SPDS
Society for Pharmaceutical Dissolution Science

e-Disso

QUARTERLY NEWSLETTER

April - June 2016

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.

Dear Readers

It is pleasure to present third issue of eDisso In this issue we have article on Data Integrity by Surekha Prabhu. It is very apt subject in the current scenario and more essentially it is coming from industrial author.

I sincerely feel the data integrity does not need any training but is an attitude. What can be better than academic environment to nurture such an attribute in future pharma professionals? Pharmacy institutes having graduate and post graduate courses need to focus on this. Industry will have to adjust themselves in this scenario to survive or otherwise perish.

As far as dissolution technology is considered automation is an important key to data integrity and we should focus on some of the aspects in the forthcoming issue.

There is an interesting article on Influence of Gut Microbota and Probiotics on Intestinal Permeability of Drugs by Hemali M. Savla, Mala D. Menon. Many times inter-individual and intra-individual variability outcome in terms of safety and efficacy of medications is scarcely understood aspect. Especially reasons behind the same. Obviously the proof of pudding would be doing appropriate human studies to verify such effects. These studies are not really very necessary and it would unethical to conduct avoidable clinical studies. Dissolution science offers an scientifically valid alternative to such expensive tool.

We have Dr. Harita Desai writng about Envisaging The Role Of A Prudent Discriminating Medium For Successful Dissolution Studies. Role of dissolution tool can be enormous and not confined to be simple QC, QA and specification parameter. The paradigms of development of a product can take different scale if the applications and importance of the dissolution is understood by appropriate persons in an organization.

Fifth certificate course on QBD – Quality by Design was conducted by Dr. Kshirsagar a stalwart in the subject. We have summary report of this important event.

This issue is an important step for eDisso. Being just third issue we are still in infancy and are crawling now but we are determined to run a long race. This can happen with support from all the concerned – academics, industry regulators as well.

We are very fortunate in releasing this issue at Disso India 2016- Ahmedabad, International Symposium on Dissolution Science on 26 th & 27 th July 2016. We have many distinguished speakers and topics to be deliberated.

There is upcoming event in Ahmedabad International Symposium on Dissolution Science on 26 th and 27 th July 2016. We have many distinguished speakers and topics to be deliberated.

Happy reading this issue. Comments are most welcome form all readers.

Best wishes
Dr. Prashant Bodhe

Surekha V. Prabhu
Designation: Gen. Q. C. manager,
Janssen Pharmaceutica

DATA INTEGRITY: A BOON OR BANE FOR THE INDIAN INDUSTRY

"In God we trust, for the rest show the data", sounds familiar doesn't it. It forms the heart of Quality assurance, but still every time there is a FDA inspection in some Asian company, we do hear of 483s being issued due to facts not being reconciled by data. In a continent, where the youth is highly qualified and by far constitute the major workforce, it seems difficult to believe that there is an issue with respect to managing data well.

Let us begin with - What is the FDA expectation about data – the acronym ALCOA says it all (Attributable, Legible, Contemporaneous, Original andAccurate). This sounds simple yet not achievable, causing recalls and financial losses for many companies.

In this article, I have tried to do a deep dive for what can be done to ensure that the data is aligned with the ALCOA principle.

1. Simplify documentation so that it is easy to follow. If the procedures are too complex and too many, they cannot be followed.

2. Keep the language simple. Being a vastly diverse culture, it is very difficult to have all the staff understanding / interpreting language English in the same way. Procedures can be multilingual if the need be.

3. The recording of data should be automated as far as possible and human intervention should be at minimum.

4. Training should be given utmost importance and every employee must be imparted detailed training. The employee should be assessed for the training effectiveness to ensure right understanding of the procedures. It is also essential that work be assigned to trained personnel only.GMP training and Data integrity training should be imparted periodically i.e. atleast annually.

5. Data review process should be strong and independent of the execution. If it is not documented, it is not done. Emphasis should also be upon scientific review of the data and not just a check box to satisfy auditors.

6. Quality assurance should be a truly independent organization and empowered to report deviations without fearing repercussions.

7. Right amount of resources should be made available for each task. An overworked employee is not a highly motivated one.

8. Last and most important is the culture in the organization. Generally, sales organization is the most glamorous one, since it is revenue generating. Quality is always seen as a revenue depleting organization. This must be changed, since if there is no quality, there will be no customers. People should be empowered to report as well as resolve issues. Quality has to be made a way of life and not something that can be externally imposed.

