Society for Pharmaceutical Dissolution Science

DISSO INDIA - AHMEDABAD 2016

Fourth International Annual Symposium

Date : 26th & 27th July, 2016

Venue : Courtyard by Marriott, Ahmedabad
Ramdev Nagar Cross Road, Satellite Road,
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Table of Contents

Message from President - SPDS

Mr. Vijay Kshirsagar

President - Society for Pharmaceutical Dissolution Science

Mr. Vijay Kshirsagar

Director & CEO, TRAC Consulting, Mumbai

Message from Scientific Committee Chairman

Prof. Padma V. Devarajan

Chairperson, Scientific Committee SPDS

Dear Delegates,

A warm welcome to Disso India Ahmedabad 2016, the International Symposium on Dissolution Science. The Society for Pharmaceutical Dissolution Science a young novice in the crowded world of scientific societies has carved a niche by organizing International symposia in this niche and critical area of formulation development.

The science and technology of dissolution testing is growing logarithmically and while on one hand newer delivery systems pose challenges in the design of apposite dissolution methods, existing methods are being actively investigated to arrive at useful in vitro in vivo correlations. Dissolution testing as a mandatory and key requirement for ANDAs has accelerated developments in optimizing test methods, standardizing dissolution media and also introduced stringent conditions to compare formulations.

In keeping with the need the symposium focuses on developing dissolution testing methodology for conventional and novel delivery systems, including nano formulations. Regulatory requirements and innovative developments in methodologies and equipment will be discussed. The role of excipients that are key modifiers of dissolution of drugs from formulations will also be dealt with. What is presented would be a very comprehensive array of topics addressing varied aspects of dissolution science and technology.

To address the same SPDS has brought together a gamut of experts from across the globe with vast experience on one common platform to present the latest developments in the growing science.

We hope you have a great learning experience with high take home value!!!

Prof. Padma V. Devarajan
Chairperson, Scientific Committee
SPDS

Message from Chairman - DISSO INDIA 2016

Dr. H. G. Koshia

Commissioner, Food and Drug Control Administration, Gujarat, India.

Dr. H.G.KOSHIA
Commissioner

Food & Drugs Control Admn.
Block No.8, 1st floor
Dr.Jivraj Mehta Bhavan
Gandhinagar-382 010
Gujarat State
Phone No.079-23253417

Date:- 12/07/2016

Message from Chairman, Organizing Committee-Disso India 2016

It is my pleasure to welcome all speakers, invitees and delegates across the country on the land of Vibrant Gujarat in the first ever event "Disso India 2016" organized by SPDS.

Gujarat is a major contributors of pharmaceutical products for the domestic & export market. As Gujarat has major share in formulation segments, this event is very important and useful for Gujarat's Pharmaceutical industry.

I hope that all delegates will actively participate in this seminar and gain maximum mileage from the eminent speakers for the benefit of pharmaceutical industry and to promote public health.

I wish Disso India 2016 all success and also wish SPDS to grow fast and contribute on this important topic of Dissolution Testing across the Globe.

With warm regards,

(Dr. H. G. Koshia)
Chairman, Organizing Committee- Disso India Ahmedabad 2016
Commissioner, Food & Drug Control Administration, Gujarat, India

Message from Organizing Secretary - Disso India 2016

R. J. Shah
RSAssociates Consultants, Ahmedabad

Message from The Organizing Secretary- Disso India 2016

NAMASTE AHMEDABAD

It is a matter of great honor that Ahmedabad has been chosen to host "Disso India 2016", The International Annual Symposium on Dissolution Science, a highly accomplished scientific and technical event of global standards which will bring together galaxy of experts in Dissolution science from Asia, Europe and USA.

I extend my warm welcome to the Chairman of the Congress, Dr H. G. Koshia – Food & Drugs Commissioner - Gujarat State, his senior colleagues who are present in today's event, all the Delegates, Resource Persons, Invitees, SPDS Executive Counsel and Members of the Organizing committee, Disso India 2016.

We are thankful to 'Society for Pharmaceutical Dissolution Science' for reposing faith in us for hosting this prestigious event in the State of Gujarat

It will be our endeavor, to not only keep the highest technical standards but also, to provide a warm and conducive environment so that it will be a memorable and enjoyable feast for each participant of "Disso India-Ahmedabad 2016".

