DISSO INDIA 2022
INTERNATIONAL SYMPOSIUM

spds.in

In association with:

aaps®
American Association of Pharmaceutical Scientists

Dates: 23-24-25 June 2022

11th Annual International Conference on Dissolution Science and Applications

SCIENTIFIC ABSTRACT BOOK

SOTAX CE 7 smart

USP Apparatus 4

SOTAX CE7 Smart (USP4 Flow Through Cell) Allows you to see differences in your formulations that apparatus 1 and 2 simply do not show. Also widely recommended for poorly soluble, modified / extended release, and low dose products; Also been used for IVIVC studies and a growing range of dosage types

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Society for Pharmaceutical Dissolution Science (**SPDS**) was formed on 16th July 2012 at Mumbai with the objective of promoting the science and technological development in the field of dissolution among pharmaceutical professionals, academia, students, regulatory bodies, etc.

SPDS was formally launched at 64th IPC congress at Chennai by Dr. B. Suresh (Pro Chancellor, JSS Academy of Higher Education and Research, Mysuru and President Pharmacy Council of India) & The Chairman Mr. S. V. Veeramani (CMD, Fourrts India) on 9th December 2012.

SPDS is the only professional body in the world dedicated to Dissolution Science and its Applications.

VISION

To be as one of the most prominent professional bodies focusing on Dissolution Science among the Pharmaceutical Industry and Academia

MISSION

To dissipate the science & advancement which is rapidly taking place in the field of dissolution related to clinical application and methods

MESSAGE FROM THE PRESIDENT - SPDS, US Chapter

JSS ACADEMY OF HIGHER EDUCATION & RESEARCH
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JSS ACADEMY OF HIGHER EDUCATION & RESEARCH
(DEEMED TO BE UNIVERSITY) MYSURU

Dr. B. Suresh
Pro-Chancellor

June 23, 2022

MESSAGE

It gives me great pleasure that Society for Pharmaceutical Dissolution Science (SDPS) in collaboration with American Association of Pharmaceutical Scientists (AAPS) is holding its 11th Annual International Symposium on Dissolution Science and applications with the theme "Advances in Dissolution Science from 23rd to 25th June 2022 through virtual mode.

The Society for Pharmaceutical Dissolution Science (SPDS) has gained international recognition and acceptance, in a short period of time, I am sure that the three days conference will provide unique platform for all practicing professionals, academia, students, regulatory bodies etc.

I take this opportunity to encourage the Society for more such efforts and wish the conference a grand success.

With best wishes and regards,

(Dr. B Suresh)
Pro-Chancellor

MESSAGE FROM THE PRESIDENT - SPDS, US Chapter

Vinod P. Shah, Ph.D., FAAPS. FFIP
President, SPDS-US Chapter.

Greetings.

SPDS has been holding their flagship event, "Disso India" conference every year since its inception. It is great to see the launch of 11th Annual International Conference of SPDS, Disso India 2022 to be held online from June 23 – 25, 2022 with a theme of Advances in Dissolution Science. Due to the Covid-19 pandemic, the conference is held virtually, and has been attracting over 2500 scientists globally.

The Disso India 2022 conference is truly an international event where eminent global scientists from pharma industry and academia will discuss advances in dissolution science. It is great to see the collaboration of SPDS, the only professional body dedicated to dissolution science and its application worldwide and AAPS, the most prestigious pharmaceutical association in the world. The participants will certainly gain a lot from the conference.

Wishing a great success,

Vinod P. Shah, Ph.D., FAAPS. FFIP

President, SPDS-US Chapter.

MESSAGE FROM THE PRESIDENT - SPDS

Prof. Padma V. Devarajan
Dean-Research & Innovation and Professor in
Pharmacy, Institute of Chemical Technology, India

Dear Delegates,

Hearty welcome to DISSO INDIA 2022. Online for the third consecutive year DISSO INDIA's outreach has expanded considerably across the globe.

The Society for Pharmaceutical Dissolution Science (SPDS) has ensured that the COVID pandemic situation, which threatened to bring the world to a grinding halt, has been judiciously harnessed by continuing our activities in online mode. DISSO INDIA has now expanded from Local to Global. You would witness an online extravaganza as we have put together not just exciting talks covering the gamut of science and technology in the area of dissolution and its outcomes, but also an exhibition and much more. This grand event would be memorable in terms of take-home value and ideas for future research particularly for the scientists from academia and industry.

The DISSO INDIA platform would provide ample opportunity for interaction and networking. We look forward to your active participation, in making this meeting a great success.

While we look forward to meeting you all online, we also hope our next conference could be hybrid and combined also with a face-to-face meeting .

Stay safe, stay happy!!

Prof. Padma V. Devarajan

President, SPDS

MESSAGE FROM THE SCIENTIFIC CHAIR - SPDS

Arvind Kumar Bansal
Professor & Head, Department of Pharmaceutics,
NIPER, SAS Nagar, India

Dear Delegates,

We are organizing 11th Annual International Symposium on Dissolution Science and Applications – Disso India 2022, on the theme of "Advances in Dissolution Science". This online event is being organized in collaboration with American Association of Pharmaceutical Scientists (AAPS). This collaboration with leading pharmaceutical professional body has helped in enhancing outreach and internationalization of Disso India 2022.

Dissolution has a pivotal role in pharmaceutical development and regulatory approvals, of diverse dosage forms. Enhancement of solubility and dissolution remains a high priority area and aggressive efforts are being made by pharmaceutical scientists in developing new technologies. Computational tools like PBPK have acquired regulatory acceptance and are evolving rapidly. Similarly important developments have taken place in the area of instrumentation, automation and dissolution methodologies.

The scientific committee has made an endeavor to capture latest development in the field of enabling technologies, dissolution methodologies and instrumentation. A galaxy of thought leaders and professionals shall share their knowledge with the participants. Each module focuses on a theme and shall have invited lectures and interactive panel discussion.

I, on behalf of SPDS, thank all the invited speakers for accepting our invitation to participate in the deliberations of Disso India 2022. Over the years Disso India attracts participation from pharma industry, academia, regulatory agencies and students. We are sure that this unique symposium shall provide a significant learning experience to all the participants.

With best wishes

Arvind K Bansal, PhD, FAAPS

Scientific Chair - SPDS

MESSAGE FROM THE GENERAL SECRETARY - SPDS

Dr. L Ramaswamy
Managing Director, Sotax India Pvt Ltd, Mumbai

Dear Colleagues,

It is indeed a pleasure and privilege for me to be the General Secretary of SPDS and Organise Disso India 2022 online together with the Scientific Committee, Organising Committee. This is the third time we are conducting Disso India online Collaborating with AAPS (American Association of Pharmaceutical Scientists) one of the largest and most prestigious Professional Pharma Body globally. I wish to express my deepest gratitude to the Leaders of AAPS & Dr Vinod P. Shah to making this collaboration.

The key role performed by our Scientific Chair and the Organising Secretary- Dr A. K. Bansal, Professor of Pharmaceutics together with other team members has been critical in successfully organising the International Conference, Disso India 2022 Online. We received excellent response from the Pharma Industry, academia, & Partners, which shall make the event a memorable one.

I am sure that all the delegates of Disso India 2021 Online shall find their time spent at the conference enriching and enlightening. My sincere thanks to all the companies & Pharmacy colleges who have registered a good number of delegates and their managers/teachers who have given the approval for their participation in this conference. Most importantly, a conference of this scale would not have been possible without the support of all our partners. My sincere thanks to all the companies who have joined as a sponsor, for helping manifest this vision of ours. I must mention the support from our President, Dr.Padma Devarajan, The Conference coordinator Ms. Bhakti Poonia, our Multi Media expert, Tarun Soni, Ms Neetu Singh, Mr. Rajesh & Team from Design Accent who are our online event Organisers, Dr Praksh Bosle for giving good press releases timely with social media marketing and all other trustees, Members, together made our functioning very easy and enjoyable at SPDS.

Encouraging young scientists and academicians has always been our way of life at SPDS. Under the Leadership of Dr. Saranjit Singh & Prof.Mala Menon we launched an innovative original research presentation competition for M.Phram, Ph.D and Industry young researchers namely DRPI. This has created a lot of momentum and this year also in July 2022 we have this event online. All delegates of Disso India 2022 are welcome for DRPI also. Please visit our website DRPI.spds.in

I wish you all a great conference of Disso India 2022 Online over these three days, 23rd, 24th & 25th June 2022.

Dr. L. Ramaswamy

11th Annual International Symposium on Dissolution Science and Applications

Theme - Advances In Dissolution Science

Venue : Online • Dates : 23rd, 24th & 25th June 2022 (Thursday, Friday & Saturday)

PROGRAM FOR THE SYMPOSIUM

DAY 1 : 23rd June, 2022

SR. NO.	TIME	TITLE AND TOPICS	SPEAKER	SPONSORED BY
1.	3.00 - 3.30 PM	**Inauguration : Address by Chief Guest - Dr. V. G. Somani, Drugs Controller General(India) & Release of 2nd Edition of Deskbook of Pharmaceutical Dissolution Science & Applications**		
2.	3.30 - 3.55 PM	Key Note Address	**Dr. Andrew M. Vick,** Immediate past president, AAPS	
		Material Properties and Formulation Development		
3.	4.00 - 4.05 PM	Inauguration of the exhibition		
4.	4.10 - 4.35 PM	Nanocrystals (NanoCrySP) for dissolution enhancement through various route of administration	**Prof. Arvind Bansal,** Professor & Head, Department of Pharmaceutics, NIPER, SAS Nagar, India	
5.	4.40 - 5.05 PM	Enhancement of Dissolution using Hot Melt Extrusion Technology	**Dr. Indu Bhushan,** CEO of STEERLife India Pvt. Ltd	STEER
6.	5.10 - 5.35 PM	Lipid Excipients: Redefining Modified Release Applications	**Dr. Rajshree Shinde,** Technical Commercial Manager, Pharmaceuticals & Nutritional Science, ABITEC	ABITEC
7.	5.35 - 6.00PM	Panel discussion and Q&A		
8.	6.00 - 6.15 PM	**Tea Break**		
9.	6.15 - 6.40 PM	Advanced Third Generation Solid Dispersions – Novel approach for bioenhancement	**Prof. Padma Devarajan** Dean-Research & Innovation and Professor in Pharmacy, Institute of Chemical Technology, India	
10.	6.45 - 7.10 PM	*In vitro* release testing and IVIVC development for long acting injectables	**Prof. Diane Burgess** Board of Trustees Distinguished Professor of Pharmaceutics, Pfizer Distinguished Chair of Pharmaceutical Technology, UCONN School of Pharmacy, Connecticut	
11.	7.10 - 7.35 PM	Panel discussion and Q&A		
12.		Networking and exhibition		