A solid foundation is what keeps buildings intact in the face of earthquakes. Similarly, for the industry too, it is resourceful to have data integrity embedded at the entry level. Pharmacy colleges can play a critical role in equipping future pharmacists with skills and techniques commensurate with recording and analyzing data. They should collaborate with Industry to create awareness of work skills as well as documentation skills as per regulatory requirements.

There is a strong case to promote Quality Assurance as a core competency area in Academics replete with case studies and field work.

If we can cater to meet the requirements, we can move ahead of the rest of the countries and thus it can be a boon for the industry.

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1. MHRA (Medicinal and Healthcare products Regulatory Agency): MHRA GMP Data Integrity Definitions and Guidance for Industry March 2015

2. USFDA: Data Integrity and Compliance with CGMP, Guidance for Industry

Disclaimer: The content in the article is a compilation of information already available and is an expression of my opinion. It does not have any bearing on J&J and its affiliate.

Influence of Gut Microbiota and Probiotics on Intestinal Permeability of Drugs

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Keywords: Gut microbiota, Probiotics, Intestinal permeability, Drug Transporters

Introduction

The human gut harbours trillions of microorganisms, of which bacteria are the most abundant. Besides bacteria, fungi and protozoa also make up a part of gut microflora [1]. The highest population of microbiota is found in the colon [2]. The gut microbiota regulate a number of metabolic, trophic, protective, antimicrobial and immune functions and, thereby, have an immense impact on the nutritional and health status of the host [3-7]. A balanced gut microflora helps to maintain homeostasis in the host. Imbalances may occur in gut microflora due to disease conditions, dietary factors, unhealthy lifestyle and drug administration. These imbalances may lead to several metabolic and immune-mediated disorders such as inflammatory bowel disease (IBD), irritable bowel syndrome (IBS), obesity, type 1 diabetes, type 2 diabetes, depression, autism and many other disorders [8-12].

Because of their ability to modulate the composition of intestinal microbiota, probiotic intervention is considered to have the potential to counter-balance intestinal dysbiosis and thus restore health of the host. Probiotics are defined by the Food and Agriculture Organization of the United Nations/World Health Organization as "live microorganisms, which, when administered in adequate amounts, confer a health benefit on the host" [13]. The commonly used probiotic strains include the Gram-positive lactic acid-producing organisms, particularly, the Lactobacilli and Bifidobacteria. In addition to these, members from other lactic acid bacterial genera, such as *Streptococcus, Lactococcus* and *Enterococcus*, members from the genera *Bacillus* and *Propionibacterium*,and yeast (e.g. *Saccharomyces*) are also employed as probiotic microorganisms [1]. The effectiveness of probiotic intervention has been studied in a number of disease states, including infections [1, 3, 14, 15] ,IBD and IBS [3, 15, 16], antibiotic-associated diarrhea [3, 14, 17], acute rotaviral diarrhea [3, 15], colon cancer [3, 15, 16], cardiovascular diseases[16], allergic diseases [14, 16], obesity [16], type 1 and 2 diabetes [8, 16], lactose intolerance and other metabolic disorders [16].

Oral route is the most common and convenient route of drug administration and is usually preferred since many drugs are well absorbed by the gastrointestinal tract. After oral administration, majority of the drugs are absorbed through the intestinal mucosa. Intestinal absorption of drugs, and hence their oral bioavailability, is significantly influenced by drug solubility and permeability, regional pH, presystemic drug metabolism and intestinal motility [1]. Since all orally administered drugs are absorbed through the gut wall mucosa their intestinal permeability plays an important role in regulating the extent of drug absorption.

Intestinal Drug Permeability

Intestinal permeability depends on many factors such as membrane transporters, mucus layer alterations, epithelial damage, lifestyle and dietary factors [18]. Also, the gut microbiota can influence this process and cause modifications, which may result in alterations in mucus layer, membrane transporters and intestinal epithelial barrier through immune mechanisms [12]. Intestinal permeability, being closely linked to the gut microbiota as well as to the components of mucosal immune system, may be significantly affected due to dysbiosis of gut microbiota or due to probiotic intervention adopted to overcome this dysbiosis [18].

The intestinal epithelial cells form a barrier between the systemic circulation and the drugs present in the gut. This barrier function is regulated by multiple elements like the mucous layer, secretory IgA, antimicrobial peptides, and the tight apical junction complex. The tight junctions seal the paracellular pathway and are the rate-limiting step in the transport of drugs between adjacent epithelial cells [19]. Alterations in gut flora increases the gut permeability, a phenomenon known as "leaky gut", and it may abruptly enhance the intestinal permeability of drugs [12].