R. J. Shah
RSAssociates Consultants, Ahmedabad

Message from General Secretary - SPDS

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

Message from The General Secretary, SPDS

I extend my warm welcome to one and all who have accepted our invitation and marked your presence here today or registered at Disso India Ahmedabad 2016 as delegates, partners of the symposium, organizers, scientific committee members, regulators and press . For us at SPDS, Disso India Ahmedabad 2016 is crossing another mile stone towards it journey to accomplish the Vision and Mission.

I wish to express my profound thanks and gratitude to our Founder President of SPDS, Mr.Vijay Khsirsagar and the Chairman of Disso India 2016, **Dr. H. G . Koshia**, **Commissioner, Food & Drug Control Administration, Gujarat, India and Organising Secretary, Mr. R. J Shah,** *RSA consultancy, Ahmedabad* who have guided us always and the Scientific Committee Chairman Prof. Padma V. Devarajan , Professor in Pharmacy, Department of Pharmaceutical Sciences and Technology, Institute of Chemical Technology, and all the other committee members who have carved a high quality , industry oriented two days scientific sessions where in a plethora of eminent global and national speakers of high repute are delivering key note address and lectures. I am optimistic that it is going to be a great value addition to the Pharma Scientists, Analysts , Pharmacy faculties, students, Ph.D Scholors and all others participating in this special event.

I must mention here Dr. Vinod P Shah from USA, Dr. Umesh Banakar, USA, and Sotax Management Team ,Switzerland who have extended unconditional support to me and SPDS right from the start till what it is today.

At all times, our endeavour in SPDS is to update the Science and Technological Advancement in Pharmaceutical Dissolution Sciences to our Industry Scientists, Pharmacy faculties & Students , and Regulatory professionals through seminars, workshops, symposium, one to one presentations and demonstrations.

I look forward a whole hearted supports from our Chief Guest of today's function, all Resource Persons, Invitees, Delegates, Conference Partners, the Organizing Committee Members of this event, Office Bearers and Executive Council Members of SPDS, Pharma Faculties and students from across the globe, Regulatory Professionals, Media & Press Reporters, Phamraceuticals Company's , Instruments and Pharma Testing Equipments Manufacturers and Marketers, CRO's CMO's and all others.

Let us all join hands together to make SPDS a great professional organization whose ultimate aim is to improve the quality of the drug produced across the Globe.

Best Regards

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

Society for Pharmaceutical Dissolution Science

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

SPDS is the only professional body dedicated to Dissolution and its application worldwide.

Vision : To be one of the most prominent professional body focusing on Dissolution Science among the Pharmaceutical Industry and Academia

Mission : To dissipate science & advancement taking place in the field of dissolution related to clinical application and methods.

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Dr. Abhijit V Gothoskar

Technical Advisor, Anshul Life Sciences, Mumbai.

Dr Abhijit V Gothoskar has completed his graduation, post-graduation and doctorate in Pharmaceutical Sciences from Pune University, India. He is the gold medalist at graduate and post graduate levels. His research areas include Oral Controlled Drug Delivery Systems and applications of polymers in the field of pharmaceuticals. He is working with Anshul Life Sciences as Technical Advisor since 2009 helping customers overcome technical problems. He has 21 research articles and two patent applications to his credit. He is also registered patent agent and ASQ certified Six Sigma Black Belt.

Role of excipients in dissolution

Dissolution testing has evolved from a mere quality control test to a predictive and discriminatory test. It has become a powerful tool for a formulator to match the expectations of all stakeholders. Any dosage form is composed of drug and excipients. Contrary to the common notion, excipients are not 'inactive' and do play a very important role in dissolution behavior of the dosage form and hence affect the bioavailability. This presentation will focus on the role of excipients in modulating dissolution.