11th Annual International Symposium on Dissolution Science and Applications

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PROGRAM FOR THE SYMPOSIUM

DAY 2 : 24th June, 2022

SR. NO.	TIME	TITLE AND TOPICS	SPEAKER	SPONSORED BY
		Dissolution of Specialized Dosage Forms and Drug Delivery Systems		
		Exhibition Open		
1.	3.00 - 3.25 PM	Address by Guest of Honor		
2.	3.30 - 3.55 PM	IVIVC for complex non-oral drug products, application for slow-release injectable formulation: importance to understand the various absorption phases to generate a good in vitro model	**Prof. Jean - Michel Cardot,** University of Auvergne, France	
3.	4.00 - 4.25 PM	IVRT to support approval of topical drug products	**Dr. Vinod P. Shah,** Ex-USFDA, Pharmaceutical Consultant, USA	
4.	4.30 - 4.50 PM	Development of solubility enhancing technologies as capsule dosage form	**Dr. Jnanadeva Bhat,** Vice President, Formulation R&D (Pharma & Nutra), ACG	ACG
5.	4.50 - 5.10 PM	Panel discussion and Q&A		
6.	5.10 - 5.15 PM	**Tea Break**		
		Dissolution Methodology and Regulatory Affairs		
7.	5.15 - 5.40 PM	Streamlined selection of *in vivo* predictive dissolution media for *in vitro* testing of poorly water soluble drugs	**Dr. Deanna Mudie,** Principal Scientist, R&D, Lonza Inc, USA	
8.	5.45 - 6.10 PM	Dissolution related trends in regulatory science	**Dr. Varsha Pradhan,** General Secretary- Society for Paediatric Medicines & Healthcare Initiative, ICT Mumbai	
9.	6.15 - 6.40 PM	Role of dissolution in biowaiver	**Samir Haddouchi,** Managing Director, SPS Pharma Services, Orleans, France	
10.	6.45 - 7.10 PM	Data required to build a fit-for-purpose PBPK model: How much is necessary?	**Dr. Anant Ketkar,** Scientific Lead-India, Simulation Plus, Inc.	ELECTROLAB
11.	7.10 - 7.30 PM	Panel discussion and Q&A		
12.		Networking and exhibition		

11th Annual International Symposium on Dissolution Science and Applications

Theme - Advances In Dissolution Science

Venue : Online • Dates : 23rd, 24th & 25th June 2022 (Thursday, Friday & Saturday)

PROGRAM FOR THE SYMPOSIUM

DAY 3 : 25th June, 2022

SR. NO.	TIME	TITLE AND TOPICS	SPEAKER	SPONSORED BY
		Technological Advancements in Dissolution Testing		
		Exhibition Open		
1.	3.00 - 3.25 PM	Address by Guest of Honor		
2.	3.30 - 3.55 PM	Productivity enhancement using robotic platforms	**Juergen Kempf,** Business Development Manager, SOTAX AG, Switzerland	sotax
3.	4.00 - 4.25 PM	Material sparing approaches in dissolution (Microdissolution)	**Dr. Ajay Saxena,** BMS, USA	
4.	4.30 - 4.55 PM	UV Spectroscopic imaging for understanding dissolution mechanism	**Dr. Xujin Lu,** BMS, USA	
5.	5.00 - 5.25 PM	Artificial intelligence based particle characterization and its influence on dissolution testing	**Sandeep Kulkarni,** Image Provision Technology Pvt. Ltd, India	ImageProVision Technology Leaders in Image Analytics
6.	5.25 - 5.50 PM	Panel discussion and Q&A		
7.	5.50 - 6.05 PM	**Tea Break**		
8.	6.05 - 6.30 PM	Data integrity in dissolution - How to ensure Compliance without compromising Usability?	**Holger Herrmann,** Head of Marketing & PM Data Management, SOTAX AG, Switzerland	sotax
9.	6.35 - 7.00 PM	QbD in dissolution	**Vijay Kshirsagar,** Director and CEO, TRAC Pharma Consulting, Mumbai, India	
10.	7.05 - 7.30 PM	Online imaging analysis and in silico tools-potential for real-time online dissolution characterization in the USP IV flow through apparatus	**Dr. Deirdre D'Arcy,** Trinity College, Ireland	
11.	7.30 - 7.55 PM	Panel discussion and Q&A		
12.	7.55 - 8.30 PM	Closing session of Disso India 2022		
13.		Networking and exhibition		

GALAXY OF SPEAKERS

DAY-1






DAY-2

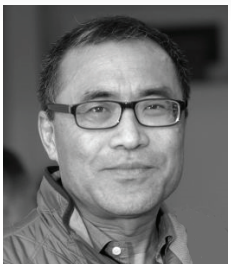






DAY-3







Andrew M. Vick, Ph.D.
Head of Toxicology, Drug Disposition, and PKPD, Attralus Therapeutics
Adjunct Professor, The Ohio State University College of Pharmacy
Immediate Past President, American Association of Pharmaceutical Scientists (AAPS)

Biosketch

Andy has over 24 years of experience working within the biotechnology and pharmaceutical industry on both the innovator and supplier sides in the fields of toxicology, nonclinical and clinical pharmacology, and drug disposition. Currently, Andy is responsible for the nonclinical safety, drug disposition, and PKPKD characterization of Attralus's therapeutic assets. Previously, Andy has served in executive roles with Charles River Laboratories, WIL Research Laboratories (acquired by CRL), Seventh Wave Laboratories, as well as served in key scientific roles at Eli Lilly and Company and Biogen. Andy earned his BS in Zoology and PhD in Pharmaceutical Chemistry from The Ohio State University. He has continued his support of the University through service on the Dean's Corporate Council for the College of Pharmacy, and he serves the Division of Pharmaceutical Chemistry as an Adjunct Professor. Andy also serves in the role of Immediate Past President for AAPS.

Abstract

"SPDS and AAPS - partnering to advance human health!"

For a combined 46 years, SPDS and AAAPS have been focused on the vision of "Advancing the pharmaceutical sciences to drive prevention and cures" and over that time, and we hope for years to come, we have and will continue to create value to those in greatest need - the patient. This session will highlight the impact of this collaboration, some of the industry challenges that we face, and how together we will continue to collaborate in pursuit of human health.

SPDS is relatively an young organisation focussing and spreading the advances in Dissolution Science and its application. For the first tine in 2021 both AAPS and SPDS came together in organising Disso India 2021 online which was witnessed by more than 2500 delegates from different parts of the world.

Not only that AAPS also partnering with another good event of SPDS namely DRPI (Disso Research Presentations India). Last year I recalled more than 200 research work was received and participated in the DRPI completion. This year also AAPS is joining as a co-sponsor for the vent.

My compliments to all the team members of SPDS who are putting their continuous efforts to spread the vision and mission of SPDS and joining with AAPS in their initiatives not only in India but also in US.

Thanks a million for all your support and co operation.

Arvind Kumar Bansal

Dean, Professor & Head, Department of Pharmaceutics, NIPER, SAS Nagar, India

Biosketch

Dr Arvind Kumar Bansal is currently Professor and Head, department of Pharmaceutics at National Institute of Pharmaceutical Education and Research (NIPER) - SAS Nagar, Punjab, India. He earned his M Pharm (Pharmaceutics) (1988) and Ph.D. (1993) from University of Delhi, India. Prof Bansal worked as Senior Scientist and Group Leader in JK Pharmaceuticals and Ranbaxy Research Laboratories, for 8 years. Therein he conceptualised, evolved formulation strategies, developed and transferred the technology to production shop floor, for NCEs and generic drug products. Prof Bansal joined NIPER in 2000 and developed expertise in areas of pre-formulation and formulation development encompassing characterization and stabilization of the amorphous form, polymorphism, pseudo-polymorphism, particle engineering, screening salt forms, improvement of oral bioavailability and lyophilization. His research group works with the mission statement - 'developing science based industrially viable pharmaceutical technologies' and works closely with pharmaceutical industry to create opportunities for commercial exploitation of the products. Dr Bansal was conferred prestigious Fellow of American Association of Pharmaceutical Sciences in 2016. He is the only Indian, working in India, to be awarded this Fellow status. He has won prestigious awards like AAiPS Distinguished Educator and Researcher Award, Innocentive Award, OPPI Award and IPA-ACG Scitech Innovation Award 2018 for Best Innovative Development of Solid Dosage Form. Prof Bansal's research group has completed more than 550 industry-sponsored projects, granted 11 patents, filed 27 patents, and published 170 research articles and 27 review articles. He has total citations of 8011, with h-index of 47, in Google Scholar. He is an editorial board member of 'Journal of Excipients and Food Chemicals', 'Drug Development Research' and 'Pharmaceutics'. He is also an Advisor to the editorial board of 'Journal of Pharmaceutical Science' and 'Molecular Pharmaceutics'. Recently his lab has out-licensed a platform technology on "Nano crystalline solid dispersions – NanoCrySP".

Abstract

Nanocrystals (NanoCrySP) for dissolution enhancement through various route of administration

Almost 70% of the NCEs entering into drug discovery pipeline pose solubility and dissolution rate challenges. Drug delivery market for solubility enhancement technologies has increased to 139 US$ million dollars. Strategies for improving apparent solubility and dissolution rate include formation of salts for ionizable drugs, reducing particle size, forming soluble pro-drugs, using amorphous forms, co-solvents, super-disintegrants and using surface active agents.

