Society for Pharmaceutical Dissolution Science (SPDS)
in collaboration with
American Association of Pharmaceutical Scientists (AAPS)

10TH ANNIVERSARY

Annual International Conference on Dissolution Science and Applications

DISSO INDIA - 2021 ONLINE INTERNATIONAL SYMPOSIUM

Theme:
Dissolution as a Pivotal Tool for Drug Product Performance

Dates:
24th, 25th & 26th June 2021

SCIENTIFIC ABSTRACT BOOK

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www.spds.in

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

PHARMACY COUNCIL OF INDIA

(Constituted under the Pharmacy Act, 1948)

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June 14, 2021

Dr. B.Suresh
Pro Chancellor, JSS Academy of Higher Education and Research, Mysuru
President, Pharmacy Council of India

MESSAGE

It is indeed a matter of pleasure that Society for Pharmaceutical Dissolution Science (SDPS) in collaboration with American Association of Pharmaceutical Scientists (AAPS) is holding its 10th Annual International Conference on dissolution Science and applications with the theme "Dissolution as an pivotal tool for Drug Product Performance from 24th to 26th June 2021 through virtual mode.

Many eminent speakers are taking part in this conference and I am sure that this conference will discuss in detail the objective of promoting science and technological development in the field of Dissolution Science among pharmaceutical professionals, academia, students, regulatory bodies etc.

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

With best wishes.

(Dr. B Suresh)
President

MESSAGE FROM THE PRESIDENT - SPDS

Vijay Kshirsagar
Director and CEO, TRAC Consulting, India

Friends, a very warm welcome to you to Disso India 2021, being held online due to ongoing pandemic situation. Society for Pharmaceutical Dissolution Science (SODS) has taken significant strides since it's inception in 2012. Thank you all for your active support without which it would not have been impossible. We consider this year as a big mile stone as AAPS (American Association of Pharmaceutical Scientists), world's most prestigious Scientist body agreed to join hands with SPDS for the arrangement of Disso India 2021.

We are also aware that it was largely possible because of Dr Vinod Shah, Ex-USFDA and our Chief Mentor since beginning. A chapter too of SPDS is formed in USA. The aim of SPDS has been to help global pharma industry to develop products which are safe, efficacious and bioavailable. When we look back, we feel happy for our small contribution in this direction. Dr Ramaswamy, General Secretary of SPDS has a still bigger vision and with his untiring efforts and drive, we know he would achieve it.

This abstract book shall reveal that best of global experts from USA, India, France, Switzerland & Ireland are going to speak to you namely Dr Tina Morris (CEO, AAPS), Dr Vinod Shah, Dr Vatsala Nageshwaran, Prof Arvind Bansal, Dr Sandip Tiwari, Dr Umesh Banakar, Mr Samir Haddouchi, Prof Padma Devrajan, Dr Umesh Banakar, Dr Andrew Vick, Dr Sandra Squarez-Sharp, Dr Deanna Mudie, Dr Andreas Abend, Mr Mark McAllister, Mr Jurgen Kempf, Dr Deirdre D'Arcy & Mr Sandeep Kulkarni. The abstract gives brief bio-sketch of each one of them. The topics are wide ranging related to dissolution studies like development of Complex Generics, Solubility-Permeability interplay, role of excipients, USP Apparatus 4, Nano systems, Biowaivers, Regulatory Compliant Dissolution testing, Absorption modelling, Intrinsic Dissolution, Biopredictive Dissolution methods, Clinically relevant Dissolution specification, Dynamic dissolution, Automation in Dissolution, Hydrodynamics and Influence of particle characteristics.

Dr Arvind Bansal, Chairperson of Scientific Committee, deserves special applause for putting such a nice program in place. I express my heartfelt thanks to all our national and international speakers of Disso India 2021 who have agreed to contribute without any hesitation/expectation, which shows their true love for the Science of Dissolution. You don't thank your family members so big kudos to our entire SPDS committee & the men behind the scene like Mr Tarun Soni, Ms Bhakti Saraf for providing best of IT support and beautiful platform. So happy learning and enjoy the conference and do give us your feedback.

MESSAGE FROM THE VICE PRESIDENT - SPDS

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

Dear Delegates,

It gives me immense pleasure to welcome you all to the second Online version of our international meeting, DISSO INDIA 2021. Astounding success of online DISSO INDIA 2020 was the greatest motivator for us at SPDS to plan the event ONLINE this year too.

The COVID pandemic threatened to bring the world to a grinding halt. Nevertheless mankind's resilience, his adaptability and the courage to tackle adversity has helped all of us remain sailing. Seeking opportunity in every hardship is a hallmark of the human race. And at SPDS we are doing just that, using the internet mode of outreach to ensure that our annual activity goes on with as much enthusiasm and vigour. Importantly we are now able to reach across the globe. No doubt, face to face meetings have their own positives, of one-to-one interaction with speakers and delegates, and networking over a cup of tea. SPDS has tried to replicate as much as possible to put together a grand event in DISSO INDIA 2021.

As in previous years this event is also studded with speakers of international repute who would be presenting to you the latest developments in the niche area of Dissolution technology and related aspects. We look forward to your active participation, intense deliberations and great take home value from this meeting.

Look forward to meeting you all online.

Stay safe, stay happy!!

MESSAGE FROM THE SCIENTIFIC CHAIR - SPDS

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

Dear Delegates,

We are organizing 10th Annual International Conference on Dissolution Science and Applications – Disso India 2021, on the theme of "Dissolution as a pivotal tool for drug product performance". It is a matter of great pride for the entire SPDS team, to present this year's conference in collaboration with American Association of Pharmaceutical Scientists (AAPS). Online format of the conference has immensely expanded the outreach beyond geographical boundaries.

Dissolution as a science continues to evolve at a fast pace and influence various facets of pharmaceutical development. On one hand, pharmaceutical industry is rigorously explores material science and formulations to address poor aqueous solubility; on the other hand exciting developments are taking place in the dissolution related methodologies, regulations, instrumentation and automation. We have captured these developments by including lectures on cocrystals, topical / ophthalmic drug products, USP Type IV apparatus, PBBM, bio-predictive dissolution, clinically relevant dissolution, dynamic dissolution, intrinsic dissolution, hydrodynamics and automation.

Highly experienced speakers from industry, academia and regulatory shall share their views with the participants. We are extremely thankful to all the resource-persons for accepting our invitation to deliver talks at Disso India 2021. This conference provides unique platform to the participants for understanding latest developments in the field of dissolution science.

Wishing everyone a significant learning experience at Disso India 2021.

Arvind K Bansal, PhD, FAAPS

Scientific Chair - 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 to organise Disso India 2021 online together with the Scientific Committee and the Organising Committee. This is the second time we are conducting Disso India online. We had the opportunity this year to collaborate 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 for formally beginning our collaboration from this year.

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 this International Conference. We have received excellent responses from the Pharma Industry , Academia ,& Partners, which shall make this event a truly memorable one

I am sure that all the delegates of Disso India 2021 Online shall find their time spent at the conference to be enriching and enlightening. My sincere thanks to all the companies who have registered a good number of delegates and their managers who have given their 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, Vijay Kshirsagar, The Conference co-ordinator Ms. Bhakti Poonia , our Multi Media expert, Tarun Soni, Ms Neetu Singh & Rajesh & Team from Design Accent who are our online event Organisers, Dr Praksh Bhosale & Mr Yash for ensuring timely press releases along with spreading the event through social media marketing and all other trustees and Members.

Encouraging young scientists and academicians has always been our way of life at SPDS. Under the Leadership of Dr. Saranjit Singh, we had launched an innovative 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 2021 we shall have this event online . All delegates of Disso India 2021 are welcome for DRPI also. Please do visit our website DRPI.SPDS.in to know more.

I wish you all a great conference of Disso India 2021 Online over these next three days.