Dr. HDR Vincent Jannin

Research Director – Pharmaceuticals, Gattefossé

Dr. HDR Vincent Jannin is Research Director - Pharmaceuticals at Gattefossé where he is responsible for the development and characterization of new lipid-based excipients, particularly in the field of solubility and bioavailability enhancement for poorly water-soluble drugs. Previously he held the position of Pharmaceutical Formulation Laboratory Manager (1999-2001) and Pharmaceutical Project Director (2002-2014) at Gattefossé. He is also a lecturer at CPE Lyon (Lyon University) since 2003 where he teaches formulation sciences. In addition, he serves as Vice-President of the International Society for Drug Delivery Sciences and Technology (APGI) since 2010.Vincent earned his Pharm. D. and Ph. D. from the University of Bourgogne (France). His doctoral work focused on pharmaceutical technologies such as tabletting and hot-melt coating with lipid-based excipients. He received his HDR (Habilitation to Supervise Research and doctoral candidates) from the University of Lyon for his work centering on the characterization of physical-chemical properties of lipid-based systems, notably of acylglycerols and polyoxylglycerides and their behavior in gastro-intestinal fluids. He has published 39 publications in peer-reviewed journals (h-index=18), 4 patent families, 3 book chapters, 54 meeting abstracts, and given more than 40 lectures as invited speaker on Lipid-based Systems.

Combined in vitro dispersion / digestion technique to assay the solubility enhancement of poorly soluble drugs: new case studies with Gelucire 48/16

Lipid-based formulations (LBFs) can be effective drug delivery systems for poorly water-soluble chemical entities, provided they are designed with careful selection of the excipients, based on their role in the delivery system and in relation to the API properties. Among the key considerations in the selection step must be the series of mechanisms underlining oral bioavailability enhancement. The primary factor leading to increased bioavailability by LBFs is the administration of the drug in a pre-dissolved state thus avoiding the solid-to-liquid phase transition process. Hence the compendial dissolution test is not as relevant for this type of formulation as for other types. However, the interactions between the LBF and the endogenous lipids such as bile salts, phospholipids lipids will help transfer the drug in solution within colloidal structures. The fate of a drug formulated in a LBF is hence dependent on the ability of the formulation components to keep the drug in solution during the initial dispersion and/or digestion processes. A combined in vitro test of dispersion and digestion is now available to help predict the in vivo performance of LBFs. The protocol to be used is presented and exemplified by case studies with model drugs.

Dr. H. G. Koshia

Commissioner, Food and Drug Control Administration, Gujarat, India.

Dr. H G Koshia is working as Commissioner at Food and Drug Control Administration (FDCA) Gujarat since January 2009. He was selected as Joint Commissioner in 2001 through competitive selection process conducted by Gujarat Public Service Commission (GPSC). He joined FDCA, Gujarat as Drugs Inspector in 1986. He had worked as Vice President of Global Regulatory Affairs in Amneal Pharmaceuticals Inc, New York, USA. He is actively representing nine national & state level committees like Drugs Consultative Committee, Govt. Of India, New Delhi, Pharmaceutical Advisory Forum, Dept. of Pharmaceuticals, Govt. of India, New Delhi, etc. and also played a vital role in the implementation of e-governance in the State of Gujarat. Dr. Koshia pursued his graduation &post-graduation in Pharmacy at L. M. College of Pharmacy, Ahmedabad. He also holds Diploma in Business Management from Rajendra Prasad Institute of Communication &Management, Mumbai.

Dissolution Testing- An Indian Regulators perspective

Dissolution testing, in terms of compliance under Indian Pharmacopeia and Drugs and Cosmetics Act as per regulatory status is considered a critical parameter for establishing the acceptability of conventional and prolonged and modified release oral dosage forms. The regulatory umbrella however is focused more on the objective of verifying the compliance on the basis of samples drawn from market as well us under mandatory pre-purchase release. The other perspective of compliance relates to the adequacy of the equipments and facilities for dissolution testing at the Quality control units of the licensed manufacturers, public testing laboratories as well as R&D institutions. The regulatory impact or coverage in terms of the control and compliance at various stages of the product development for generic drugs, excluding new drugs is much limited in comparison to the product licensing procedures of developed countries. As much as there have been advances in the formulation developments, especially the prolonged release formulations technologies- the challenges on the typical validation parameters of analytical techniques and methods such as Robustness ,Instrument precision etc for Dissolution testing is a major challenge to which the regulators are looking for continuous update on training and information sharing. The dissolution or release being a critical parameter of the efficacy of the solid dosage forms , will progressively find applicability for compliance in many other dosage forms in times to come i.e. various types of trans dermal patches etc. Regulatory systems will thus be under continuous challenges to build infrastructure for testing and analysis for such parameters which will have to be comparable to the high tech infrastructure of pharma manufacturers and research institutions.