Nanocrystals, consisting of API crystals in the nanometer range, have attracted a lot of attention for formulation development of hydrophobic APIs. Many products like Gris-Peg® (Griseofulvin), Cesamet® (Nabilone), Rapamune® (Sirolimus), Tricor® (Fenofibrate), Emend® (Aprepitant), Megace® (Megestrol acetate) and TridlideTM (Fenofibrate) have been commercialized using nanocrystals. Nanocrystals can be generated by top-down (size reduction by advanced milling techniques) or bottom-up approaches like nano-precipitation. These technologies pose challenges like high energy requirements, API degradation, generation of impurities, limited extent of particle size reduction, long processing times, residual solvents and high costs of the processes.

NanoCrySP is a novel spray drying based method to generate solid particles containing API nanocrystals dispersed in the matrix of small molecule excipients. A solution of API and excipient in a solvent or solvent mixture is co-spray dried to obtain discrete particles of 2 to 10 micron size and contain API nanocrystals (10-1000 nm) embedded in excipient matrix. NanoCrySP provides enhanced solubility and dissolution rate, thus resulting in increased oral bioavailability. Molecular mechanisms like drug-excipient miscibility, crystallization induction by excipient and classical nucleation theory govern the generation of nanocrystalline solid dispersions. Applications of NanoCrySP based nano crystalline solid dispersion, through various routes of administration shall be discussed.

Indu Bhushan
CEO, STEERLife India Pvt. Ltd.

Biosketch

Indu is currently working as CEO of STEERLife India Pvt. Ltd. and is also a founding Director of the Company with a vision of "Changing the way we make and take medicines." He is Post graduate in Pharmacy from Punjab University, Chandigarh and has been associated with Development of Pharmaceutical Products in various capacities in last three decades.

In his current role, he is leading Company's vision of "Changing the way we make and take medicines" using proprietary platform technologies developed to process food and pharmaceutical product using Continuous Twin Screw Processors.

In the past, he played key role in setting up facilities and resources for the development of Generic and Specialty Pharmaceuticals in leading Indian Multinational Companies. He has been bestowed with "Chairman's Excellence Award" during his tenure with Dr.Reddy's Laboratories for his contribution towards maximisation of success during bioavailability studies and playing expert nucleus for the technological and infrastructure needs of integrated product development.

He is a co-inventor of more than 50 patents or publications related to pharmaceutical composition and process. His current work includes development of pharmaceutical product with enhanced bioavailability and stability using STEERLife's proprietary technologies.

Abstract

Solubility Enhancement by Hot Melt Extrusion Technology

Hot melt extrusion (HME) processes have been used in pharmaceutical applications for many years, the production of amorphous solid dispersion/solution (ASD) being one of the most prominent examples. Compared to other pharmaceutical production processes, HME has the benefit of being a solvent free, environmentally friendly, and cost-efficient technology.

HME processes, unlike other batch processes, work on the principle of 'steady state' hence needs careful considerations of process design to create and maintain steady state to get desirable output throughout the run. Typically, steady state is defined and measured in terms of residence time distribution, specific mechanical and thermal energy. Recent advancement in the design of equipment and processes to improve efficiency and wider applications will be presented and discussed during the talk.

Improving solubility of poorly water-soluble drug by HME process requires knowledge of highly diversified areas such as polymer science, solid state characteristics of the active ingredients, thermal behaviour of polymer and drug and role of plasticizer or surfactant both in terms of processability and solubility performance. A case study of aqueous solubility behaviour of ASD of Ritonavir prepared by Hot-Melt Extrusion with and without added surfactant/plasticizer has been considered important for the presentation as it has been approved recently along with Nirmatrelvir to treat Covid-19. Solubility study of ASD carried in more biorelevant media under non-sink condition, unlike USP recommended dissolution medium, shows supersaturation followed by a time and concentration dependent fall, due to crystallization of excess drug. These findings clearly indicate that a choice of surfactant or plasticizer by a formulator while preparing ASD should be based on a balanced view of solubility enhancement and solution stability.

STEER

Rajshree Shinde, PhD

Technical Commercial Manager, Pharmaceuticals & Nutritional Science, ABITEC

Biosketch

PhD (Tech) in Pharmaceutics, Institute of Chemical Technology, formerly known as UDCT, Mumbai. Masters in Medicinal Chemistry, Bombay College of Pharmacy, Kalina, Mumbai. Bachelor of Pharmacy, Bombay College of Pharmacy, Kalina, Mumbai .

Published research papers, review paper and book chapter internationally. Participated and presented research in scientific conferences nationally and internationally.

Worked with Evonik Industries at R & D (formulation development) as a scientist, Mumbai, India in 2008. Presently, working with ABITEC Corporation as a Technical Commercial Manager from past 6 years. Dr. Shinde's role is to support ongoing and new business with key customers and distributors in the Pharmaceutical Science and Nutrition markets

Dr. Shinde is a Technical Commercial Manager, Pharmaceuticals & Nutritional Science and is a key member of the global Pharmaceutical/Nutritional business units, and technical liaison between customers in India and ABITEC, USA.Dr. Shinde plays a critical role in supporting ABITEC's scientific and business initiatives, both strategically and operationally, to facilitate and drive future growth of the Pharmaceutical & Nutritional business units across India and potentially Asia.

Dr. Shinde spends approximately 50% of time in the field managing key accounts, and creating new relationships with existing and potential customers. Dr. Shinde is scientifically and technically skilled in identifying new applications for existing products and responsible for leading the development of profitable differentiated new products for new applications. As appropriate, Dr. Shinde is responsible for implementing and leading academic and industrial scientific programs and establishing science-driven marketing to support the pharmaceutical and nutritional science initiatives.

Abstract

Lipid Excipients: Redefining Modified Release Applications

ABITEC has an expansive portfolio of bioavailability enhancers, which are medium-chain mono- and di-glycerides, propylene glycol esters and pegylated esters. These functional lipid excipients can be used in modified drug delivery systems. 70% of sustained release dosage forms, approved by FDA, contain swellable cellulosic polymers. Alternatively, lipid excipients can be used as sustained release agents. Lipids can provide different biopharmaceutical properties, compared with polymers; essentially different drug release mechanism that provides formulators wider choices to modify drug release and shall assist to develop innovative dosage forms. Furthermore, lipid excipients are attracting interest from drug developers due to their performance, ease of use, chemical inertness, biocompatible, has versatility in applications. Lipids can be processed by multitude of methods for developing solid oral dosage forms. ABITEC products Capmul GDB (Glyceryl dibehenate) Sterotex (HVO), Acconons (polyoxyglycerides) can be employed in both matrix and encapsulated sustained release systems. These high quality excipients are the ideal candidates to form Self-Emulsifying Drug Delivery Systems (SEDDS) specifically designed for meeting the solubility and bioavailability challenges of the pharmaceutical industry. This talk describes two in-house case studies:

1. Capmul GDB EP/NF for matrix sustained release

2. Tableted self-emulsifying drug delivery system (SEDDS) for Improving Dissolution.

ABITEC lipids hold promises to develop modified release dosage forms in innovative ways and has potential to generate intellectual property through innovation

ABITEC AN ABF INGREDIENTS COMPANY

Prof. Padma V. Devarajan
Dean Research & Innovation and Prof. in Pharmacy,
Institute of Chemical Technology, Mumbai

Biosketch

Dr (Ms) Padma V. Devarajan, President Society for Pharmaceutical Dissolution Sciemce (SPDS) is Dean Research and Innovation, Professor in Pharmacy and former Head, Department of Pharmaceutical Sciences and Technology at the Institute of Chemical Technology, Mumbai, India. She is also a member of the Board of Governors and Head of the Incubator ICT-NICE, at the Institute of Chemical Technology, the only ELITE University and Centre of Excellence in the state of Maharashtra in India.

Her research interests include colloidal carriers for targeted delivery in cancer and infectious diseases, Veterinary Drug delivery and Bioenhancement strategies. Her work is extensively published in peer-reviewed journals. She has many granted patents, has licensed technologies to industry and commercialized products in India and Europe. Her research is funded through a number of Grants from the Government and the industry including companies from Japan, Germany and USA. She is also a consultant to the Pharma Industry. Her books on "Targetted Drug Delivery-Concepts and Strategies" & Targetted Intracellular Delivery by Receptor Mediated Endocytosis published by Springer won her the Prof. N. R.Kamath Book Award at ICT.

She was actively associated with Controlled Release Society Inc.,USA as Board Member, Member on the Board of Scientific Advisors and Chair of the Young Scientist Mentor Protégé Committee and Chair of the Outstanding Paper Award Committee of the Journal Drug Development and Translational Research. She is Patron Member of the Controlled Release Society Indian Chapter and Member on the Editorial board of the Asian Journal of Pharmaceutical Sciences and the European Journal of Drug Metabolism and Pharmacokinetics.

Prof. Devarajan is a nominated Fellow of the Maharashtra Academy of Sciences, and Life Fellow of the Indian Chemical Society. She is a recipient of the American Association of Indian Pharmaceutical Scientists Distinguished Educator and Researcher Award 2011, the VASVIK award for Industrial Research to Women in 2011 and the Association of Pharmaceutical Teachers of India (APTI) Prof. C J Shishoo Award for Research in Pharmaceutical Sciences. She won the Bengaluru Nano Innovation Award for a Nanosystem developed for Veterinary Infection, the IPA-ACG Scitech award for innovation in Solid Dosage form, and the OPPI Scientist Award 2018, the Panjabrao Deshmukh Outstanding Woman Scientist Award 2019 awarded by the Indian Council of Agricultural Research, Government of India. She is also the first woman President of the Alumni Association of UDCT/ICT and a Distiguished Alumnus of her Alma Mater, ICT Mumbai.

Abstract

Advanced Third Generation Solid Dispersions- Novel approach for Bioenhancement

Bioenhancement strategies are imperative for BCS II, BCS III and BCS IV drugs to ensure aqequate bioavailability and efficacy. Among various strategies solid dispersions provide a practical approach for bioenhancement, particularly for BCS II drugs. Various generations of solid dispersions are reported with the third generation providing additional advantages. In this talk we propose an advanced third generation Solid dispersion which comprises not just a surfactant as in the third generation, but a SMEDDS embedded in a polymeric film to combine the advantages of SMEDDS and the high surface area of film technology for bioenhancement of BCS II drugs. Importantly this advanced system is developed using facile technology and despite being based on films, does not employ standard film forming technologies of casting/extrusion as deployed for oral thin films or even transdermal films. Out technology presents an In-Situ film which is extemporaneously generated in the stomach following oral administration of a tablet. The advanced third generation solid dispersion synergises multiple innovative aspects to arrive at a simple final dosage form which is as simple as a coated tablet. A case study will be presented to demonstrate this new Advanced Third Generation Solid Dispersion Technology.