The enterocytes in the intestinal mucosa consists of many drug transporters. These membrane transport proteins play important roles in absorption of drugs from the intestine. The amount of drug reaching the systemic circulation after oral administration is governed by the extent of transporter expression in the intestinal mucosa. Thus, factors which affect their expression and function, may change the permeability, and hence the pharmacokinetics, efficacy and safety profiles, of drugs. Numerous drug transporting membrane proteins have been described in intestinal tissues. These transporters belong to two major classes - ATP-binding cassette (ABC) and solute carrier (SLC) family. Of these, ABC transporters determine oral bioavailability, tissue penetration, cellular accumulation and excretion of many drugs, and thus influence their basic pharmacokinetic parameters [20].SLC transporters are involved in absorption of structurally different drugs, carcinogens and other toxins [21, 22] .

Role of Probiotics in Intestinal Drug Permeability

As the intestinal microflora confers various health benefits to the human host, a lot of interest is currently being taken in using the probiotic approach to manipulate its composition and activity or to restore the gut microbial imbalance so as to achieve its protective effect [23].

Probiotics may modulate the intestinal epithelial barrier of the host by preventing pathogenic bacterial growth, blocking of pathogen binding to intestinal mucosal surfaces, stimulation of mucosal barrier function, and through immunomodulation [24].A study has demonstrated that probiotics *B. infantis* and *L. plantarum* increase the expression of tight junction proteins such as zonula occludens and thereby improve the epithelial barrier function [25]. In another study, two soluble proteins, p75and p40, from *Lactobacillus rhamnosus* GG have been demonstrated to promote cell survival and growth in human and mouse colon intestinal epithelial cells. These proteins inhibit TNF-α-induced cell apoptosis by activation of the anti-apoptotic factor Akt and protein kinase B [26] All these effects of probiotics help to strengthen the gut epithelial barrier [27].

Another way by which probiotics may alter drug permeability is by modulating the expression of transporters involved in drug transport across the intestinal membrane. Findings of a study showed that Lactobacilli or their soluble factors significantly enhance the expression and function of P-gp under normal and inflammatory conditions. This could be of considerable importance for the permeability of drugs which are substrates of this transporter [28] .

In an *ex-vivo* study carried out in rats, it was observed that probiotic pre-treatment reduced gliclazide absorption and bioavailability in healthy rats whereas, in diabetic rats, its absorption was enhanced. The study proposes that, in healthy rats, bacterial metabolites are produced. These metabolites may upregulate the intestinal efflux drug transporter Mrp2 which controls gliclazide transport, resulting in reduced intestinal permeation of gliclazide in healthy rats. In contrast, the fluxes are restored after probiotic treatment in diabetic rats and therefore the functionality of drug transporters is normalized, resulting in net absorption of gliclazide. Another possible explanation suggested for this is suppression of Mrp3 expression by probiotics in healthy rats, which causes less gliclazide being removed from the ileal enterocytes into the blood, thereby leading to a decrease in net gliclazide absorption. Another mechanism proposed is formation of a thicker layer of the adherent mucous, which enhances the physical barrier protecting the enterocytes [29] . Another investigation was consequently carried out to determine the influence of probiotics on monoketocholate (MKC) pharmacokinetics when MKC is administered orally with gliclazide to diabetic and healthy rats. Probiotics resulted in a decrease in MKC bioavailability in healthy rats and this may be explained to be due to induction of presystemic metabolism, impairment of absorption and stimulation of degradation of MKC by probiotics [30] .

Conclusion

In conclusion, the intestinal microflora and probiotics may influence the intestinal permeability of drugs and thereby lead to altered pharmacokinetic profile of drugs in terms of increased toxicity, altered efficacy, and adverse drug reactions. Consumption of probiotics modulates the composition and functionality of intestinal microflora, as well as expression of intestinal enzymes and transporters, consequently affecting the permeability and bioavailability of a vast number of drugs. The mechanisms proposed in this review are limited to few probiotic strains and drugs. Investigations with different strains of probiotics and different categories of drugs in healthy and diseased conditions are necessary to deepen the knowledge in this domain.

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Envisaging The Role Of A Prudent Discriminating Medium For Successful Dissolution Studies

Dr. Harita Desai

The drug release characteristics of New Chemical Entities (NCEs) as well as novel drug delivery systems have been invariably studied using dissolution technology. Dissolution testing has been frequently used as a quality control test to assess batch-to-batch consistency. It has been widely explored as a technique for generation of data relevant in achieving product biowaivers, establishment of product bioequivalency. Some of the important parameters influencing the success of a dissolution test evaluation include the medium characteristics, temperature maintenance, rpm, dosage form. Now and then, the drug release differences induced by changes in manufacturing techniques, formulation components, processing methods and parameters have been studied using a '*discriminating dissolution medium*'. Selection of a specific discriminating dissolution medium is very important in differentiating the drug release patterns of different formulation systems which indirectly affect the performance of the system *in vivo*.

