUBMISSION AUTHORS: TIME: TIME:

Howard Stevens Lee Ann Hodges, Sarah Connolly, Dominique Cadé, Chang Lee, W5173 1:30PM - 4:30PM

Howard Stevens

Thursday, November 6th

Designer Modified Release Microspheres for Preclinical Drug Discovery Research - *In Vivo* Performance: A Joint Presentation with Capsugel and BMS

PRESENTING AUTHOR: SUBMISSION AUTHORS: POSTER NUMBER: TIME:

Kim Tye Kim Tye, Mike Morgen, Matt Shaffer, Brice Murri R6062 8:30AM - 11:30AM

Development of an Accelerated Stability Test: Application of Thermoanalytical Methods to Predict Crystallization of Amorphous Ternary Systems

PRESENTING AUTHOR: SUBMISSION AUTHORS: POSTER NUMBER: TIME:

Piero Piccinni Piero Piccinni, Jane Fraser, David Jones, Stephen Brown, Gavin Andrews R6098 8:30AM - 11:30AM

Feasibility Studies for 505(b)(2) Product Development of Three BCS Class II Compounds Using Lipid-Based Formulations

PRESENTING AUTHOR: SUBMISSION AUTHORS: POSTER NUMBER: TIME:

Prashant Agarwal Prashant Agarwal, Hywel Williams, Pietro Treviso, Eduardo Jule R6225 8:30AM - 11:30AM

Hard Capsules for Vaginal Applications

PRESENTING AUTHOR: SUBMISSION AUTHORS: POSTER NUMBER: TIME:

Dominque Cadé Hugues Straub, Dominique Cadé, Laurence Canu, Charlene Picon R6248 8:30AM - 11:30AM

Lipid-Based Capsule Products to Increase Bioavailability and Reduce Food Effect for a Poorly Soluble Compound

PRESENTING AUTHOR: SUBMISSION AUTHORS: POSTER NUMBER: TIME:

Annabel Igonin Annabel Igonin, Jurgen Mensch, Sabine Inghelbrecht, Jens Ceulemans, R6154 8:30AM - 11:30AM

Hassan Benameur, Hans Vermeersch, Jan Vertommen

Lipid Multiparticulates (LMPs) for Improving Intestinal Absorption of Low Solubility Compounds: *In Vitro* Digestion as a Tool to Support Formulation Design and Mechanisms of Solubilization

PRESENTING AUTHOR: SUBMISSION AUTHORS: TIME: TIME:

Hywel Williams Jason LePree, Hywel Williams, Chris Diorio, Eric Ehrnsperger, R6226 8:30AM - 11:30AM

Brian Malone, John Lokhnauth

Lipid Multiparticulates Physical and Chemical Instabilities, an Unresolved Issue?

PRESENTING AUTHOR: SUBMISSION AUTHORS: POSTER NUMBER: TIME:
Simon Pondaven Simon Pondaven, Hywel Willams, C. Labeye, Hassan Benameur R6318 8:30AM - 11:30AM

NMR and IGC Analysis of the Concentration Dependence of HPMCAS Polymer Dynamics to Inform Droplet Drying Models for

NMR and IGC Analysis of the Concentration Dependence of HPMCAS Polymer Dynamics to Inform Droplet Drying Models for Spray Dried Dispersions

PRESENTING AUTHOR: SUBMISSION AUTHORS: POSTER NUMBER: TIME

David Vodak Amber Broadbent, David Vodak, Richard Falk, Nathan Williamson, R6267 8:30AM - 11:30AM

Joseph Seymour, Sarah Codd, Justin Moser, Ronald Danner

Capsugel Expert Seminars

Room 1B – 3rd on the Upper Level of the San Diego Convention Center Monday, November 3rd

11:00 AM - 11:45 AM

Enlarging the Design Space: Optimizing Development in Solid Oral and Pulmonary Applications with a Novel New Capsule

PRESENTERS:

Matt Richardson

Dominque Cadé

Polymer science and engineering have opened a new era of functional development, which offers the potential for selecting the right capsule for different APIS. New HPMC capsules represent a unique and valuable contribution - they dissolve quickly and predictably at different pH levels and are independent of cations and other food components. This webinar will provide an in-depth update on the oral and pulmonary application of this new generation.

12:00 PM - 12:45 PM

Top 10 Tips for Formulators and Manufacturing to Optimize Encapsulation

PRESENTERS:

ABSTRACT

Paul Davis and John Davidson

The path to successful encapsulation starts in the lab, not on the factory floor. Black Belt Quality and Encapsulation engineers will share 10 top tips for ensuring success from scale up through commercialization.

1:00 PM - 1:45 PM

Capsugel Innovation in Pediatric and Geriatric Drug Delivery

PRESENTER:

ABSTRACT

Hywel Williams

New lipid multiparticulate (LMP) technology offers the combined benefits of lipid-based formulations and multiparticulate (MP) drug delivery. LMPs are formulated from a range of GRAS lipid excipients to provide bioavailability enhancement (BAE), taste-masking and/or extended release, and complement Capsugel's premier range of BAE and MP technologies. Coni-Snap® Sprinkle capsules have been engineered for ease of opening to facilitate dosing with food for patient populations with swallowing issues. In this seminar, the integrated offering of LMP technology and specialized capsules will be presented along with representative case studies.

2:00 PM - 2:45 PM

Using Engineered Particles in Capsules for Rapid-to-Clinic Dry Powder Inhalation Applications

PRESENTERS:

Jeff Breit and Dominique Cadé Particle engineering via spray drying combined with formulation and process platform are innovating delivery to the lung versus traditional crystalline lactose based systems. Developers today can easily target upper respiratory tract versus deep lung through particle engineering. Presentation will describe a pulmonary platform technology for the rapid development of inhaled formulations.

3:00 PM - 3:45 PM

Optimizing Technology Choice to Enhance Bioavailability

PRESENTER:

David Lyon

Many active compounds require functional formulation to improve efficacy. With an expanding array of technologies combined with the need to save time and drug in early development, choice of the right drug delivery approach can be daunting. This describes an efficient strategy for matching enabling technologies to product concepts based on PK/PD, physicochemical properties and the target profile.