Prof. Diane Burgess

Board of Trustees Distinguished Professor of Pharmaceutics, Pfizer Distinguished Chair of Pharmaceutical Technology, UCONN School of Pharmacy, Connecticut

Biosketch

Dr. Burgess received her B.Sc. degree in Pharmacy from the University of Strathclyde, U.K. (1979) and her Ph.D. in Pharmaceutics from the University of London, U.K. (1984). She was a postdoctoral fellow at the Universities of Nottingham, U.K. (1984-1985) and North Carolina (1985). Dr. Burgess joined the faculty at the University of Illinois at Chicago in 1986 as Assistant and then Associate Professor and moved to the University of Connecticut in 1993. She was promoted to Professor in 1999, and in 2009 she was appointed Board of Trustees Distinguished Professor of Pharmaceutics at the University of Connecticut.

Dr. Burgess has been active in teaching, research and service throughout her career. Her students have recognized her with the Outstanding Teacher of the Year Award (2005 and 1992). She received the 2009 Distinguished Service award from the University of Connecticut, School of Pharmacy. In 2010, she became the first recipient of the CRSI (Controlled Release Society, India Chapter) fellowship award for outstanding contributions in drug delivery research. Dr. Burgess is the 2011 recipient of the Nagai APSJ International Women Scientist Research Achievement Award. Dr. Burgess also received the 2013 AAPS IPEC Ralph Shangraw Memorial Award for her outstanding research in the area of pharmaceutical excipients. In 2014, Dr. Burgess was recognized for her exceptional commitment in CRS, and was selected as the recipient of the Distinguished Service Award. She has over 130 refereed publications. She is the editor of two books. She has given over 330 research presentations, over 170 invited lectures, and 12 keynote addresses at major international scientific meetings; Dr. Burgess has served as major adviser for four M.S. and 22 Ph.D. graduates as well as 12 post-doctoral fellows. She is currently directing the research of seven Ph.D. students, two post-doctoral fellow, and two assistant research professors.

Dr. Burgess is a fellow of AAPS (American Association of Pharmaceutical Scientists) and of AIMBE (American Institute for Medical Biological Engineering). She served as elected President of AAPS in 2002 and CRS (Controlled Release Society) in 2009. She is a member of the USP Biopharmaceutics Expert committee and the USP Advisory Panel on Injectables. Dr. Burgess is editor of the International Journal of Pharmaceutics (2009 – to date). She was an editor for AAPSPharmSci (1999 - 2005) and editor of the Journal of Drug Delivery Science and Technology (2003 - 2008). Dr. Burgess serves on the editorial boards of seven international journals. Dr. Burgess has severed on NIH study sections on Drug Delivery and Biomedical engineering, Drug Delivery and Drug Discovery, Gene and Drug Delivery, and Nanomedicene as well as many special study sections for NIDA, NIDDK and NCI (2001-to date). In 2001 she undertook a sabbatical at the Office of Testing and Research at CDER, FDA. She consults for pharmaceutical, food, cosmetic and other industries.

Abstract

In Vitro Release Testing and IVIVC Development for Long Acting Injectables

This presentation will focus on the development of in vitro release testing methods for long acting injectables (LAIs) that are suitable for use in in vitro-in vivo correlation (IVIVC). Release testing methods typically used for LAIs are very rapid and accordingly are unlikely to result in IVIVCs. Depo-SubQ Provera 104® was used as the model product and Q1/Q2 (qualitatively and quantitatively equivalent) formulations were prepared with manufacturing differences. These formulations were used in the development of in vitro release testing methods using USP apparatus 2 with dialysis sacs and with enhancer cells, as well as USP apparatus 4 with semisolid adapters. In vitro release testing methods with good discriminatory ability were developed. Level A IVIVCs were successfully developed using data obtained with USP apparatus 4 with semisolid adapters.

Prof. Jean-Michel Cardot
Professor in Biopharmaceutics and Pharmaceutical Technology, University of Auvergne, France

Biosketch

Jean-Michel Cardot, Pharm. D., Ph. D. is Professor and Head of the Department of Biopharmaceutics and Pharmaceutical Technology of University of Clermont Auvergne, France. Jean-Michel was in various research departments of pharmaceutical industries before he joined the University as Professor and Head of Department in 2002. His research fields are biopharmaceutical development of drugs, in vitro dissolution and in vivo bioequivalence, and in vitro-in vivo correlation.

Abstract

IVIVC for complex non-oral drug products, application for slow-release injectable formulation: importance to understand the various absorption phases to generate a good in vitro model

Vinod P. Shah, Ph.D., FAAPS, FFIP
Pharmaceutical Consultant
North Potomac, MD USA

Biosketch

Dr Shah is a Pharmaceutical Consultant; International Chairman of Society of Pharmaceutical Dissolution Science (SPDS) (2012 – Present) and President of SPDS-US chapter (2019 - present). He received his Pharmacy degree with Gold Medal distinction from Madras University, India in 1959 and Ph. D. in Pharmaceutical Chemistry from the University of California, San Francisco in 1964.

Dr Shah worked at US FDA (Food and Drug Administration) from 1975-2005. At FDA, he developed several Regulatory Guidances for Industry in the area of dissolution, SUPAC, SUPAC-SS, bioanalytical method validation, topicals, bioequivalence and biopharmaceutics; and pioneered method development for in vitro drug release for semisolid dosage forms. He is a recipient of many FDA Awards. Dr Shah was Scientific Secretary (2003 – 2011) of International Pharmaceutical Federation (FIP). He is author/co-author of over 330 scientific papers and is a co-editor of four books.

Dr Shah was the President of American Association of Pharmaceutical Scientists (AAPS) in 2003. He is a Fellow of AAPS and FIP. Dr Shah is a recipient of FIP Lifetime Achievement Award in Pharmaceutical Sciences; IDMA Eminent Pharmaceutical Analyst Award (India); Honorary Doctorate from Semmelweis University, Budapest, Hungary; Honorary Doctorate from University of Medicine and Pharmacy Carol Davila Bucharest, Romania; SPDS Award of Excellence; AAPS Distinguished Pharmaceutical Scientist Award and AAPS Global Leader Award.

Abstract

IVRT to Support Approval of Topical Drug Products

In vitro release test has become one of the most important tools for drug development and approval process of semisolid dosage forms. Genesis of In Vitro Release Testing (IVRT), IVRT method development and IVRT requirements for regulatory approval process will be discussed. In addition, Topical Drug Classification System (TCS) system along with evolving concept for topical dermatological drug products from Q1, Q2, Q3 sameness to Q1, Q2, Q3 similar allowing greater permissiveness in generic drug products will be discussed.

Dr. Jnanadeva Bhat
Vice President,
Formulation R&D (Pharma & Nutra),
ACG

Biosketch

An astute professional with 27+ years of rich & extensive experience in the development of new products for regulated market and semi regulated markets with the knowledge to handle various dosage forms like Tablets, Hard Capsules, Soft Gelatin Capsules, Semisolids (Creams and Gels), Liquid Orals, External solutions, Parenteral products (SVP/Lyophilised powder/PFS). In-depth knowledge in PK and BE studies, Lyo Cycle development, Filter validation and validation documents.

Skilled in Strong Project management (MSP) and customer liaison skills. financial and budget management capabilities for smooth business operations. Able to adhere and manage timelines, risk assessment of projects, timely execution and delivery of products. IP strategy and market intelligence – during project selection and development cycle.

Expertise in developing Generic formulations, (including Lyo & Dispersed MR parenterals), Liposomes and nanoparticles, IR and MR orals, ARVs, anti TB and Anti Malarials.

Specialties: Lyophilisation cycle development. Filter validation, QbD implementation, Reduced exposure Terminal Sterilization.

Several ANDAs filed; conversant with fast paced pharmaceutical environment requiring high quality results;

Abstract

Development of solubility enhancing technologies as capsule dosage form

The pharmaceutical ecosystem is constantly expanding, with delivery technologies rapidly reflecting to the changing market as well as consumer demands. Although there are many different delivery routes, oral administration is largely the preferred choice, due to its ease of administration, better patient centricity and safe to handle.

Current day formulation scientists always think in an unconventional way and allows them to innovatively design medications that are not only patient-friendly but are also effective. Most importantly release modifications and improving solubility and bioavailability. Achieving these objectives can be challenging, given the evolving properties of active pharmaceutical ingredients (API), and the increasing desire to develop more targeted medicines.

Poorly soluble drug molecules are frequently correlated with lower bioavailability and absorption after oral consumption. Consequently, it is a great challenge for formulation scientists when looking to create new drug delivery systems and formulation approaches, to overcome the solubility and bioavailability challenges.

Techniques like Nanocrystals, liquid formulations, solid dispersions, hot melt extrusions, pellets coatings and various other drug delivery systems can be filled in hard capsules as a preferred delivery solutions.

Formulation challenges particularly with factors like impurity generation and incompatibilities between two APIs can be resolved with combination filling in hard capsules.

Dr. Deanna Mudie
Principal Scientist, R&D,
Lonza Inc, USA

Biosketch

Deanna Mudie is a Principal Scientist in Research and Development at Lonza's site in Bend, Oregon, USA. Since she joined Lonza in 2016, her focus has been on enabling bioavailability-enhancing amorphous solid dispersions by developing dosage form platforms and in vitro dissolution methodologies to predict bioperformance. Deanna earned her B.S.E. degree in Chemical Engineering and her Ph.D. in Pharmaceutical Sciences from the University of Michigan. She has seven years of experience at Pfizer and Merck developing and manufacturing oral dosage forms from preclinical to commercial scales.