Prof. Mangal S. Nagarsenkar

Head of the Department Bombay College of Pharmacy, Mumbai

Dr. (Mrs.) Mangal S. Nagarsenker completed her B.Pharm from Institute of Chemical Technology, Mumbai University with University Gold Medal in 1978. She received her Ph.D in Pharmaceutical Sciences from Mumbai University in 1989. She has been a recipient of awards including Prof. (Mrs.) M. R. Baichwal Visiting fellow in Pharmaceutical Sciences and Technology in UICT, AmrutMody Research Fund, Distinguished Researcher National Award (2012), Association of Pharmaceutical Teachers of India (APTI) Dr. (Mrs.) Manjushree Pal Best Researcher National Award (2013). She is a member of the editorial advisory board of IJPS, editorial board of Drug Delivery Letters, and reviewer for national and international journals. She has over 100 publications, 3 book chapters and 2 books and more than 100 research presentations. She has three Indian patents and three trademarks. She is a coveted speaker at conferences, both national and international. She has 34 years of research experience and mentored more than 40 M.Pharm and 30 Ph.D students. Her key areas of research interest entail design and formulation of nanosystems (GeluPearl and LeciPlex) cyclodextrin based drug delivery, controlled release systems for different routes and gene delivery. She has research collaborations with university of Jena, Germany, University of Helsinki ,Finland,and reputed Indian institutes. She has successfully completed many projects for pharmaceutical Industry. She is currently Professor and Head, Dept. of Pharmaceutics, Bombay College of Pharmacy, Mumbai and is a Member of several professional scientific organisations.

Challenges in conducting drug release studies from nanomedicines

With the advent of nano technology and its application to drug delivery, various nanosystems loaded with actives have been designed to improve the therapeutic efficacy. One of the significant property which influences efficay of nanosystems is the ability of these systems to release the drug and present it in a form that aids in its solubilization and permeation. *In vitro* drug release testing of nanosystems is of prime importance as a characterization test to understand the effect of nanosization on drug release, to investigate the possible release mechanism of the system *in vitro* and to ensure product performance and quality. The release profile information will be useful to tailor the formulation for optimum spatial placement and temporal delivery. Unlike for conventional dosage forms, pharmacopoea does not recommend method or apparatus to perform release profiling of nano systems. Different methods and apparatus suited to the formulation and intended application have been employed by various researchers for release testing. This presentation will cover methods for release testing of nano systems and elaborate important considerations while designing release testing of these systems.

Dr. Mukesh C. Gohel
Professor and Postgraduate Director - Anand Pharmacy College, Anand, Gujarat

Dr. Mukesh C. Gohel Professor and Postgraduate Director at Anand Pharmacy College, Anand, Gujarat since 2014 is B. Pharm., M. Pharm. (Pharmaceutics) and Ph. D. (Pharmacy). He served as a Principal and Professor at L. M. College of Pharmacy (LMCP), Ahmedabad, Gujarat from 1997 to 2011. From 2011 to 2013, he worked as a professor at Ahmedabad University, Ahmedabad. He has got a total teaching and research experience of 44 years. Dr. Mukesh Gohel has 178 publications in reputed journals. He has guided 178 M. Pharm. students and 21 Ph. D. students. He has to his credit 11 granted Indian patents. He has delivered 65 invited guest lectures in the last five years (2010 onwards) in various scientific meetings/workshops/conferences. He has provided training in the area of Design of Experiments (DoE) and QbD in many leading pharmaceutical companies of India. He is a reviewer in many national and international journals. He is recipient of The IPA HCG Scitech Innovation Award 2016 in solid dosage form development. He has received best research paper award from IDMA(2016) and IPA(2015) for research publication in Indian Drugs and Indian Journal of Pharmaceutical Sciences respectively. He wrote a book chapter on "Mathematical treatment of dissolution data for extraction of vital product information(2015)