Dr. L. Ramaswamy

10th Annual International Conference on Dissolution Science and Applications

Dissolution as The Pivotal Tool for Drug Product Performance, Mumbai

Venue : Online • Dates: 24th to 26th June, 2021

PROGRAM FOR THE CONFERENCE

DAY 1 : 24th June, 2021

SR. NO.	TIME	TITLE AND TOPICS	SPEAKER	SPONSORED BY
1.	3.00 - 4.00 PM	**Inauguration**		
2.	4.05 - 4.35 PM	**AAPS Role in Advancement of Pharmaceutical Science**	Keynote Address by **Dr. Tina Morris,** Chief Executive Officer, AAPS, USA	
3.	4.35 - 4.45 PM	Release of Desk Book of Pharmaceutical Dissolution Science and Application - 2nd Edition by **Dr. Tina Morris,** Chief Executive Officer, AAPS, USA	**Dr. Sandip Tiwari,** Editor, Desk Book of Pharmaceutical Dissolution Science and Application	
		Material Properties and Formulation Development		
1.	4.50 - 5.20 PM	The Role of Dissolution in The Development of Complex Generics Including Topical / Ophthalmic Drug Products	**Dr. Vinod P Shah,** Ex-USFDA, Pharmaceutical Consultant, USA	ACG
2.	5.25 - 5.40 PM	**Inauguration of the Exhibition**	**Dr. Vinod P Shah,** Ex-USFDA, Pharmaceutical Consultant, USA	
3.	5.45 - 6.15 PM	Cocrystals for Solubility Enhancement	**Prof. Arvind Bansal,** Professor & Head, Department of Pharmaceutics, NIPER, SAS Nagar, India	
4.	6.20 - 6.50 PM	Solubility-Permeability Interplay in the Dissolution	**Dr. Vatsala Nageshwaran,** Chief Business Officer, Absorption Systems, USA	
5.	6.55 - 7.25 PM	Excipients for Enabling Technologies	**Dr. Sandip Tiwari,** Head of Technical Services - Pharma Solutions, North America, BASF, USA	
6.	7.30 - 8.10 PM	Panel Discussion and Q&A	Speakers of the Day are in the Panel	
7.	8.10 PM onwards	Networking and Exhibition	Delegates to Visit Networking Lounge and Exhibition	

10th Annual International Conference on Dissolution Science and Applications

Dissolution as The Pivotal Tool for Drug Product Performance, Mumbai

Venue : Online • Dates: 24th to 26th June, 2021

PROGRAM FOR THE CONFERENCE

DAY 2 : 25th June, 2021

SR. NO.	TIME	TITLE AND TOPICS	SPEAKER	SPONSORED BY
Dissolution of Specialized Dosage Forms and Drug Delivery Systems				
	2.00 - 3.00 PM	Exhibition Open		
1.	3.00 - 3.10 PM 3.10 - 3.20 PM	Special Guest Address	**Ajit Singh,** Chairman ACG, India & **Prof. Biswajit Mukherjee,** Jadhavpur University, India	
2.	3.25 - 3.55 PM	**Scientific Pursuit for Improving Human Health**	**Keynote Address,** **Dr. Andy Vick,** **President AAPS, USA**	
	4.00 - 4.30 PM	Nanosystems: Dissolution Methodologies and Biorelevant Media	**Prof. Padma Devarajan,** Dean-Research & Innovation and Professor in Pharmacy, Institute of Chemical Technology, India	
3.	4.35 - 5.05 PM	Usp Apparatus 4 as a Biowaiver Tool for Specialized Formulations	**Samir Haddouchi,** Managing Director, SPS Pharma Services, Orleans, France	
4.	5.10 - 5.40 PM	Networking and Exhibition	Delegates to Visit Networking Lounge and Exhibition	
Dissolution Methodology and Regulatory Affairs				
1.	5.45 - 6.15 PM	Physiologically Based Absorption Modeling (PBAM)	**Dr. Sandra Suarez-Sharp,** Vice President of Regulatory Affairs, Simulations Plus Inc., USA	ELECTROLAB
2.	6.20 - 6.50 PM	Biopredictive Dissolution Methods	**Dr. Deanna Mudie,** Principal Scientist, R&D, Lonza Inc, USA	
3.	6.55 - 7.25 PM	Clinically Relevant Dissolution Specifications / Patient-Centric Dissolution Testing	**Dr. Andreas Abend,** Director in the Analytical Sciences Group, Merck, USA	
4.	7.30 - 8.00 PM	Intelligent Vs. Intellectual Vs. Regulatory Compliant Dissolution Testing : Where Do We Draw the Lines!!	**Dr. Umesh Banakar,** Professor and President, Banakar Consulting Services, USA	
5.	8.05 - 8.35 PM	Panel Discussion and Q&A	Speakers of the Day are in the Panel	

10th Annual International Conference on Dissolution Science and Applications

Dissolution as The Pivotal Tool for Drug Product Performance, Mumbai

Venue : Online • Dates: 24th to 26th June, 2021

PROGRAM FOR THE CONFERENCE

DAY 3 : 26th June, 2021

SR. NO.	TIME	TITLE AND TOPICS	SPEAKER	SPONSORED BY
		Automation and Instrumentation		
	2.00 - 2.40 PM	Exhibition Open		
1.	2.40 - 3.10 PM	Intrinsic Dissolution-Important Tool for API Characterisation	Key Note Address, **Vijay Kshirsagar,** TRAC Consulting, India	
2.	3.15 - 3.45 PM	Automation for Dissolution Data Integrity	**Juergen Kempf,** Sotax AG, Switzerland	sotax
3.	3.50 - 4.20 PM	Hydrodynamics in Dissolution Apparatus (Role of Designing of Dissolution Vessel)	**Dr. Deirdre D'Arcy,** Associate Professor, Trinity College, Ireland	
4.	4.25 - 4.55 PM	PIV Measurements of USP Apparatus 1 Hydrodynamics - a Close-up Story	**Dr. Satish Perivilli,** Senior Scientist II, Dosage form performance laboratory USP, USA	usp
5.	5.00 - 5.30 PM	Advances in Dynamic Dissolution	**Mark McAllister,** Senior Scientific Director, Pfizer, USA	
6.	5.35 - 6.05 PM	Influence of Particle Characteristics on Dissolution Testing	**Sandeep Kulkarni,** Scientific Director, Image Provision Technology Pvt. Ltd., India	ImageProVision Technology Leaders in Image Analytics
7.	6.10 - 6.40 PM	Automated Spectroscopic Measurement	**Dr. Hans-Joachim Muhr,** Head of Strategic Product Group UV/VIS Scientific Director, Mettler-Toledo GmbH, Analytical, Switzerland	METTLER TOLEDO
8.	6.45 - 7.15 PM	Panel Discussion and Q&A		
	7.15 - 7.45 PM	Closing Session of Disso India 2021		
	7.45 PM onwards	Networking and Exhibition		

GALAXY OF SPEAKERS

DAY-1





DAY-2







DAY-3







Dr Tina Morris
Chief Executive Officer, AAPS, USA

Biosketch

Dr. Morris is the Executive Director of the American Association of Pharmaceutical Scientists (AAPS). She leads the staff team that supports all operational aspects of the Association and works with the AAPS Board of Directors and other Volunteer Leadership Committees on the strategic and direction-setting activities that guide the work of the scientific society. Prior to that, she was Vice President of Scientific and Regulatory Affairs at the Parenteral Drug Association (PDA). Until 2018, Dr. Morris held several scientific senior leadership positions at the United States Pharmacopeia (USP), including as the Global Head of Biologics and Senior Vice President of Compendial Science. Before joining USP in 2003, Dr. Morris worked in the biopharmaceutical industry, with an expertise focus on analytical development and product characterization. She completed her postdoctoral research at the National Institutes of Health. She holds a Ph.D. in molecular virology from the Medical University of Luebeck, Germany, and a master's degree in biology from the Carl von Ossietzky University of Oldenburg, Germany.

https://www.linkedin.com/in/tina-morris-6a527b/

Abstract

AAPS Role in the Advancement of Pharmaceutical Science

Since its founding in 1986, the American Association of Pharmaceutical Scientists has been fulfilling its mission of advancing the capacity of pharmaceutical scientists to develop products and therapies that improve global health. As a scientific association that is based on individual membership of dedicated experts from across the pharmaceutical development spectrum, AAPS has always had the unique opportunity to reshape and accelerate the scientific discovery dialog by bringing the pharmaceutical science disciplines together around critical issues that affect the development of safe medicines. This role of the independent scientific convener with international reach has never been more important than now, as we face an unprecedented global public health crisis that will have a lasting impact on our approach to the development and supply of life-saving medicines. AAPS is constantly enhancing its ability to give our members access to the latest cutting-edge science and regulatory developments. The implementation of AAPS' new strategic plan will further strengthen our organization's ability to connect our members and other relevant stakeholders around the world in the scientific dialog that is critical to move our field forward. This presentation will discuss some key areas that AAPS is focusing on and investing in to accelerate our continuing contribution to excellence in the pharmaceutical sciences.

Vinod P. Shah
Ex-USFDA, Pharmaceutical Consultant, USA

Biosketch

Dr Shah is a Pharmaceutical Consultant; Steering Committee member of Non-Biological Complex Drugs (NBCD) hosted at Lygature in The Netherlands (2011-Present); International Chairman of Society of Pharmaceutical Dissolution Science (SPDS) (2012 – Present); President of SPDS-US chapter (2019 - present) and expert consultant with NDA Partners (2016 – 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, bioanalytical method validation, topicals, bioequivalence and biopharmaceutics.

Dr Shah was Scientific Secretary (2003 – 2011) of International Pharmaceutical Federation (FIP); Chair of Regulatory Sciences Special Interest Group of FIP (2011-2016) and Biopharmaceutics Consultant at USP (2005-2014). Dr Shah 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 many FDA, National and International Awards.

Abstract

The Role of Dissolution in the Development of Complex Generics including Topical/Ophthalmic Drug Products.