Abstract

Streamlined selection of in vivo predictive dissolution media for in vitro testing of poorly water soluble drugs

Oral drug product administration is the most common delivery method in the pharmaceutical industry. Successful oral delivery requires dissolution of solid dosage forms in gastrointestinal (GI) fluids and permeation across the GI membrane. Therefore, efficient development of robust oral drug products requires the use of biopredictive in vitro dissolution methods to evaluate how the interplay between drug formulation and GI fluid properties impacts bioperformance.

This webinar focuses on the design of dissolution media to support biopredictive dissolution testing, and highlights a method for selecting practical, yet physiologically relevant media based upon drug, formulation and GI fluid properties.

Dr. Varsha Pradhan

General Secretary- Society for
Paediatric Medicines &
Healthcare Initiative, ICT Mumbai
Partner - Regulatory Affairs,
Roche Products (India) Pvt. Ltd.

Biosketch

Dr. Varsha Pradhan has a professional career spanning 28 years which includes life cycle management of drugs coupled with an understanding of global Pharma education. She is a MS in Regulatory Sciences from the University of Maryland Baltimore USA, MPharm from ICT Mumbai & a PhD from School of Pharmacy & Technology Management, NMIMS Mumbai. She was the recipient of UNIDO fellowship for Post graduate training in Pharmaceutical Technology in Belgium in 1992.

Her industrial experience includes Production areas of GSK in Sterile Process department, Formulation development in Cipla & Sandoz. She has done consulting roles related to regulatory intelligence and Pharmacovigilance in various organizations like Sidvim Life Sciences, APCER Life Sciences, Asia Actual India Pvt. Ltd. & Roche Products India Pvt. Ltd.

In academia she contributed to bridge the gap between industry and academia & bagged the "Best Faculty Award 'in 2010 at NMIMS Mumbai. She holds an Indian Patent for her formulation work on Nasal drug delivery systems. She has been an invited speaker on various PCI sponsored Faculty Development programs & has also conducted technical refresher programs for industry employees.

She is a Guest Faculty for the Executive MPharm DRA at Delhi Pharmaceutical Sciences & Research University, which has working professionals from industry and CDSCO. She is also working on several collaborative projects with European Paediatric Formulation Initiative related to paediatric medicine.

Dr. Varsha is also an active member in SPDS since its inception and is now a member of the Core Scientific committee for DRPI 2022

Abstract

Dissolution related trends in Regulatory Science

Regulatory science is the science of developing new tools, standards and approaches to assess the safety, quality and efficacy of a medicinal product. It involves collaboration between various stakeholders like national regulatory agencies, industry, academia, patient groups with a common goal of achieving public health. The Pan American Network for Drug Regulatory Harmonization (PANDRH), Pan American Health Organization (PAHO), ICH, WHO, European Innovative Medicines Initiative (IMI) are some of the several organizations which focus on recognizing pre-existing asymmetries and support regulatory harmonization.

Dissolution is a critical quality attribute in the life cycle management of a drug product. Several collaborative projects have contributed towards dissolution science involving physicochemical tools to understand API, invitro in vivo tools for formulation system characterisation and in-silico tools for integrating data towards in vivo predictability. Global Bioequivalence Harmonization initiatives involving assessment of BE for long-acting injectables and implants, immediate-release (IR) dosage forms in the fed and/or fasted state, and current challenges for demonstration of therapeutic equivalence for orally inhaled drug products (OIDPs) based on surrogate endpoints have been undertaken. Efforts are being made by regulatory bodies for research in Complex Generics to facilitate safe and effective use. The transition towards continuous manufacturing from the traditional batch manufacturing has led to studies involving Real Time Release testing (RTRT).

Covid pandemic has brought to the forefront the need to generate collaborative evidence to address global health threats. Emerging technologies and AI in healthcare calls for more collaborative project initiatives between regulatory bodies so that resources can be optimized which will reduce the regulatory burden leading to timely access of drugs in the global market.

Samir Haddouchi
Managing Director, SPS Pharma Services, Orleans, France

Biosketch

Prior to joining SPS Pharma Services in 2005, Samir spent more than 10 years in the pharmaceutical industry. As a chemist, he started working on the analytical development of agrochemical compounds at Sandoz Agro in the region of Basel (Switzerland). During the Novartis merger, he moved to Orléans (France) in 1998 to join the analytical group in the technical development department where he became responsible for dissolution. In 2005, he resigned from Novartis to create SPS Pharma Services in Clermont Ferrand which is the first and only CRO specialized in Dissolution and Release Testing. Since then, Samir manages SPS facility and is in charge of projects management.

In April 2013, SPS Pharma Services moved to a new larger facility in Orleans (France) in order to ensure better efficiency and provide a broader range of services to its clients, including cGMP routine testing.
The facility has been successfully inspected by US FDA and is registered as Pharmaceutical Establishment for both US and Europe.
Fields of interest and expertise: analytical development (LC), in vitro dissolution and release testing (all techniques from USP1 to USP7), in vitro-in vivo correlations (IVIVC), formulation development, laboratory automation.
Samir is regularly invited as speaker in international conferences as well as expert for various organizations (scientific societies and Health Authorities).

Abstract

Role of Dissolution in Biowaiver

Dr. Anant Ketkar
Scientific Lead-India,
Simulation Plus, Inc.

Biosketch

Anant Ketkar is working with Simulations Plus, inc., as a Principal Scientist in the role of 'Scientific Lead – India'. He is involved in the application of PBPK/PBBM modelling and simulation to meet the objectives of various client projects. He also provides scientific input both in terms of software applications and project proposals to the Indian distributor to support their marketing and sales efforts.

In partnership with Indian distributor, Electrolab, he supports Simulations Plus's many customers in India and serves as a thought leader to increase awareness and adoption of PBBM/PBPK modelling throughout the country. He delivers modelling and simulation projects to address client objectives and inform regulatory interactions.

Anant earned his doctorate in Pharmaceutical Sciences from Poona College of Pharmacy (Bharati Vidyapeeth Deemed University), Pune, India. He carries 20 years of experience in formulation research, including 6+ years of experience in PBPK/PBBM modelling and biorelevant dissolution method development for modified complex generics and enabled formulations for poorly soluble NCEs.

Prior to joining Simulations Plus, Anant was Head of Technical Services at IQGEN-X Pharma, where he led a team of formulation team leaders and scientists for development of solid and liquid orals, and injectables for the global market. Prior to that he worked in positions of increasing seniority with pharmaceutical research companies, including Bioved Pharmaceuticals Inc., Ranbaxy (now Sun Pharma), Pfizer Animal Health (now Zoetis), Sandoz and Sun Pharma Advanced Research Company (SPARC). He has also served as a PBPK/PBBM modelling consultant for one of the leading Indian multinational pharma companies, and also worked as a freelance PBPK modeller for Indian generic pharma client on US-FDA submission of a PBPK modelling project.

Abstract

Data required to build a fit-for-purpose PBPK model: How much is necessary?

Use of in-silico modelling tools, such as PBPK modelling and simulation (Physiologically Based Pharmacokinetic M&S) and PBBM (Physiologically Based Biopharmaceutics Modelling) has been acknowledged and encouraged by Regulatory Agencies across the globe. The applications of these tools span from early discovery to clinical phases of drug development and may form part of the regulatory approval of drug products. These tools enable informed decision making at various stages of product development, be it for NCE research or for Generic drug product research. However, such mechanistic modelling tools require a significant level of input data to build and validate the models. This aspect might lead to a reluctance to adopt such tools.

To address this gap, Simulations Plus, Inc. offers some very useful software tools in addition to GastroPlus®, which is an industry leading software package for PBPK and PBBM analysis. These software tools include ADMET Predictor®, DDDPlus™ and MembranePlus™. Through a Case Study this presentation will focus on how a fit-for-purpose PBPK model can be built using structure-based in-silico inputs from ADMET Predictor® together with minimal experimental data. The benefits of timely implementation of PBPK and PBBM in Generic Drug Product Development will also be discussed.

Jürgen Kempf
Sotax AG, Switzerland

Biosketch

He started his professional career in the electronics field in 1988. After getting a degree in electronics & transmission he started his career in the laboratory automation field with Zymark in Germany in 1996. From 1999 to 2008 he was the service manager for Zymark and Caliper Life Sciences in Switzerland covering the pharmaceutical and biotech business areas. He joined Sotax in 2008 and worked for Sotax as a Product Manager and Application Specialist for Automation in the automated sample preparation and dissolution areas. Later working as Business Development & Project Manager for automation at Sotax. From 2008 until 2020 he was responsible for the business areas Europe, Middle East/Africa (EMEA) and Asia-Pacific. In 2021 he took over the role as distributor manager for Asia-Pacific managing directly all distributors (B2B) in that area. He will be running the Sotax Asia office in Bangkok once the current global travel Covid situation is under control.

Abstract

Productivity enhancement using robotic platforms

How do robotics and automation enhance and improve the productivity in an analytical laboratory?

Manual laboratory tasks vs automation – where are the advantages?

Ho deep is it already implemented and in which areas does it make sense?

What are the key factors to implement successfully automation?

Does automation and robotics comply with pharmacopeial requirements

Ajay Saxena, Ph.D.
BMS, USA

Biosketch

Dr. Ajay Saxena is Associate Scientific Director in Drug Product Development at Bristol-Myers Squibb, New Jersey. Dr. Saxena has more than 13 years of industrial experience. He is an experienced biopharmaceutics and formulation scientist who has led multiple teams to Pre-clinical (solution and suspension) and clinical (oral solid dosage form) formulation development. His focus area involved development of Novel Drug Delivery Systems (NDDS) likes Nanosuspension, liposomes and microspheres to deliver complex modalities.

He received his doctoral degree in Pharmaceutics from University of Bradford, and pursued Post-Doctoral Research at University of Minnesota.

He has been felicitated with several awards for his contributions. He has several research articles in international peer-reviewed journals and patents to his credit.