Study on combined influence of alcohol and food on the in vitro performance of modified release lornoxicam tablet

Dissolution is the most extensively used performance test by the QC/QA team and R&D personnel. Continuous efforts are made by the regulators to make the test more clinically relevant. Burst drug release has been shown by some of the sustained release formulations, when consumed with alcoholic beverages. It may be either due to collapse of release retardant or due to higher drug solubility in alcohol. Lornoxicam modified release tablets were formulated using different release retardants. It is well known fact that the alcoholic beverages are generally consumed after meal. The current practice in dissolution science ignores this fact. Dissolution study was conducted to examine the combined effect of alcohol and food. The dissolution study was also conducted in bio-relevant dissolution media containing 0, 20 and 40% alcohol. The present practice of conducting dissolution in aqueous alcoholic media for a period of two hours have raised concerns since ethyl alcohol is very quickly absorbed from GIT. There appears to be scope of improvement in this area. Our efforts in this direction will be included in the presentation. Concomitant ethanol intake can increase solubility of lipophilic compound from immediate release medicaments containing solid dispersion or inclusion complex. It is proposed that the dissolution study in alcoholic media may be extended to active pharmaceutical ingredients belonging to the BCS class II.

Prof. Padma V. Devarajan
Professor in Pharmacy, Dept of Pharmaceutical sciences and Technology, ICT, Mumbai,india

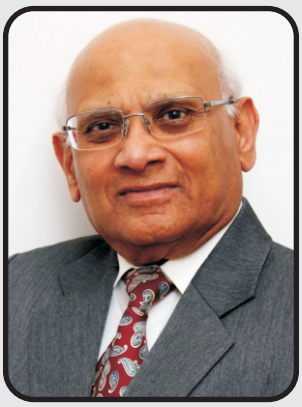
Dr. Padma V. Devarajan is Professor in Pharmacy and formerHead, Department of Pharmaceutical Sciences and Technology at the Institute of Chemical Technology, Mumbai, India. She is also coordinator of the World Bank programme TEQIP for ICT. Her research interests are Targeted delivery in cancer and infectious diseases, Bioenhancement strategies, and Mucosal DDS. She has many publications, book chapters, seven granted patents and four licensed. Her book as Editor on "Targetted Drug Delivery - Concepts and Strategies" has been recently published by Springer. She has been actively involved with the Controlled Release Society Inc.,USAin various capacities including Board Member, Member on the Board of Scientific Advisors, and Chair of the Young Scientist Mentor Protégé Committee. She is currently Co-chair of the Outstanding Paper Award Committee of the journal Drug Development and Translational Research. Prof. Devarajan is a nominated Fellow of the Maharashtra Academy of Sciences and 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 in 2013.

Dissolution Testing during Product Development

Drug **dissolution testing** a routine test recognised by regulatory agencies worldwide serves manifold purposes. On one hand while it is a regulatory compliance requirement on the other hand it is an important quality standard in house to assess batch to batch reproducibility and long term stability. Monographs that delineate dissolution testing methodology for a number of formulations are official. An important aspect of dissolution testing that makes it an important research tool is the ability of the in vitro test to predict *in vivo* drug release profiles to provide *in vitro- in vivo* correlation (IVIVC) and hence as serve as an important surrogate to in vivo studies. The challenge nevertheless is an appropriate dissolution test design which addresses all critical aspects to ensure high levels of prediction. Yet an important feature of a dissolution test is as a screening test during R&D development of different formulations and more importantly novel drug delivery systems. The present talk would comprehensively address the role of dissolution testing during product development, illustrating the same with some relevant case studies.