What are complex Generics? Generic drug products containing complex active pharmaceutical ingredient like polymeric compounds and peptides; complex formulations such as liposomes, suspensions, emulsions, gels; drug products for complex routes of delivery like locally acting dermatological, ophthalmic and inhalation; complex dosage forms such as long acting injectables, implantable; complex drug-device combination products like transdermals, metered dose inhalers; and other products where complexity or uncertainty concerning the approval pathway exists are defined as complex generics. Determining the bioequivalence (BE) of complex generics is challenging. The FDA is conducting research to develop an alternative approach, including in vitro BE options, to determine BE for complex generics.

Drug release from complex generics plays an important role in product development and drug approval process. Its role in topical and ophthalmic drug products will be highlighted. An evolving concept for topical complex drug products from comparative clinical endpoint studies to Q1, Q2, Q3 sameness to allowing greater permissiveness in formulation and proposed Topical Drug Classification System (TCS), for reducing regulatory burden will also be presented.

Arvind Kumar Bansal
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'. He is the Scientific Chair of Society for Pharmaceutical Dissolution Science (SPDS), since 2018. Recently his lab has out-licensed a platform technology on "Nano crystalline solid dispersions – NanoCrySP".

Abstract

Cocrystals for solubility enhancement

Solubility enhancement remains an important challenge for pharmaceutical scientists. Solid state forms like metastable polymorphs, salts and amorphous form - are a versatile tool for modulating solubility. Cocrystals like salts and solvates are multi-component crystalline solids. They are defined as "solids that are crystalline single phase materials composed of two or more different molecular and / or ionic compounds generally in a stoichiometric ratio, which are neither solvates nor simple salts". They can provide solubility enhancement similar to amorphous form (approximately 4 to 20 times) and do not suffer from poor physical stability. This presentation shall focus on the fundamental aspects of solubility enhancement from cocrsytals. Eutectic constant is a valuable indicator of solubility advantage from cocrystals. Parameters like pH of the dissolution medium and surfactant concentration can influence the solubility advantage from cocrystals. Solubilization from cocrystals is profoundly affected by the events related to conformer in the 'static water layer', around cocrystal particles. Supersaturation of drug in the bulk solution may trigger precipitation which can potentially reduce biopharmaceutical advantage from cocrystals. Inclusion of surfactants and polymers can modulate supersaturation and prevent 'solution mediated phase transformation' of cocrystals.

Dr Vatsala Naageshwaran
Chief Business Officer, Absorption Systems, USA

Biosketch

Vatsala Naageshwaran is Vice President of Operations at Absorption Systems, a Pharmaron company. Prior to joining Absorption Systems, she has worked for several biotechnology / pharmaceutical companies as a research scientist with experience in drug discovery, assay validation, and product development. Her research has been featured at national conferences such as AAPS, SOT, AACR and EORTC and in publications submitted to peer-reviewed journals. She has been a speaker at AAPS and other forums on in vitro models for clinically relevant drug transporters and non-clinical methods for establishing bioequivalence of oral and complex drug products. Vatsala has a master's degree in Biochemistry from Mt Holyoke College (MHC), a master's degree in Pharmacometrics from the University of Maryland Baltimore (UMB) and is completing her Ph.D. in ocular pharmacokinetics and modelling through the University of Eastern Finland (UEF). Her research interests are in the areas of pharmacokinetics, ophthalmology, and bioequivalence.

Abstract

Solubility-Permeability Interplay in Drug Absorption

In vitro dissolution experiments have been successfully employed to replace clinical bioequivalence according to the Biopharmaceutics Classification System (BCS) for immediate release solid oral dosage forms for many decades. However, as formulations become more complex or administered via non-oral routes, there is a requirement to improve product evaluation using bioassays that can explore the interplay between critical compound characteristics such as solubility and permeability to identify the rate limiting step to absorption. An integrated and dynamic experimental approach which simulates the actual conditions of drug administration, incorporating in vitro, in situ or ex vivo nonclinical models can be used to compare and optimize formulations to understand the impact of changes in critical quality attributes or excipient changes. This presentation will highlight several examples of such formulation modifications and the benefit of biorelevant models to understand the interplay of combined product characteristics to ensure quality and predict performance correlated with and translatable to human in vivo performance.

Sandip Tiwari
Head of Technical Services, Pharma Solutions, North America, BASF, USA

Biosketch

Dr. Sandip B. Tiwari is Head of Technical Services-Pharma Solutions North America at BASF and is responsible for providing technical support to help solve formulation challenges of the pharmaceutical companies. Prior to joining BASF, Sandip was a Fellow, Manufacturing Science & Technology at Teva Pharmaceuticals, Davie FL leading the scale-up and commercialization of complex new technologies. Sandip also worked at Coloron Inc. as a Senior Manager, Product Development, Modified Release Technologies and then as a Technical Director for South Asia. He also worked for Zydus Cadila in the novel drug delivery systems area. Sandip earned his PhD in Pharmaceutical Sciences from College of Pharmaceutical Sciences, Manipal, Karnataka, India, and did his post-doctoral fellowship from Northeastern University, Boston, MA. He has written one book, eight book chapters/ monographs and contributed more than 100 research publications and conference presentations in the areas of dosage form design, new technologies, dissolution science and excipients.

Abstract

Excipients for Enabling Technologies

Poorly water-soluble drugs are the bulk of new APIs coming to market, and as such, methods to increase dissolution or maintain solubility in the body are needed. Softgels are a unique, liquid dosage form that is ideal for enhancing the bioavailability of difficult APIs from solution by pre-dissolving and maintaining the API into a liquid-based system. However, when the liquid contents are released, typically in the stomach, or the intestine, poorly water-soluble drugs often crash out of solution through recrystallization in the gastrointestinal fluid. During the 4 to 6-hour gastrointestinal transit time, poorly water-soluble APIs must remain dissolved or in solution for a significant time window to be available for absorption.

It is a well-known and widely used practice by the formulators to use low molecular weight. polyvinylpyrrolidone as crystallization inhibitors, particularly Kollidon® 12 and Kollidon® 17 PF. In this work, novel techniques using the Pion Inform® are used to monitor recrystallization rates in the presence of various polymers and surfactants to uncover additional enabling excipients that can be utilized within the softgel formulations to maximize the drug dissolution and subsequently increase the bioavailability window. This presentation will discuss this concept of crystallization inhibition in softgel formulations using enabling excipients with selected practical examples.

Andrew M. Vick, Ph.D.
President, AAPS, USA

Biosketch

Dr. Andrew Vick has 23 years of experience working within the pharmaceutical industry in the fields of toxicology, nonclinical and clinical pharmacology, and drug disposition. Currently, Dr. Vick is responsible for financial, operational, and scientific oversight of all Midwest sites within Charles River's North American Safety Assessment business. In this role, Dr. Vick oversees a biomedical staff of >3,000 who are involved in diverse aspects of nonclinical and clinical development. He also serves as the Executive Sponsor to several global pharmaceutical companies, where he provides strategic advice, customized program and study designs, regulatory advice, and risk mitigation tactics.

Previous roles have included: VP of Analytical Services for WIL Research, EVP of Pharmacokinetics, Dynamics, and Metabolism at Seventh Wave Laboratories, Scientific Director of the BioPharma Services Division of Millipore, Principal Scientist within the Drug Disposition and Toxicology department of Eli Lilly and Company, and preclinical scientist at Biogen. In these roles, Dr. Vick contributed to the design, conduct, and interpretation of preclinical and clinical testing strategies for both small organic and biotherapeutic molecules across a variety of therapeutic indications and stages of development.

Dr. Vick earned his B.S. in Zoology and Ph.D. in Pharmaceutical Chemistry from The Ohio State University. He continues his support of the University as an Adjunct Professor in the College of Pharmacy. Dr. Vick also serves in the role of President for the American Association of Pharmaceutical Scientists.

Abstract

Scientific Pursuit For Improving Human Health

For 35 years, the American Association of Pharmaceutical Scientists have been focused on the vision of "Advancing the pharmaceutical sciences to drive prevention and cures" and over that time we have created healthier lives together. Mila's battle with Batten's disease is a great testimony of the impact that we have had on improving human health. Further, AAPS recently completed our Strategic Plan in support of our mission and vision. Of the five strategic goals, all highlight the importance of diversity, global community, and working together towards the pursuit of improving human health. This session will review those goals, highlight the impact of working together, and share a powerful testimony of the impact of our collective efforts.

Padma Devrajan

Dean-Research & Innovation and Professor in Pharmacy, Institute of Chemical Technology, India

Biosketch

Dr (Ms) Padma V. Devarajan is Professor in Pharmacy and former Head and Coordinator M.Tech Pharmaceutical Biotechnology, Department of Pharmaceutical Sciences and Technology at the Institute of Chemical Technology, Mumbai, India. She is a Member of the Board of Governors, President of the Innovation Council and Incharge of the World bank Technical Education Quality Improvement Programme(TEQIP) at the Institute of Chemical Technology, the only ELITE University and Centre of Excellence in the state of Maharashtra in India, among the top institutes in the country and also globally acclaimed. Her research interests include colloidal carriers for targeted delivery in cancer and infectious diseases, Veterinary Drug delivery, Bioenhancement strategies, and Mucosal DDS as alternative to parenteral administration and QbD in drug development. She has over 100 publications and presentations in cited journals and national/international conferences, and five book chapters in the area of drug delivery. Her book on "Targetted Drug Delivery- Concepts and Strategies " published by Springer won her the Prof. N. R.Kamath Book Award at ICT. Her book on Intracellular Targetted Delivery by Receptor Mediated Endocytosis as Editor and Author is recently published by Springer.