Abstract

Material sparing approaches in dissolution (Microdissolution)

Development of a biopredictive method in early stages of a drug product development ensures product in vivo performance prediction and helps in controlling product quality throughout the development cycle. Biorelevant dissolution method, considering luminal conditions (pH, buffer capacity, bile salts, transit time, etc.) can be predictive of in vivo dissolution profile of the drug product. The complexity of biorelevant dissolution method depends on the drug substance properties like, pH-dependent solubility, propensity to supersaturate, or potential to precipitate. However, major challenge in developing a biopredictive method at early stage of development is the limited availability of drug substance and drug product. Therefore, a material sparing biorelevant dissolution methods can be a good starting point to differentiate formulations and to assess bioperformance risk. These methods can help in screening multiple drug substance (polymorphic forms, salts, SDDs or particle sizes) and drug product (suspension, tablet, or capsule) options to assess potential risks and evaluate mitigation strategies. This presentation will provide regulatory perspective on biorelevant dissolution method, factors impacting drug product in vivo performance, and different material sparing biorelevant dissolution methods to assess these factors.

Xujin Lu, Ph.D.
Scientific Director
Drug Product Development
Bristol-Myers Squibb Company

Biosketch

Dr. Xujin Lu is a Scientific Director at Bristol-Myers Squibb Company in the department of Drug Product Development. With 30 years of experience in the pharmaceutical industry, Dr. Lu currently focuses on drug release and in-vitro biopharmaceutics for drug product development. Dr. Lu is a past Chair of the In Vitro Release and Dissolution Testing (IVRDT) Focus Group of AAPS, and a current member of the Scientific Advisory Board of the Society for Pharmaceutical Dissolution Science (SPDS-US). He serves on the USP Expert Committee of Dosage Forms and USP Expert Panel on New Advancements in Product Performance Testing. Dr. Lu is also a member of the Editorial Advisory Board of Dissolution Technologies journal.

Abstract

UV Spectroscopic Imaging for Understanding Dissolution Mechanism

Advanced spectroscopic imaging technologies have been developed and applied to characterize formulation and guide drug product development by providing qualitative and quantitative understanding of in-vitro drug release and dissolution mechanism. Among variety of the spectroscopic imaging technologies, UV imaging has advantages in simple instrumentation, low cost, commercially available, simple quantification of drug release, and compatibility to biorelevant media. It has been used to observe drug diffusion and release, dosage form swelling, and drug concentration gradient close to the surface of dosage form during dissolution, and generate absorption maps with high spatial and temporal resolution. This presentation will introduce this technology and demonstrate the benefits with application examples.

Sandeep Kulkarni
Scientific Director,
Image Provision Technology Pvt. Ltd., India

Biosketch

Sandeep Kulkarni, Founder & CEO – ImageProVision Technology, is Mechanical Engineer from NIT and has done Management Course from IIM Ahmadabad. He has also done special course in Image Processing from Duke University.

He has more than 31 years of work experience in diversified businesses and held senior positions in reputed companies. He has extensive experience in manufacturing; setting-up & running manufacturing plants. He has set-up 3 green field factories. Having successfully implemented various ERP Systems & other IT systems, he also has expertise in IT systems. After spending 22 years in professional life, he started entrepreneurial journey.

ImageProVision Technology is his entrepreneurial venture. He has built ImageProVision from scratch to a well-known name in Image Analytics arena. ImageProVision has developed unique physical testing products with an emphasis on Image Analytics. Under his leadership, ImageProVision has become a well-known brand in Analytics solution provider to Pharmaceutical Industry in a very short time. ImageProVision's innovative products in Microscopic Particle Size and Shape analysis has been appreciated by top most pharma companies in India. ImageProVision has initiated five patents in this field and won several awards like "Winner – India Pharma Awards for Most Innovative Product in Pharmaceutical Machinery Category in CPhI 2015 Mumbai", "Winner of Sharktank – Best startup company of Pune", "Winner – Top 50 upcoming companies of India by NASSCOM, Bangalore",

An avid enthusiast in the field of training & teaching, he always finds opportunities to interact with people and extends his experience, and learn from them.

Abstract

Artificial intelligence based particle characterization and its influence on dissolution testing

In the Pharmaceutical Industry, Particle Size, Particle Size Distribution and Particle Shape of active pharmaceutical ingredients (API) is known to strongly affect the stability and aesthetics of drug formulation. In addition, the size and shape of particles used in a pharmaceutical product can (but not always) impact the dissolution rate of drug in the gastrointestinal tract. Dissolution of the drug substance depends on surface area. A smaller particle size implies a larger surface area. In case of similar particle size, the particle shape is yet another factor that affects the dissolution rate. For example, rough particles have a higher surface area and in turn higher dissolution rate. For the same Particle Size determined by Laser Diffraction Technology, the particles of different shapes have different surface area and hence shape of particle plays a significant role in dissolution of drug particles.

There are latest technologies to determine particle size and shape. One such technology is Microscopic Particle Size and Shape Analysis technique. Advanced Motorized stage microscopic systems powered by strong analytical software programs help researchers in correlating dissolution profiles with particle size and shapes of APIs. New generation systems work on latest software with artificial intelligence and machine learning algorithms. These systems comply to USP <776 >Optical Microscopy for Particle Characterization. The particle size distribution calculations and algorithms follow the ISO 13322 standards.

The lecture also discusses few case studies on the influence of particle size and shape on dissolution profiles.

ImageProVision Technology
Leaders in Image Analytics

Holger Herrmann
Head of Marketing & PM Data Management, SOTAX AG, Switzerland

Biosketch

Holger Herrmann is Head of Marketing and Data Management at SOTAX Group with more than 20 years of experience in process automation and information management. Working in the pharmaceutical industry since 2009, Holger specializes in user-centric workflows and the development of UI technology with applied data integrity according to regulatory requirements, guidelines, and international Pharmacopeia. In addition to his global marketing role at SOTAX, he is responsible for guiding software engineering in the implementation of new generation platforms combining SOP-guided testing processes and compliant data management into one seamlessly networkable framework.

Abstract

Data integrity in dissolution - How to ensure Compliance without compromising Usability?

Performing dissolution tests has frequently remained a relatively poorly documented manual process in quality control (QC) at a surprisingly high number of pharmaceutical companies all over the world. This is particularly surprising given the importance of dissolution for releasing commercial batches. Following the first 'Data Integrity and Compliance With CGMP' draft guidance in April 2016 by the US FDA – initially released as a reaction to increasingly observed CGMP violations involving data integrity – local regulatory authorities and pharma companies alike have recognized the importance of data integrity and are implementing processes geared to close potential gaps in the dissolution workflow from documentation of test conditions & data acquisition to analysis and evaluation of results according to ALCOA principles.

While changed processes, SOPs, and policies usually improve data integrity, they often tend to turn test execution into an operational nightmare for laboratory staff, analysts, and managers, thus negatively impacting lab efficiency, productivity, and costs. In this talk we take a closer look at common data integrity challenges in the dissolution process and how they can be addressed without making the execution of dissolution tests and associated analytics a cumbersome and highly inefficient process.

Vijay Kshirsagar
Scientific Director,
Image Provision Technology Pvt. Ltd., India

Biosketch

Vijay is an accomplished Quality, Regulatory & Analytical professional with more than 40 years of rich experience of working for reputed Indian & MNC Pharma firms. Till April 2013, he worked for Unichem as Executive Vice President responsible for CQA, Regulatory & Analytical Research, based in Mumbai, where he continues to be as Advisor on Quality & Regulatory matters.

Prior to Unichem he worked for Ranbaxy, Sun , Lupin, IPCA, German Remedies in various senior positions like Director-Quality , GM-Quality etc . He has successfully represented his company in US and UK courts regarding IP related matters (Para IV filings).

Vijay has led from front for successful completion of several regulatory inspections by US FDA, MHRA, EDQM, ANVISA, WHO, PICS, PMDA, Health Canada, TGA etc. both for Drug Products (Non-Sterile & Sterile) & API's. He has been a frequent trainer in India & abroad having spoken on wide range of topics including cGMP/ GLP/ PQS/QRM/Validations (Process, AMV, Cleaning, Microbiological) /QbD/ Dissolution/ Stability/ Handling Regulatory Queries/ Investigations/ CAPA/ Auditing/ Documentation/EM etc.

He is the founder President of 'Society for Pharmaceutical Dissolution Science' He has also worked on the board of Directors of ISPE-India for 12 years. IDMA has conferred upon him an 'Outstanding Analyst Award 2011' for his contribution towards pharmaceutical analysis. He has been a Trainer for USP's training programs for young pharmaceutical professionals and also authorised as a Trainer by HRDF, Malaysia.

He has published articles on topics like OOS, QbD & cGMP in reputed journals/books. His chapter on 'OOS Investigations' is a reference material being a part of the book for Pharmacy students. Guideline written by him on CAPA is published by IDMA. He is M.Sc. by Research in Organoanalytical Chemistry from Mumbai University. He has a good Microbiological background too having done his graduation with Microbiology. He is a Mentor to two reputed pharmacy colleges in Mumbai including BCP.

Post retirement in 2013, he has formed his own Pharma Consultancy called TRAC offering specialized services globally, for cGMP Training, Regulatory Filings, Auditing & Compliance. His current clients include reputed Pharma/API companies based in India, China, US, Europe, Turkey, Bangladesh, Malaysia etc. As a consultant, he has helped number of companies to get their first time international regulatory approvals & also sustain them over a long period. He is also advising some companies for their remediation plans to revive their regulatory approvals.

Abstract

QbD for Dissolution Method Development

Quality of the analytical method needs to be built in rather than judging it from it's limited performance through method validation exercise. This is further more important for dissolution method where the concept is significantly different. In assay/content uniformity content test etc we aim at the method which will give estimation of total content. Whereas in dissolution our aim is to get idea about it's ability to distinguish between a good bioequivalent product and a non-bioequivalent product. So the risk elements are many. Method has to be designed properly. Regulatory guidance itself talks about pharmacopeial methods being found non-discriminatory. So the responsibility lies on generic company to develop a suitable method where a good in-vitro and in-vivo co-relation is established. The presentation is aimed at explaining this aspect. How to set Quality Target Method Profile (QTMP) & link Critical Quality Attributes (CQA's) of material, method & process to it, what are the most significant risk elements, how to plan Design of Experiments (DoE's) & analyse the output shall be covered in the presentation. Will also talk about a good control strategy and life cycle management approach for dissolution method monitoring.