Dr. Vinod P Shah

Ex-US FDA, Maryland, USA



Dr. Shah is a pharmaceutical consultant. He was Scientific Secretary (2003 – 2011) of International Pharmaceutical Federation (FIP), and is now Chair of Regulatory Sciences Special Interest Group of FIP. Dr. Shah retired from US FDA (Food and Drug Administration) as a Senior Research Scientist after 30 years of service in July 2005. At FDA, he has developed several Regulatory Guidances for Pharmaceutical Industry in the area of dissolution, SUPAC, bioequivalence and biopharmaceutics. He has received several FDA Awards including Award of Merit, Scientific Achievement Award and Distinguished Career Service Award. Dr. Shah is an Honorary Member of Indian Pharmaceutical Association (2003), and a recipient of IDMA Award (India, 2009) and SPDS Excellence Award (India, 2014). Dr. Shah is author/co-author of over 300 scientific papers and is a co-editor of four books. Dr. Shah was the President of American Association of Pharmaceutical Scientist (AAPS) in 2003. He is a Fellow of AAPS and FIP. Dr. Shah is a recipient of AAPS Distinguished Service Award, Pharmaceutical Sciences World Congress (PSWC) Research Achievement Award, FIP Lifetime Achievement Award in Pharmaceutical Sciences, Honorary Doctorate from Semmelweis University, Hungary and from University of Medicine and Pharmacy Carol Davila Bucharest, Romania.

Regulatory Updates: What is new in BCS and Biowaiver ?

The mission of a regulatory authority is to assure that safe and effective drugs are marketed in the country and are available to the people. FDA ensures that the generic drug products are safe and effective, are pharmaceutically equivalent and bioequivalent (BE) to the brand-name counterparts. The regulatory requirements are dynamic in nature, and keep changing to meet new challenges. Biopharmaceutics Classification System (BCS) is a framework for classifying drug substance based on its solubility and permeability. Drug products under BCS Class 1 and 3 are eligible for biowaiver if it meets appropriate dissolution test criteria when compared with the brand name (innovator) drug product. Lower strengths of IR products are also eligible for biowaiver if they are formulation proportional; ER products are also eligible for Biowaivers if they are formulation proportional and employ same type of drug releasing mechanism. The biowaiver criteria reduce regulatory burden without sacrificing the drug product quality.

Have we reached the limits of using dissolution tests in pharmaceutical industry?

Dissolution / In vitro drug release testing over the last half a century has emerged as a highly valuable and powerful tool for assurance of drug product quality and performance. Its application has now expanded to all areas in the pharmaceutical industry, drug development as well as quality control. Its usefulness has entered in regulatory arena of bioequivalence, to assure product sameness after SUPAC related changes, to provide biowaiver and to reduce regulatory burden in drug approval process, and in maintaining the product quality and performance. Field of dissolution is dynamic in nature; it is constantly improving. This has been primarily possible because of the advancing knowledge of dissolution science and technology and also improvement in design of dissolution equipment. Research in dissolution has expanded globally for all types of pharmaceutical dosage forms. Dissolution / drug release is a powerful tool, we have not yet reached the limits of its application, it is still growing. It is hoped that academia, industry, pharmacopeia and regulatory authorities will work together globally in enhancing and harmonizing dissolution regulatory requirements.

Dr. Umesh Banakar

PhD, Professor and President, Banakar Consulting Services, Carmel, IN 46032 USA

Dr. Umesh V. Banakar is on the International Scientific Advisory Board of several pharmaceutical corporations world wide. He has successfully completed several Pharmaceutical Product Development Technology Transfer through education assignments. He has served as **testifying/non-testifyingexpert in patent litigations** in the disciplines of pharmaceutical formulations/technology, clinical investigations and dissolution testing. He has planned and executed *in vitro* and clinical development, of **several NDAs and ANDAs(IRandMR)**. He is the Founding **Chairperson of 2 International CROs**. Thus far, he has **successfully executed ~ 400 clinical investigations (Phase I, II and III including BE)** for regulatory submissions worldwide. He is the founding Board Member and Principal Scientific Adviser of **Society for Pharmaceutical Dissolution Science [SPDS]**. He has over 100 publications and 100 presentations and published numerous specialized workshop manuals, several chapters and monographs, and the book **Pharmaceutical Dissolution Testing, Drug Development Process: Increasing efficiency and coste ffectiveness** and an E book **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.