She has filed many patents international/ national, has seven patents granted and five patents licensed. 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.

She was Board Member, Member on the Board of Scientific Advisors and Chair of the Young Scientist Mentor Protégé Committee of the Controlled Release Society Inc.,USA, Chair of the Outstanding Paper Award Committee of the journal Drug Development and Translational Research, of the of the Controlled Release Society Inc., USA. She is Patron Member of the Controlled Release Society Indian Chapter and Member on the Editorial board of the Asian journal of Pharmaceutical sciences an Elsevier publication and European Journal of Drug Metabolism and Pharmacokinetics a Springer Publication.

Prof. Devarajan is a gold medallist of Mumbai university at B.Pharm, and former President of the Alumni Association of UDCT/ICT. She is a nominated Fellow of the Maharashtra Academy of Sciences, 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. Her publication in the International Journal of Pharmaceutics on Gastroretentive drug Delivery, won the prestigious Eudragit Award 2015. 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.

Abstract

Nanosystems: Dissolution Methodologies and Biorelevant Media

Developments in nanomedicine have made several in roads in the therapeutic arena. Nanosystems have enabled significant success in cancer therapy, while the COVID pandemic highlights the importance of safe nanosystems for the fungal disease mucormycosis. Commercialization of nanomedicines is on the rise necessitating the need for dependable and sturdy in vitro evaluation tests. One important test that has a direct relevance to in vivo performance of nanosytems is the In vitro dissolution test. Development of standard dissolution testing methods which could become compendial is an urgent need of the hour. The present talk would focus on three aspects related to dissolution methodologies and would first address different approaches for drug release testing of nanosystems. Case studies would be presented with a focus on developing a discriminating dissolution test. Scope for developments in this field especially in the context of developing biorelevant dissolution media based on the nanosystem application and route of administration would be discussed.

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

Usp Apparatus 4 as a Biowaiver Tool for Specialized Formulations

The availability and utilization of generic alternatives to brand-name drugs have a significant effect on cost savings for health care consumers. Since the original active ingredient was already proven safe and effective, the manufacturer must only prove bioequivalence for the pharmaceutically equivalent generic drug product.

Although bioequivalence is usually demonstrated using clinical studies, in certain instances, based on the biopharmaceutics properties of the product, in vitro testing, when properly carried out, may be used to waive an in vivo bioequivalence study.

In order to achieve such objective, the authorities are usually paying lot of attention to the in vitro testing conditions, especially with regards to the discrimination power of the method. Thus the flow through cell, known as Apparatus 4, is showing big advantages compared to the other conventional methods.

This lecture will present the usual requirements to demonstrate pharmaceutical sameness of products as well as some specific situations where in vitro data may be use in lieu of of clinical data.

Dr. Sandra Suarez-Sharp
Simulations Plus, USA

Biosketch

Dr. Sandra Suarez-Sharp obtained a bachelor's degree in Industrial Pharmaceutical Chemist at the National Polytechnic Institute of Mexico City. After graduation, she worked for Johnson and Johnson in Mexico. She obtained a PhD in Pharmaceutical Sciences in 1997 from the University of Florida and her postdoctoral research was carried out at Chapel Hill University in North Carolina, in the areas of Pulmonary drug delivery and Pharmacokinetics.

In 1999, she joined the FDA, Office of Clinical Pharmacology supporting several therapeutics divisions. Later, she became master reviewer and scientific advisor to the Division of biopharmaceutics, Office of Product Quality in areas such as in vitro-in vivo correlation, biowaivers, RTRT dissolution models, and Physiologically based biopharmaceutics modeling (PBBM).

Dr. Suarez-Sharp collaborated in the development of different guidance for industry, among them the one on The Use of Physiologically Based Pharmacokinetic Analyses — Biopharmaceutics Applications for Oral Drug Product Development, Manufacturing Changes, and Controls (PBBM) published in October 2020. She represented the FDA at different National and international scientific events.

Dr. Suarez-Sharp has a large number of publications related to the areas of dissolution, in vitro-in vivo correlation, establishment of specifications with clinical relevance, physiology-based biopharmaceutics modeling (PBBM) . She joined Simulations Plus in March 2020 as Vice President of Regulatory Affairs.

Abstract

The Application of Physiologically based Biopharmaceutics Modeling (PBBM) in Support of Biopredictive Dissolution Method Development

Drug product development continues to be a costly enterprise despite ongoing efforts across pharmaceutical companies to rein in growing R&D costs. In the case of complex generics, demonstration of bioequivalence (BE) relies, for the most part, on costly and lengthy unconventional in vivo BE studies, which contribute to a significant cost burden to the healthcare system.

To facilitate drug product development and the approval process, regulatory agencies (i.e., FDA) have published several guidance documents for industry, including drug product specific guidance and the recently available draft guidance on the use of physiologically based pharmacokinetic analysis-biopharmaceutics applications for oral drug product development, manufacturing changes and control (also known as physiologically based biopharmaceutics modeling (PBBM)). PBBM can accelerate drug product development by informing the design of formulation and process, the design of BE clinical study, etc. However, a rational, science-based approach to incorporating biopredictive dissolution into PBBM is key as industry seeks to use modeling to gain manufacturing and regulatory flexibility. This presentation will focus on: 1) The impact of biopredictive dissolution methods in drug product development and lifecycle management; 2) A general work flow of PBBM development and validation; 3) The application of PBBM to support the assessment and mitigation of risk including informing the development of biopredictive dissolution methods.

Deanna Mudie

Principal Scientist, R&D, Lonza, Bend, OR, 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 predoctoral experience at Pfizer and Merck developing and manufacturing oral dosage forms from preclinical to commercial scale.

Abstract

Biopredictive Dissolution Methods

Oral drug product administration is the most common and preferred 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, which vary depending on the drug and formulation properties and physiology of the target patient population. 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 physiology impacts bioperformance.

This talk will highlight biopredictive dissolution methods for evaluating oral drug product bioperformance. Case studies of amorphous solid dispersion (ASD) formulations will be presented highlighting how biopredictive dissolution methods can be used to streamline formulation development and enable right-first-time drug product formulations.

Dr. Andreas Abend

Director in the Analytical Sciences Group, Merck, USA

Biosketch

Andreas Abend received his PhD degree in Organic Chemistry from the University of Karlsruhe in Germany. Prior to joining MSD as a Senior Project Chemist, Andreas spent 3 years as a Post-Doctoral Fellow at the University of Wisconsin's Enzyme Institute. He is currently a Senior Principal Scientist in the Pharmaceutical Sciences Department supporting a range of different formulations under development at MSD. Throughout his career, he supported small molecule API and drug product development spanning all clinical phases as an Analytical Scientist and manager. Andreas is a member of MSD's Biopharmaceutical Advisory Team, PQRI's BTC, and a member of IQ's Analytical Leadership Group. He presented at many national and international meetings, published several manuscripts on Clinically Relevant Dissolution Specifications and he recently served as co-organizer of two workshops at the Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI).

Abstract

Clinically relevant dissolution specifications / patient-centric dissolution testing

Dissolution testing is extensively used in the pharmaceutical industry to guide formulation development, routine product quality control, to support post-approval changes and in support of biowaiver applications. Justifying dissolution specifications to confirm consistent product quality without being overly sensitive towards normal manufacturing process variability can be a major challenge for industry. Likewise, from a regulatory perspective, gauging whether an applicant's proposed dissolution specifications are adequate to ensure patients have access to products with unfailing performance as demonstrated in pivotal clinical trials can be daunting. In order to address this dilemma, a road map for IR solid oral dosage forms based on biopharmaceutics risks was developed by members of the International Consortium for Innovation and Quality in Pharmaceutical Development (IQ). In addition, this topic was debated at recently held workshops attended by regulators and industry which highlighted the need for developing dissolution specifications that are clinically relevant. Outcomes from these workshops will be discussed along with recommendations when Clinically Relevant Dissolution Specifications (CRDS) should be developed. In addition, a decision tree will be shared which clarifies the application of CRDS in support of product life-cycle management.

Umesh V. Banakar

Professor and President, Banakar Consulting Services, USA

Biosketch

Umesh V. Banakar, Ph.D. is Professor of Pharmaceutics and an Independent Consultant/Advisor to Pharmaceutical Industry and Academia worldwide with extensive contribution in drug product development and evaluation (in vitro and clinical).

During his academic career, he has served as Professor of Pharmaceutics, Director of Research, Chairperson of Department of Pharmaceutical Sciences and Head/Dean of Graduate School at 3 Universities in the US.