Historically regulators have found that mostly the end product quality is 6 Sigma but when it comes to built in quality it was just 2 or 3 Sigma, accepting the fact that there could be some exceptions. Contribution of analytical method is significant here to achieve 6 Sigma Quality of the product. Is it mandatory to follow QbD route? Per say yes but in practice no. One could file the dossier without QbD based development but chances of getting it approved without significant queries are less. Queries may make you almost rework hitting your timelines and the cost. So we have to make a good choice for which the presentation would help.

Deirdre D'Arcy
Associate Professor, Trinity College, Ireland

Biosketch

Dr. Deirdre D'Arcy qualified as a pharmacist in 1999. After initial training in clinical pharmacy, she commenced research in pharmaceutical technology, in the area of hydrodynamic simulations and dissolution testing. She is currently Associate Professor in Pharmaceutics and Pharmaceutical Technology in the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin (TCD), Ireland. Her research interests relate to hydrodynamics in dissolution testing, clinically relevant dissolution testing and clinical pharmacokinetics.

Her current research focuses on computational simulation and imaging of particulate dissolution to capture the effects of dissolution test set-up on particulate behaviour, including particle motion and viscosity effects. She has co-authored more than 65 peer-reviewed presentations and publications, was PI on two clinical trials and is currently supported by SSPC, The Science Foundation Ireland Research Centre for Pharmaceuticals and TCD Provost's PhD awards.

Abstract

Online imaging analysis and in silico tools–potential for real-time online dissolution characterisation in the USP IV flow through apparatus

Understanding dissolution behaviour of particulate systems is of broad relevance from API characterization through formulation development to selection of robust quality control methods. This session will focus on two aspects of exploration of particulate behaviour in the flow-through dissolution apparatus. Firstly, a brief exploration of the definition of the available volume for simulating and interpreting dissolution in the flow-through apparatus will be presented. Consideration of a reduced available instantaneous volume for dissolution simulation will be discussed, and how consideration of available volume is relevant when trying to simulate effects of flow rate on particulate dissolution in sink conditions. This then provides greater insight into the impact of the local dissolution environment on the dissolution kinetics. Secondly, some potential applications of online real-time dissolution imaging will be presented. Shadowgraph Imaging (SGI) can be used to characterize particulate size and dispersal during dissolution testing in the flow-through apparatus. This can be used to interpret, characterize and quantify effects of the dissolution environment, such as medium and flow rate, on dissolution, using ibuprofen particles as a model system in the current work. Given the range of particle properties which can be produced from SGI analysis, a further application is explored -that of automated online agglomerate detection and quantification during the dissolution test. The results illustrate the broad potential for online and real-time image analysis to inform dissolution testing.

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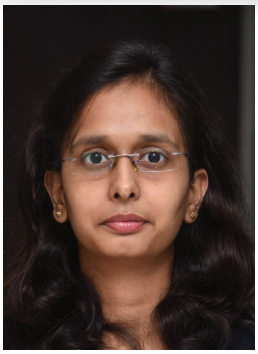

Ms. Renuka Tiwari

Gattefosse India Pvt. Ltd

Co-authors: Dr. Agnivesh Shrivastava, Dr. Ketkee Deshmukh, Dr. Sunil Bambarkar, Dr. Kavita Singh

In-vitro Dissolution vs In-vitro Lipolysis: Which is Better to Predict the in-vivo Performance of Lipid Formulations

ABSTRACT

Background & Rationale: Lipid Based Formulation Systems (LBFs) are widely used technique to enhance solubility and bioavailability of poorly water-soluble drugs. However, prediction of in vivo performance of LBFs using commonly used in vitro dissolution techniques is a complicated process. Generally, it is difficult to clinically correlate the formulation performance due to lack of physiological conditions simulation in dissolution testing. In vitro lipolysis technique is a promising alternative tool to predict the in vivo performance of LBFs. In present work we evaluate solubilization capacity of lipid-based formulations of curcumin and ticagrelor using in vitro lipolysis technique. Selected formulations were further evaluated for in vivo pharmacokinetic study on suitable animal model to correlate the in vitro in vivo performance.

Methods: Various formulations of curcumin and ticagrelor were prepared using different composition of lipid excipients. Three variants of 30 mg curcumin capsules with different fill weights 495 mg, 750 mg and 900 mg were prepared similarly two variants of 90 mg ticagrelor capsules with different fill weights 750 mg and 900 mg were prepared. The developed formulations of both the drugs and marketed reference were evaluated for in vitro dissolution using USP Type II dissolution apparatus in various dissolution media, in vitro lipolysis study and in vivo pharmacokinetic studies. In vitro lipolysis study was performed on pH-stat apparatus (Metrohm AG, Switzerland), by adding the formulation to 36 ml of lipolysis medium at 37°C. After 10 minutes, 4 ml of pancreatin solution was added. To determine the solubility of the drug in the micellar phase aliquots of 1 ml were sampled at various time points up to 1 h. Each sample was immediately after withdrawal treated with inhibitor solution to stop lipolysis followed by centrifugation and analysis of supernatant using a validated HPLC method. Based on the performance of these formulations in lipolysis study the best formulations were selected for in vivo studies. In vivo performance of formulations of both the drugs was studied on Wistar rats.

Results and Discussion: The dissolution profiles for curcumin formulations matched with that of the market reference in all the biorelevant media i.e. Hydrochloric Acid buffer of pH 1.2; Acetate buffer of pH 4.5 and Phosphate buffer of pH 6.8; and in distilled water. The ticagrelor formulations showed remarkable increase in the dissolution in above dissolution media compare to market reference. In both the case all lipid formulations produced up to 100% dissolution therefore it was difficult to select a formulation which could give similar in vivo performance. Therefore, in vitro lipolysis study was performed and the solubilization capacity of each formulation was estimated (Fig. 1). The capsule formulations with 750 mg and 900 mg filled weight of both the drugs showed superior solubilization in in vitro lipolysis study therefore these formulations were selected for animal studies and compared with market reference (Fig. 2).

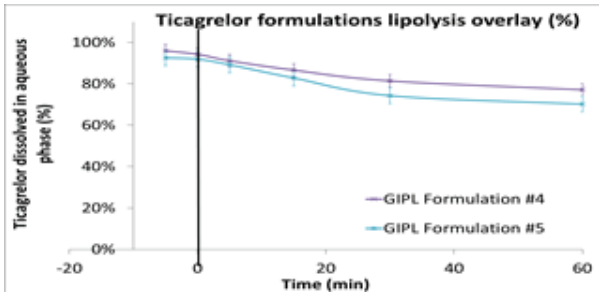

Fig. 1: In vitro lipolysis of Ticagrelor formulations.

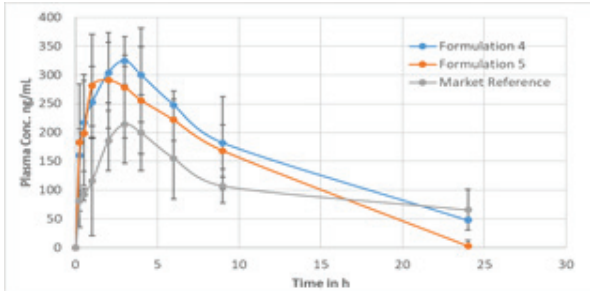

Fig. 2: In vivo PK study of Ticagrelor formulations

Conclusions: Although the in vitro dissolution profiles for all the formulations were good, the in vitro dissolution test was not sufficient to discriminate an optimum formulation for pharmacokinetic studies. In vitro lipolysis test proved to be an excellent discriminatory tool to evaluate the solubilization capacity of lipid-based formulations and to establish in vitro and in vivo correlation. Therefore, it can be concluded that In vitro lipolysis study is a promising tool to choose right LBFs prior to clinical studies to save time and expenses.

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Supersaturated Self-Emulsifying Drug Delivery System for Improving Oral Bioavailability of Quercetin

Background & Rationale: Conventional SEDDS exhibits limited drug solubility in the pre-concentrate phase making them less desirable for oral delivery1. Hence, we aim to develop supersaturated SEDDS (sSEDDS) with high drug loading in pre-concentrate along with rationally screened precipitation inhibitor (PI). Here, Quercetin (QT) is selected as a model drug. The QT-sSEDDS enables QT to extend and maintain the supersaturated (metastable) state by inhibiting nucleation rate and crystal growth formation when exposed to the aqueous environment. This allows a higher amount of QT to be in solubilized form and exhibit improved oral bioavailability2.

Methods: Drug loading and screening of PI was performed based on pre-concentrate solubility and apparent solubility profile to formulate QT-sSEDDS. Physicochemical characterization for QT-sSEDDS was performed to evaluate droplet size, drug release and functional stability. Optimised QT-sSEDDS was assessed for its GI fluids, physicochemical and storage stability. Lipid digestion rate and solubilisation potential of QT-sSEDDS was evaluated using pH-stat lipolysis method. In vitro biological characterization (uptake, cytotoxicity and apoptosis) in HeLa, A549 and Caco-2 cells was performed. Finally, in vivo pharmacokinetic profile was examined in Sprague Dawley rats.

Results and Discussion: Based on pre-concentrate solubility and apparent solubility profile, drug loading of 60 mg/g and HPMC E5 (2.5% w/w) as PI was optimised to form QT-sSEDDS. The formulation revealed spherical droplets of size 127±25 nm with PDI of 0.45±0.11. The QT-sSEDDS was able to maintain the DPPH scavenging ability of QT indicating its functional stability. The QT-sSEDDS was found to be stable in SGF and SIF in terms of their size and PDI. Further, 3 month stability data (as per ICH guidelines) also confirmed that the QT-sSEDDS were stable. The formulation revealed ~75, 85 and 80 % drug release in SGF, SIF and phosphate buffer respectively. The pH-stat lipolysis correlated the volume of NaOH required to neutralize the liberated fatty acid with the extent of lipid digestion. QT-sSEDDS and other counterparts revealed almost similar lipid digestion rate as lipid components were kept unchanged. The solubilisation potential using pH-stat was evaluated for 1 h and demonstrated a higher aqueous drug fraction for QT-sSEDDS than QT-sSEDDS without PI. This indicates that PI in QT-sSEDDS was able to maintain the supersaturated state in lipolysis media which may drive the absorption flux. In cell culture studies the QT-sSEDDS revealed significantly higher uptake (qualitative and quantitative) in all the cell lines in comparison to naïve groups. Moreover, QT-sSEDDS exhibited an improved cytotoxic effect by exhibiting ~1.9 fold reduction in IC50 values in HeLa and A549 cells. Similarly, QT-sSEDDS exhibited higher apoptotic potential in both the mentioned cancer cell lines in comparison to free QT. This is due to the higher internalization ability of sSEDDS which allows higher cytosolic QT level. However, Caco-2 cells revealed >80% viability at all tested concentrations indicating the biocompatibility of the developed system. The in vivo pharmacokinetic study showed ~2.2 increase in Cmax for QT-sSEDDS in comparison to conventional QT-SEDDS. Further, QT-sSEDDS exhibited ~ 2 and 1.7 fold increase in AUC compared to conventional QT-SEDDS and QT-sSEDDS (without PI).