Dissolution Testingand Intellectual Property: *Millions at stake !!*

Dissolution testing, of course, is a regular quality control procedure in good manufacturing practice. Whether or not its numbers have been correlated with biological effectiveness, the standard dissolution test is a simple and, perhaps, an inexpensive indicator of the physicochemical consistency of the product. Dissolution test can be employed prospectively while developing a formulation with appropriate drug release characteristics, and retrospectively to assess whether a dosage form is releasing the drug at prescribed/predetermined rate and extent.Over the past decade, the dissolution test in drug development has matured from a simple convenient test for routine testing to assure batch-to-batch quality of the product to extremely complex application to predict bioefficacy of the product through demonstration of IVIVC. This test has now forayed into the discipline of intellectual property (IP) wherein the novel as well as innovative considerations of the invention has been secured. Often these inventions are worth 'multi-million dollars' and their ratification through (in)validity and/or (non)infringement focuses on convincing and compelling rationale based on principles of dissolution science and applications. The presentation will address the emerging *et* fascinating role of dissolution testing in intellectual property where millions are at stake !!

Challenges in Meeting Regulatory Requirements for IVIVC – *Case study approach*

Dissolution testing, is employed prospectively – while developing a formulation with appropriate drug release characteristics, and retrospectively – to assess whether a dosage form is releasing the drug at predetermined rate and extent. The assumption that the dissolution test is able to adequately represent, the bioavailability, of the drug has resulted in the emergence of the “Regulatory” guidance describing the requirements for demonstration of *in vivo – in vitro* correlations (IVIVC). The “Regulatory” guidance describing the requirements for demonstration of IVIVC are fairly elaborate and straight forward, yet are subject to interpretation. Additionally, the total potential applicability and utility of the Regulatory Guidance on IVIVC, which the industry in still grappling with, is yet to be recognized. Challenges in applying the Regulatory Guidance to its full potential often deter the scientist resulting in incomplete application, if not abandoning it completely.

This presentation will provide an insight into some, if not all, of the challenges in meeting Regulatory requirements *et* expectations for an IVIVC through a sample case study, with the intention to influence the thought process(es) of the scientists to explore and exploit the full potential of IVIVC in demonstrating quality performance of pharmaceutical products.

Mr. Samir Haddouchi

Managing Director, SPS Pharma Orleans, France

Prior to joining SPS Pharma Services in 2005, Samir spent more than 10years in the pharmaceutical industry. As a chemist, he started working onthe analytical development of agrochemical compounds at Sandoz Agroin the region of Basel (Switzerland).During the Novartis merger, he movedto Orléans (France) in 1998 to join the analytical group in the technicaldevelopment department where he became responsible for dissolution. In 2005, he resigned from Novartis to create SPS Pharma Services inClermont Ferrand which is the first and only CRO specialized in Dissolutionand Release Testing. Since then, Samir manages SPS facility and is incharge of projects management. In April 2013, SPS Pharma Servicesmoved to a new larger facility in Orleans (France) in order to ensure betterefficiency and provide a broader range of services to its clients, includingcGMP routine testing. Fields of interest and expertise: analyticaldevelopment (HPLC), in vitro dissolution and release testing (alltechniques from USP1 to USP7), in vitro-in vivo correlations (IVIVC),formulation development, laboratory automation. Samir is regularlyinvited as speaker in international conferences as well as expert forvarious organizations (scientific societies and Health Authorities).

Regulatory applications in area of drug release using flow through apparatus

New types of formulations and drug delivery technologies call for a new approach to in-vitro drug release testing. Indeed, characterizing drug release rate is of outmost importance and traditional dissolution methods such as paddle and basket are not tailored to these novel dosage forms.

Products such as medical devices, combination products, injectable suspensions, nanoparticles and other parenteral formulations can be challenging when it comes to the development of a dissolution method:

- the physiological conditions are different than the gastro-intestinal tract
- the release timeframe can range from hours to months
- the drug concentration is not always related to the therapeutic effect
- etc…

Moreover, the development of generic products may be challenging due to :

- Limited information about the RLD formulation
- Differences in sourcing the Active Ingredient
- etc…

Among the existing dissolution tools, the flow through cell technique is able to fulfill the requirements of complex formulations. Its flexibility and ability to characterize the release properties of a wide variety of formulations make it a powerful tool for pharmaceutical development as well as for QC often ensuring a better discrimination thus better safety for the patient.

This presentation will go through and discuss current and new applications related to the USP Apparatus 4.

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