He is on the International Scientific Advisory Board of several pharmaceutical corporations worldwide. Of date, he has successfully completed several Pharmaceutical Product Development Technology Transfer through education assignments sponsored by the UN/IESC and other pharmaceutical corporations worldwide. Additionally, he has planned and executed the development, both in vitro and clinical, of several NDAs [including 505(b)(2)] and ANDAs (both IR and MR products).

Furthermore, he has served as testifying/non-testifying expert in over 65 patent litigations in the disciplines of pharmaceutical formulations/technology, clinical investigations and dissolution testing.

He is the Founder of Goa – Center for Excellence in Intellectual Property [G-CEIP] – non-profit, personally funded Center to promote IP Awareness nationwide.

He is the Founding Chairperson of 2 International CROs and has executed over 750 clinical trials (Phase I-IV including BE studies).

Additionally, he is the founding Board Member and Principal Scientific Adviser of Society for Pharmaceutical Dissolution Science [SPDS].

He has authored over 100 publications, over 100 published abstracts and presentations, numerous specialized workshop manuals, several chapters and monographs, over 45 expert book reviews and 5 guest editorials. The texts that he has authored include: Pharmaceutical Dissolution Testing, Drug Development Process: Increasing efficiency and cost effectiveness, and co-edited include: NanoBioMedicine (6 volume; 91 chapters series), Desk Book of Pharmaceutical Dissolution Science and Applications, among others. He is the co-author of an electronic text: Basic Pharmacokinetics.

He is on the roster of experts with WHO, United Nations – TOKTEN program and International Executive Service Corps (IESC). He is listed in Who's Who in Biotechnology, Who's Who Among Asian Americans, and American Men and Women of Science. He is the founding Editor-in-Chief and on Editorial Boards of several scientific journals. He has received numerous awards for excellence in teaching, research/scholarly activity, two Service to Country Awards from the UN and nomination for the distinguished Fulbright Scholar Award for Teaching.

Abstract

Intelligent vs Intellectual vs Regulatory Compliant Dissolution Testing: Where do we draw the lines !!

In vitro dissolution test(ing), beyond doubt, is an integral component of the life cycle management of a pharmaceutical drug product. The science behind solubilization and apparent dissolution provides the necessary understanding of the processes, respectively. It provides the means and tools to present the resulting data to support, establish, demonstrate, and qualify the functional and performance attributes of the pharmaceutical product. While the fundamentals of the science of dissolution do not change, the applications of dissolution science and technology are varied, thus, foraying into disciplines of intellectual property determinations, biosimilars, bioefficacy predictions of complex products comprising of practically insoluble drug substances, nutraceuticals and natural products, just to mention a few. The scientific rationalization of applications of dissolution test(ing) provides the fodder and the support to the initiative of 'science based review' of the data for regulatory approval of a pharmaceutical product. Yet, there appears to be very limited flexibility in the requirements to comply with the stated acceptance criteria with respect to dissolution test(ing) data. On the other hand, the same scientific rationale which may (or not) be compliant with regulatory requirements could be sufficient to demonstrate the unique attributes (functional and/or performance) of the pharmaceutical product worth protecting through securing intellectual property rights. Thus, clearly, over time, the vast expanse of literature on in vitro dissolution test(ing) can be segregated in predominantly three categories, namely, intelligent, intellectual and regulatory compliant. The presentation will attempt to provide the delineations within these categories which will be beneficial for professionals in defining career objectives as well as achieving the necessary expertise.

Vijay Kshirsagar
Director and CEO, TRAC Consulting, India

Biosketch

Vijay Kshirsagar is M.Sc. by Research in Organoanalytical Chemistry from Mumbai University after his graduation in Microbiology

He is an accomplished Quality, Regulatory & Analytical professional with around 40 years of rich experience. In 2013, he retired as Executive Vice President Unichem, responsible for CQA, Regulatory & Analytical Research and then formed his own Pharma Consultancy called TRAC offering specialized services globally, for Training, Regulatory Filings, Auditing & Compliance. He is an Advisor on Quality & Regulatory matters.

Prior to Unichem he worked for Ranbaxy, Sun, Lupin, IPCA, German Remedies in various senior positions. He has successfully represented his company in US and UK courts regarding IP related matters (Para IV filings). He has completed several regulatory inspections by global regulatory bodies. He has been a frequent trainer in India & abroad having spoken on wide range of topics related to cGMP & GLP.

IDMA has conferred upon him an 'Outstanding Analyst Award 2011' for his contribution towards pharmaceutical analysis. He has published articles on topics like OOS, QbD & cGMP in reputed journals/ books. Guideline written by him on CAPA is published by IDMA. He is a Mentor to two reputed pharmacy colleges in Mumbai including Bombay College of Pharmacy.

He is founder President of SPDS and was part of Board of Directors of ISPE, India

Abstract

Intrinsic Dissolution-Important Tool for API Characterisation

Intrinsic dissolution rate has been defined as "the rate of dissolution of a pure pharmaceutical active ingredient when conditions such as surface area, temperature, agitation or stirring speed, pH, and ionic strength of the dissolution medium are kept constant". Most of the new molecules are insoluble/ less soluble molecules, many exhibiting polymorphism. Hence it has become a challenge to understand API characteristics for developing discriminatory/ bio predictive invitro methods and finally a good bioequivalent product.. The presentation is designed to explain Intrinsic Dissolution testing which is official in USP/EP. The survey conducted reveals that though it is extremely important but it is less practiced. Studies conducted on Intrinsic dissolution testing shall be discussed and its interpretation. This presentation shall also be extended to Apparent Dissolution which is official in EP. Will also compare Intrinsic Vs Apparent Dissolution as a technique.

Jürgen Kempf
Sotax AG, Switzerland

Biosketch

He started his professional career in the electronics field in 1988. After getting his degree in electronics he started with Zymark in Germany in 1996. From 1999 to 2008 he was 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. Now he is working as Business Development Manager. He is responsible for the business areas Europe, Middle East and Asia-Pacific. He is 53 years old and lives in Germany and has 2 sons.

Abstract

Automation for Dissolution Data Integrity

Still until today the majority of dissolution testing is still handled by manual processes, which puts the integrity of the data at risk.

Data is prone to errors caused by inaccurate transcription and standard operating procedures that cannot be precisely controlled using manual methods.

When the integrity of the data is compromised, the safety and quality of the final product is compromised, putting consumer health at risk and the viability of pharmaceutical companies at risk from lawsuits and damage to their brands.

Data integrity refers to the accuracy, completeness and consistency of GxP-data over its entire lifecycle. The steps that need to be overseen include the initial generation and recording, the processing (incl. analysis, transformation or migration), the outcome/use, the retention, retrieval, archive and finally the destruction. Data integrity means that all the steps defined above are well managed, controlled and documented and therefore the records of the activities follow the ALCOA principles described in the guidelines. The ALCOA and ALCOA+ principles have been in place for several years in the industry and are widely known and implemented. Achieving data integrity compliance, for paper, electronic and hybrid systems, requires translation of these principles into practical controls in order to assure GxP-impacting business decisions can be verified and inspected throughout the data lifecycle

The aspect of paper based systems vs electronic recording will be discussed and a practical example on how to introduce and implement a software solution is shown in this presentation.

Session Partner:

sotax

Dr 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

Hydrodynamics in Dissolution Apparatus (Role of Designing of Dissolution Vessel)

Consideration of hydrodynamics in dissolution testing apparatuses is crucial for informed apparatus selection and dissolution test set-up. Hydrodynamics are affected by the apparatus used and selected agitation rate. However the dissolution medium itself will also have an impact on hydrodynamics, through medium viscosity in particular. The impact of hydrodynamics in the dissolution test on dissolution/release rates will depend on the drug release mechanism and dosage form behaviour. The velocity relevant to the dissolving particle will be influenced by particle motion and sedimentation. This presentation will give an overview of hydrodynamics in the commonly used dissolution test apparatuses, and will consider the impact of hydrodynamics and viscous effects on particle motion with a focus on the flow-through apparatus.

Dr Satish Perivilli

Senior Scientist II, Dosage form performance laboratory USP, USA

Biosketch

Satish Perivilli, Ph.D., is currently a Senior Scientist II in the Dosage Form Performance Laboratory of the United States Pharmacopeial Convention (USP) at Rockville, MD, USA. He holds a Doctorate and Masters in Mechanical Engineering from Tennessee Technological University, USA. He joined USP in 2010 and has been involved in various research projects aimed at characterizing the hydrodynamics in various dissolution apparatuses since then. He mainly employs numerical simulation tools (i.e., Computational Fluid Dynamics) to build models that predict the hydrodynamics as a function of the design and operation of the apparatuses. He has also worked with collaborators in additionally using Particle Image Velocimetry for similar research objectives.