Conclusions: Overall this work demonstrated that high drug loading and incorporation of PI improved the biopharmaceutical performance of poorly water-soluble drug i.e. QT. Thus, sSEDDS can be explored further for oral delivery of other poorly soluble drugs.

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Understanding the in vivo behavior of celecoxib-sodium polymeric amorphous salt solid dispersions using biorelevant dissolution

Background and Rationale: Recent studies show that amorphous salts and their polymeric solid dispersions enhance in vitro solubility and dissolution rate in buffers, improve the in vivo pharmacokinetics, and increase physical stability.1,2 However, mechanisms on how these amorphous salt solid dispersions (ASSDs) behave inside the body remain elusive. Biorelevant dissolution, which has quite recently been increasingly used to understand the intraluminal behavior of supersaturating drug delivery systems, offers a good way to explore the in vivo performance of our formulations. Accordingly, we investigated the in vivo behavior of celecoxib-sodium ASSDs (with PVPVA and Soluplus as the polymers) using this approach.

Methods: A) Generation of amorphous formulations: The ASSDs and ASDs were prepared by spray drying with optimized parameters. The drug-to-polymer ratio was 6:4 (% weight by weight basis) and the drug-to-counterion ratio was 1:1 (stoichiometric basis).

B) In vitro dissolution studies: The dissolution studies were conducted using USP Type II apparatus containing 500 mL biorelevant media (FaSSGF and FaSSIF V1) set at 37±0.5 □ and 75 rpm. 5 mL aliquots were withdrawn at predefined time points, and an equal volume was replenished to maintain sink conditions. The samples were quantified using a validated analytical method.

C) Solubility studies: The solubility studies were carried out for both the crystalline and amorphous forms of the drug in both biorelevant media. The concentration obtained after 24h was reported as the crystalline solubility, whereas the onset of liquid-liquid phase separation from the supersaturated solution of celecoxib was reported as the amorphous solubility.

Results and Discussion: The ASDs with PVPVA showed the highest release in both FaSSGF and FaSSIF V1. Also, a large difference was obtained between the crystalline and amorphous solubility of celecoxib in both media. Moreover, the ASSDs with Soluplus released lower amounts of the drug than those with PVPVA, possibly due to Soluplus' interaction with lecithin in FaSSIF V1. Several other insights could then be obtained. First, the polymer type affects the maximum concentration obtained in both media. Second, in the gastric environment, the ASSDs do not show any significant performance improvement ($p>0.05$) over the crystalline drug. Third, the ASDs show a higher release ($p<0.001$) than the corresponding ASSDs. Moreover, none of the amorphous formulations release drugs to an extent that liquid-liquid phase separation occurs. Lastly, future studies on salt disproportionation and recrystallization could confirm the mechanism for the peculiar profile of celecoxib-sodium-PVPVA ASSD in FaSSIF V1.

Conclusion: Biorelevant dissolution provides significant insights into the in vivo behavior of celecoxib-sodium polymeric ASSDs. The ASDs show a better dissolution performance than the corresponding ASSDs, and none of the amorphous formulations undergo liquid-liquid phase separation in the biorelevant media.

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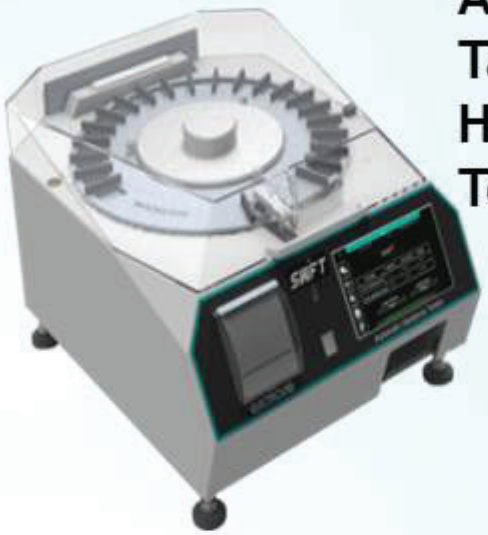

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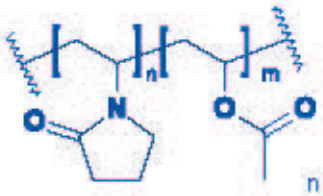

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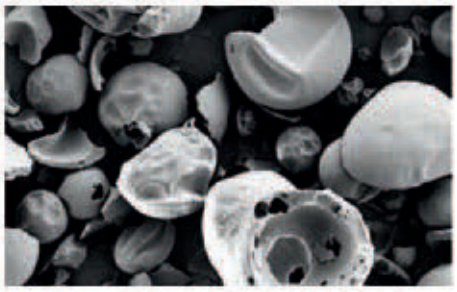

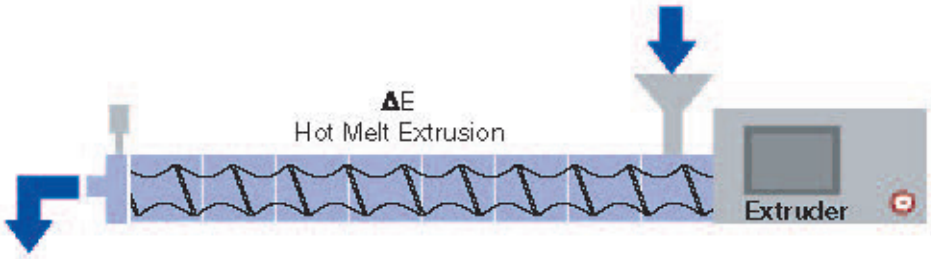

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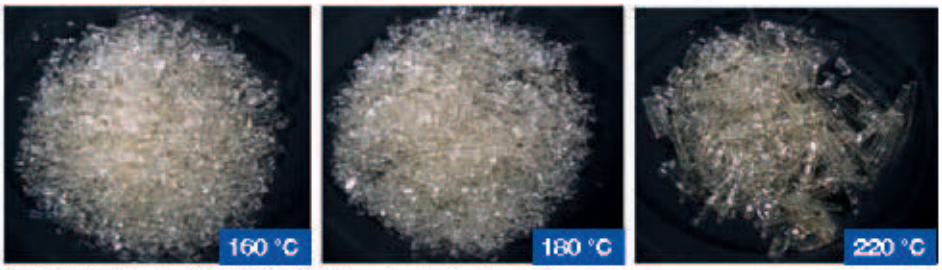

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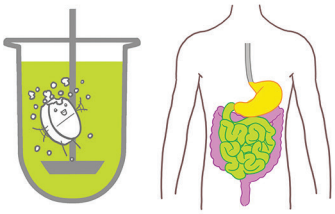

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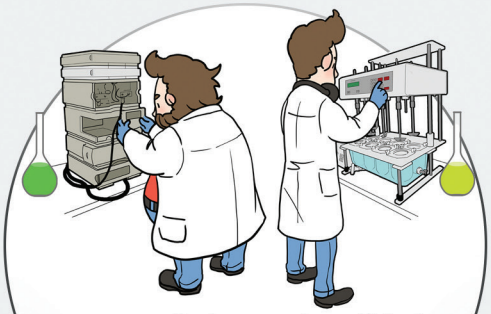

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Panel discussion during
Disso India - Hyderabad 2018

Dr. Vinod Shah answering the questions at the Panel discussion during Disso India - Hyderabad 2018

Dr. Roger William
during his talk
Disso India - Hyderabad 2018

Chairperson Dr. Rajeev Raghuvanshi presenting a momento to Dr. Jennifer Dressman

PHOTO GALLERY

Dr. Arvind Bansal
presenting a momento
to Speaker Dr. Grove Geoffrey

Dr. Dange Veerpaneni
during his talk

Dr. Raghuram Rao
addressing the delegates
during the inauguration
at Disso India - Hyderabad 2018

Dr. Umesh Banakar
during his talk
at Disso India - Hyderabad 2018

The poster session
at Disso India - Hyderabad 2018

Delegates interacting
with the Poster presenters

Delegates interacting
with the Partners

Delegates interacting
with the Partners

PHOTO GALLERY

Mr. Amit Lokhande from ICT, Mumbai
receiving 1st Prize
for his poster presented
at Disso India - Hyderabad 2018

Mr. Pankaj Sontakke
from BCP, Mumbai
receiving 2nd Prize
for his poster presented
at Disso India - Hyderabad 2018

Mr. Rijo John from ICT, Mumbai
receiving 3rd Prize
for his poster presented
at Disso India - Hyderabad 2018

The ACG Team
at the stall

The SOTAX India Team
at their Booth

The Lab India Team
at their stall

The Shimadzu & Electrolab
Teams
at their stall

The Inveniolife
Team
at their stall

It may have something to do with home schooling three children, but Lakshmi is suffering more frequently from headaches at the moment, and relies on paracetamol to help her through.

Now, as an integrated pharma supply company, ACG may not actually make the medication Lakshmi uses. But we do provide the capsules her medication is packed into, the blister packs used to protect them, and equipment used to pack and track them – ensuring they always arrive safely in her hands.

The benefits of using an integrated supplier go beyond things simply working better together. It also means having a single source of supply. So, while you help Lakshmi cope with her headaches, you should experience far fewer too.

Contact us to learn more.
www.acg-world.com

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