Session Partner:

Abstract

PIV Measurements of USP Apparatus 1 Hydrodynamics -a Close-up Story

The hydrodynamics that a dosage form experiences in a dissolution apparatus is defined by the design and operation of the apparatus. Understanding the hydrodynamics in a dissolution apparatus can therefore lead to important insights with regards to spatial and temporal variations in fluid flow within the vessel containing the dissolution medium. The spatial variation in hydrodynamics in Dissolution Apparatus 1 was investigated using Particle Image Velocimetry (PIV)*. The influence of impeller rotation speed (rpm) on the hydrodynamics in Apparatus 1 was investigated by comparing velocity magnitude data over a central vertical cross-section and different horizontal cross-sections along the vessel height. At all speeds, high velocity magnitudes were obtained near the basket surfaces generally and near the basket clips while lower velocity regions (whose expanse changed with increasing rpm) were obtained towards the vessel bottom. A stream of jet near the top of the basket was found to divide the fluid flow into two recirculation patterns: one with fluid flowing downwards towards the vessel wall and entering mainly as axial flow into the basket bottom and another in which fluid moves upward along the vessel wall to recirculate downward to the origin of the jet. The influence of increasing rpm was mainly to increase the velocity magnitudes everywhere (almost linearly) except in certain areas such as the vessel bottom where the magnitudes stayed low independent of the rpm. The study provided useful insights into the hydrodynamics of Apparatus 1 which can be used as an aid in understanding changes in dissolution behavior when all other factors affecting dissolution are kept constant.

* Results from this study were recently published online in the International Journal Of Pharmaceutics: X as " Experimental determination of the velocity distribution in USP Apparatus 1 (basket apparatus) using Particle Image Velocimetry (PIV)" by Chadakarn Sirasitthichoke, Satish Perivilli, Mark R Liddell and Piero M. Armenante (https://doi.org/10.1016/j.ijpx.2021.100078, under Creative Commons License CC BY 4.0). This abstract compiles information and paraphrases text from the original paper. The journal does not endorse the presenter or the abstract.

Dr Mark McAllister

Senior Scientific Director, Pfizer, USA

Biosketch

Dr Mark McAllister is a Senior Scientific Director in the Drug Product Design group at Pfizer (Sandwich) with responsibility for mid-to-late stage development projects. He is a Pharmacy graduate from Queen's University Belfast and has a pharmaceutics PhD from Aston University. Mark has over 25 years industrial development experience and has specialised in oral delivery systems and biopharmaceutics. He is the former chair of the Academy of Pharmaceutical Sciences and is currently a visiting senior lecturer at King's College London. Mark co-led the IMI 'OrBiTo' project, an academic/industrial collaboration, developing the next generation of models to predict oral absorption.

Abstract

Advances in Dynamic Dissolution

Abstract: Prediction of oral drug product performance using in vitro tools is a key enabler for efficient drug development. Compendial methodologies have a limited capacity to accurately capture sources of variability attributable to gastrointestinal physiology and dynamic lumenal environment. This presentation will discuss the use of simple and complex gastrointestinal simulators to characterise formulation performance and will share details of a case-study which used the artificial stomach-duodenal model and the TIM-1 system to profile formulation performance under simulated clinical conditions.

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

Biosketch

Sandeep Kulkarni, Co-Owner & Director – 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 28 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, along with his partner Mr. Prithviraj Jadhav, 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 topmost pharma companies in India. ImagesProVision 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

Influence of Particle Characteristics 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.

Dr. Hans-Joachim Muhr
Head of Strategic Product Group UV/VIS
Mettler-Toledo GmbH, Analytical, Switzerland

Biosketch

Ph.D. in Chemistry, Exec. MBA, 16 years experience in project innovation management, global sales & marketing for analytical instruments (Titration/UV/Vis/Thermal Values), 8 years executive management responsibility in analytical instrument businesses (UV/Vis, Thermal Values).

Abstract

Automated, Pharmacopeia-compliant UV/Vis spectrometer calibration for dissolution testing

Thanks to its low complexity and specificity UV/Vis spectrometry represents a powerful, cost-efficient analytical technique. It makes it suitable for integration into automated dissolution systems for time-to-result-optimized quantitative analysis. Regulation requirements defined by the US or Eur. Pharmacopeias demand for a fully qualified dissolution system, encompassing the UV/Vis spectrometer.

Keeping on par with the latest changes in the optical chapters of both Pharmacopeias, METTLER TOLEDO offers a data-integrity compliant qualification solution for the UV7 Excellence spectrometer integrated in automated SOTAX dissolution systems. It allows automated qualification of 10 optical parameters with NIST-traceable certified reference materials within 30 min. The fit-for-dissolution purpose assessment of the UV7 spectrometer according to Pharmacopeia guidelines is achieved in a very efficient way - if desired prior to each dissolution test run.

This contribution provides an overview of the latest UV/Vis spectroscopy-relevant requirements in both USP and Ph. Eur., taking a closer look at their impact and presenting appropriate automated METTLER TOLEDO solutions. The beneficial impact of automation on workflow efficiency, security and data-integrity in optical performance verification of UV/Vis spectrometers is assessed against manual execution and its relevance towards automated dissolution testing outlined.

Session Partner:

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[Disso Research Presentations India]

Ms. Anjali Mishra

Amity Institute of Pharmacy, Noida, Uttar Pradesh, India

Co-authors: Dr. Giriraj T. Kulkarni, Mr. Navdeep Jaiswal, Dr. Saurabh Gupta, Dr. Bhupesh Sharma, Dr. Rajendra Awasthi

In vitro Release Studies of Timolol Maleate from Ocular Inserts developed using Plantago ovata mucilage and HPMC

ABSTRACT

Background: For the effective treatment of chronic ocular diseases, controlled release ocular inserts are most popular formulations that enhance precorneal residence time, corneal penetration and reduce the drug loss due to nasolacrimal drainage [1]. Natural polymers are gaining importance due to their lower cost and abundant availability, but very few reports of their use in ocular delivery systems can be found.

Objectives: The objective was to develop sustained release ocular inserts of timolol maleate using combination of mucilage from Plantago ovata and HPMC and to study the in vitro release profile as well as mechanism of drug release to find out the suitability for ocular delivery.

Methodology: The mucilage was isolated from epidermal layer of P. ovata seeds following a reported method [2]. The pH of 1% w/v solution of mucilage was measured. The ocular inserts were prepared by solvent casting technique using different combinations of P. ovata mucilage and HPMC by a reported method [3]. The dried films were cut into circular discs (ocular inserts) of diameter 0.8 cm and heat-sealed in polyethylene bags. The ocular inserts were evaluated for surface pH using a digital pH meter, thickness, weight uniformity, folding endurance, drug content and in vitro release profile [3].

To assess in vitro drug release from ocular inserts, an in-house method was developed. The insert from each batch was placed in a 15 ml vial containing 10 ml of phosphate buffer saline solution (pH 7.4) and placed in an oscillating water bath at 32 ± 0.5°C with 25 oscillations per minute. One ml of medium from each vial was withdrawn at every hour till the 9 h. Equal volume of fresh pre-warmed buffer was added immediately after each sampling. The samples were filtered through 0.45 µm membrane and analyzed at 294 nm spectrophotometrically. To determine the drug release kinetics, the drug release data was fitted according to zero-order equation. Further, to determine the release mechanism, the dissolution data was plotted according to Korsmeyer-Peppas' equations.

Results: The pH of isolated mucilage was found to be 6.8, indicating its non-irritant nature. The developed ocular inserts had good physical properties, weight and thickness uniformity and folding endurance values between 55-60. The surface pH of inserts was near to 7, indicating non-irritant nature. The drug content was found to be nearly 100%. The developed formulations showed in vitro release between 92.77 and 97.31% after 9 h of dissolution study. Based on the release profiles, Batch N7 (1:1 ration of polymers) was considered as optimized batch. The kinetic treatment of diffusion data of selected batch showed that the formulation followed zero order kinetics. Korsemeyer-Peppas' plots were straight lines indicating diffusion controlled release.

Conclusion: From the physicochemical properties and in vitro release, it can be concluded that the ocular inserts follow diffusion controlled zero order release and hence can be used for controlled delivery of timolol maleate. This may overcome the problem of nasolacrimal drainage and enhance the corneal residence time of the drug. Natural polymers, being cheaper alternatives to synthetic ones, have the commercial viability also.

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Inhalable Lipid Nanovesicles Encapsulating Voriconazole with Modulated Drug Release and Improved Lung Pharmacokinetics

INTRODUCTION:
Pulmonary delivery of antifungals has been gaining enormous interest in the management of fungal lung infections as it allows higher drug concentrations to be achieved at the infection site with lower systemic exposures. In this context, the current study was embarked on systematic development and characterization of lipid nanovesicles (LNVs) of an antifungal triazole viz., voriconazole (VRC) to improve the release profile and prolong drug retention in lungs.

METHODS:
LNVs were prepared by thin film hydration method employing dipalmitoylphosphatidylcholine (DPPC), hydrogenated phosphophatidylcholine (HSPC) and cholesterol[1]. Factor screening studies was performed using fractional factorial design, followed by optimization of the NLs by Box-Behnken design. The LNVs were optimized taking particle size, entrapment efficiency and drug release studies in PBS 7.4 as the pivotal CQAs. In vitro drug release studies of VRC and LNVs were conducted using dialysis sac method. LNVs were placed in the dialysis membrane (12 kDa), tethered at both the ends and suspended in 20 mL of the dissolution medium, i.e., phosphate buffer saline (PBS 7.4) containing 0.1% Tween 80, in order to maintain the sink conditions at 37 ± 0.5 °C at 100 rpm. Lung and plasma pharmacokinetic studies were carried out in Balb/c mice by nebulization of 20 minutes using a lab-scale nose-only inhalation chamber [2].

RESULTS:
The optimized batch have a particle size in range of 130-160 nm, and entrapment efficiency of 68-72%. LNVs were nebulized employing in-house nose only inhalation chamber for the generation of LNVs-embedded into microdroplets. The generated microdroplets have a mass median aerodynamic diameter and volume mean diameter of less than 4 μm, thereby corroborating the potential of the developed nanosystem to target the lungs effectively. Drug release studies showed negative influence of cholesterol, and positive influence of both the lipids in controlling the release rate of VRC. More than 95% of VRC was released in 6 h while developed LNVs sustained the drug release, when observed for 48 h (57.24 ± 2.61%) with an initial burst release for 2 h (36.52 ± 2.95 %). Drug release showed best fit into the Korsmeyer-Peppas model (R=0.932) with the value of diffusional release exponent, being less than 0.45, indicating drug release to be primarily governed by Fickian mechanism. Pharmacokinetic studies revealed marked improvement in the lung retention profiles vis-a-vis marketed VRC formulation upon nebulization.

CONCLUSION:
Overall, the study describes the potential of LNVs for sustaining the drug release of VRC and improving its retention profile in lungs.

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Discriminating Dissolution Rates of Anti Tubercular Drug Microparticles in Biorelevant Lung Media using USP I, USP II & USP IV Apparatus

Background & Rationale: Tuberculosis, mainly a lung disease, fundamentally necessitates multidrug therapy. Particulate DDS provide improved targeting potential with the possibility of improved efficacy and dose reduction. However, there exists a quest to discriminate the release performance of drug-loaded particulate carriers in different biorelevant media, through an appropriate dissolution method. Currently, there is no official dissolution testing method for nano and micro systems. Flow-through cell dissolution apparatus (USP Type IV) has used for release testing of such particulate carriers [1,2]. We have evaluated and compared the release of our anti-tubercular drug polymeric microparticles in two biorelevant lung fluids using three dissolution apparatuses, Float-A-Lyzer® in USP IV (SOTAX) dissolution apparatus, and Dialysis membrane sac method in USP type I (basket) and USP type II (paddle) apparatus.

Methods: The polymeric microparticles of first-line anti-TB drugs Rifampicin, Isoniazid, Ethambutol and Pyrazinamide were prepared separately by simple one-step precipitation method. The particles were characterized for physicochemical properties and evaluated for in vitro release in two different biorelevant lung media namely Simulated Lung Fluid (SLF) pH 7.4 and Artificial Lysosomal Fluid (ALF) pH 4.5, over 24h. The release was conducted using three different methods 1. Flow-through cell USP IV dissolution apparatus (CE7 SOTAX, AG) in a closed-loop system, with a Float-A-Lyzer® (MW cut-off 17-20kD) at three different flow rates (8mL/min, 16mL/min and 24mL/min), 2. USP Type I Basket apparatus (Veego instruments, India) at 100rpm, and 3. USP Type II paddle apparatus (Veego instruments) at 50rpm, with a Dialysis Sac membrane (HiMedia MW Cut off 17-20kD). The Rifampicin, Isoniazid and Pyrazinamide were analyzed by UV spectrophotometric method at λmax of 475 nm, 263 nm and 269 nm respectively. Whereas, Ethambutol was analyzed by Colorimetric method using Acetylacetone Reagent at λmax 412 nm.

Results & Discussion: The polymeric microparticles showed an average particle size of 2.0-3.0 µm and 12-14% drug loading, with % entrapment efficiency of >40% for all four drugs. The differential release rate was observed for all the drugs based on their solubility, physicochemical properties, and pH of the release media. The release rate for all drugs was rapid in ALF pH 4.5 compared to SLF pH 7.4. Lower release in SLF could allow particles to efficiently phagocytosed by alveolar macrophages. In contrast, rapid release in ALF pH 4.5 proposes their efficient intracellular release delivery at the site of action and hence efficacy. USP IV demonstrated slower release and better discrimination compared to USP type I & II methods in both the biorelevant media.

Conclusion: The USP IV, Flow-Through Cell Apparatus with Float-A-Lyzer®, is an optimum and discriminatory method for in vitro release studies from nano and micro systems compared to conventional USP type I and II apparatus with dialysis sac method.

References:

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[2] Jie Shen, Diane J. Burgess, Drug delivery & translational research Vol-3 (5), (2013) 409-415.

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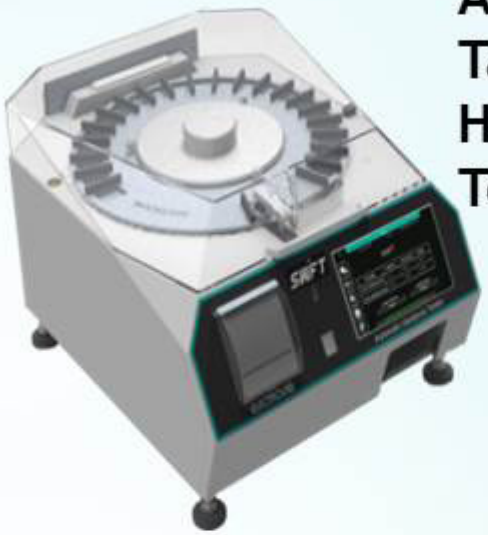

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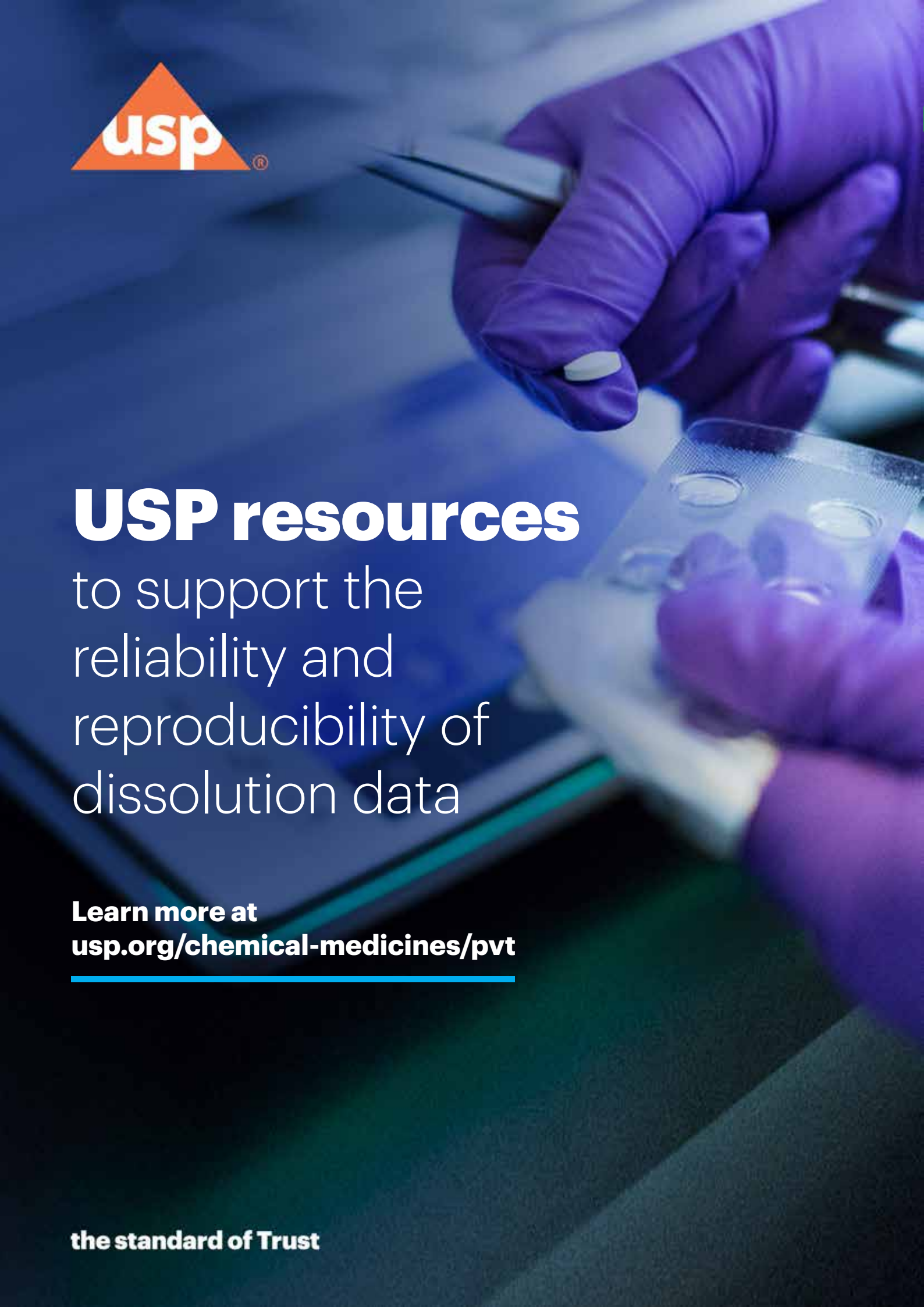

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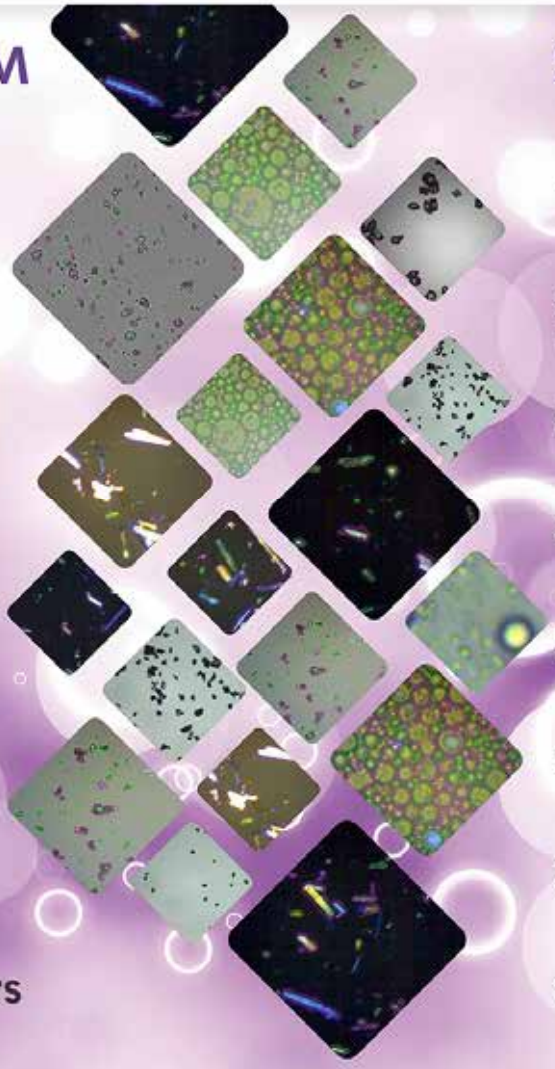

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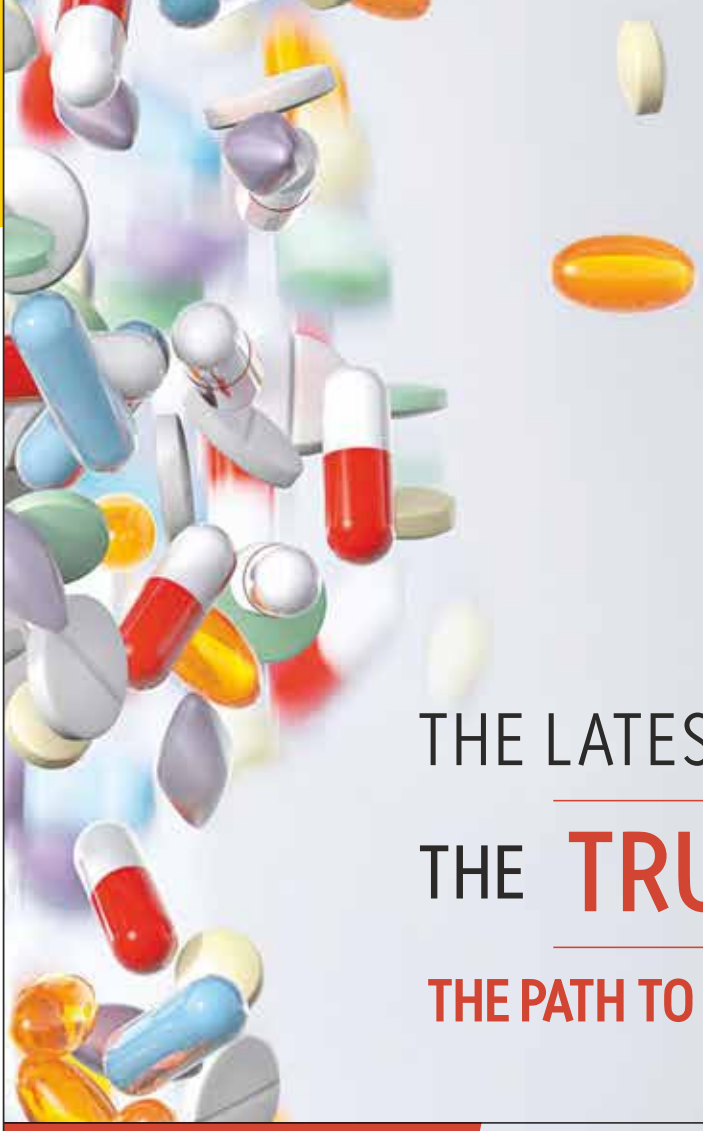

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Marlin – Online Tablet/capsule Inspection
Snipe – Induction Seal Inspection System

Applying the latest computer vision technology and machine learning techniques, Spookfish offers cutting edge solutions for the Pharmaceutical Industry. Designed to provide improved visual inspection of tablets and capsules, and to ensure seal integrity, these online inspection systems provide a competitive edge with their speed and accuracy.

MARLIN
ONLINE TABLET/CAPSULE INSPECTION

Marlin is a family of visual inspection systems for orals, including tablets, hard-gel capsules and soft-gel capsules (including transparent capsules). Marlin's innovative design makes the inspection stations retro-fittable onto existing machines to enable seamless inspection of products without any reduction in production throughput.

Marlin X: Visual inspection of orals on bulk counting lines

Marlin Blue: Visual inspection of orals on blister packaging lines

Marlin Flip: Visual inspection of orals on conveyor belts

SNiPE
INDUCTION SEAL INSPECTION SYSTEM

Snipe is an online induction seal inspection system which retrofits onto existing bottle packaging lines.

Poor induction seal quality remains a serious concern in the pharmaceutical industry. Sub standard seals can lead to contamination and reduced potency when exposed to harsh environments.

Using the latest high resolution thermal technology, Snipe accurately detects any areas of potential leakage on a seal, verifying the integrity of the bottle and rejecting any defective products via a pneumatic rejection mechanism.

Configurable for bottle variants of any height, the system has also been designed with a high level of versatility.

Get in touch for fast, accurate and safe production

Mob: +91 9108 993 345 | Email: innovate@spookfish.co.uk

VISION INTO PERSPECTIVE

www.spookfish.vision

Spookfish Innovations Pvt Ltd, founded by a team of scientists, is on a quest to offer a fresh approach to solving problems using computer vision. The company builds technology by applying the latest computer vision and machine learning techniques to help manufacturing companies with high speed automated quality inspection of products. Spookfish's systems have inspected and verified millions of day to day products used by consumers on a regular basis such as tablets/capsules, food products and metals such as currency coins and paper to name just a few.

More recently, Spookfish is contributing to the containment of Covid-19 with HARLEQUIN, a quick, effective and non-contact fever detection system for mass-screening in multiple settings.

SNIPE, one of the latest innovations from Spookfish, provides an effortless and efficient way to ensure quality of a packaged bottle seal. Poor quality of induction seals leads to exposure of the products such as tablets, to harsh environments and results in severe contamination and reduced potency.

SNIPE is an online inspection system and retrofits onto packaging lines to verify the integrity of bottle seals following the sealing process using a non-destructive approach. SNIPE stands out due to both the high precision of leakage detection and cost-effectiveness of technology, coupled with simple, intuitive software.

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PHOTO GALLERY

Delegate Registering for
Disso India - Hyderabad 2018
at Hotel Avassa

Lighting of the lamp
during the Inauguration
Disso India - Hyderabad 2018

Delegates interacting
with the partners

Attentive delegates
during
Disso India - Hyderabad 2018

The Organising Committee
of Disso India - Hyderabad 2018

Dr. Sandip Tiwari
during his talk
at Disso India - Hyderabad 2018

Vijay Kshirsagar, Dr. B. M. Rao,
Dr. Uday Bhaskar, Dr. Raghuram Rao,
Prof. Padma Devarajan,
Dr. Ramaswamy releasing
the Scientific Abstract Book
of Disso India - Hyderabad 2018

Dr. Ramaswamy, Dr. Alka Mukne,
Vijay Kshirsagar, Dr. Vinod Shah,
Prof. Padma Devarajan,
releasingthe Pharma Times
Dissolution Special issue
joint project of IPA & SPDS

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

CAPSULES / ENGINEERING / FILMS & FOILS / INSPECTION

ACG

Make it better.