The success of a dissolution methodology is based on its extent of robustness, discriminative power, transferability, *in vivo* core-relativity and controlled variability. A discriminating medium plays an important role in routine dissolution evaluation tests by aiding to differentiate between good and bad formulations. Along with selection of a good formulation, a discriminating medium also aids to have thorough understanding of dissolution release which can furthermore aid in advanced formulation development.

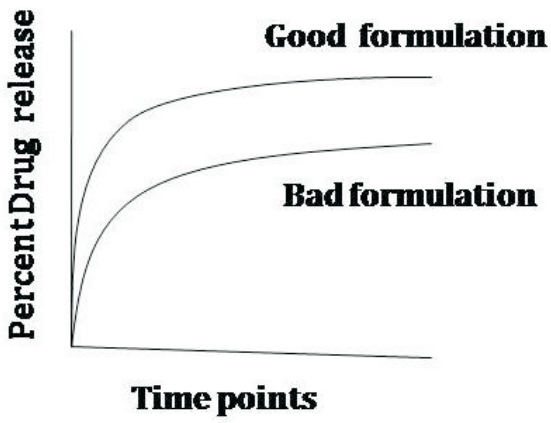


Figure :1 : Differentiation of Formulations from dissolution profiles

Dissolution profiles generated by use of discriminating media can be used to compare the performance of two formulations *in vivo*. If the dissolution profile generated for a sample formulation matches with the dissolution profile of the standard formulation, it can be predicted that both the sample and standard formulation will exhibit similar performance *in vivo* (i.e. similar bioavailability and hence bioequivalence). The test can then be utilized as a discriminative test for performance of such formulations.

A discriminating medium can be utilized to differentiate manufacturing batches of the same formulation by differences in the exhibited profile. A discriminatory test utilizing a discriminatory medium can be called *discriminating* only if the different dissolution profiles also exhibit differences in *in vivo* drug release patterns thus indicating the product bioinequivalency. Thus if comparison of two formulations of the same batch using a discriminating medium yields different *in vitro* drug release patterns; however the *in vivo* performance of the two formulations exhibit equivalence, in such cases the specific test can be utilized to determine tolerances for acceptable formulations in same batch in quality control analysis.

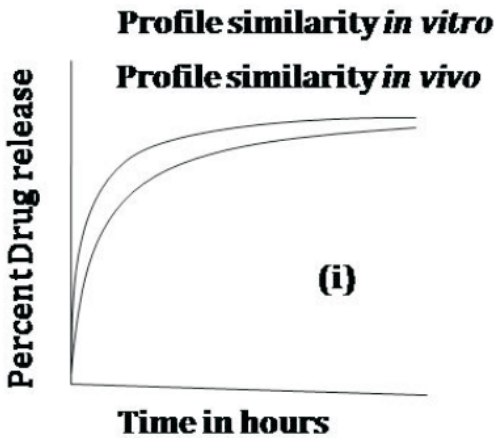
The discriminatory nature of a test utilizing a discriminatory medium is dependent on the *in vivo* profile observed for two products being compared. Considering a situation where two formulations X and Y are compared *in vivo* to a standard product P where formulation X is found to be bioequivalent to product P and formulation Y is found to be bioinequivalent to product P. Both the formulations X and Y exhibit differences in manufacturing as compared to standard product P. The dissolution testing of both the formulations X and Y is conducted in similar environmental conditions. Dissolution testing of such formulations can yield results as indicated in Fig 2:

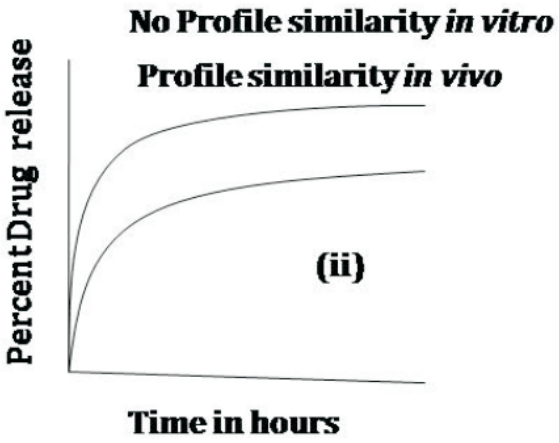
i)Formulation X bioequivalent to product P shows dissolution profile same as P

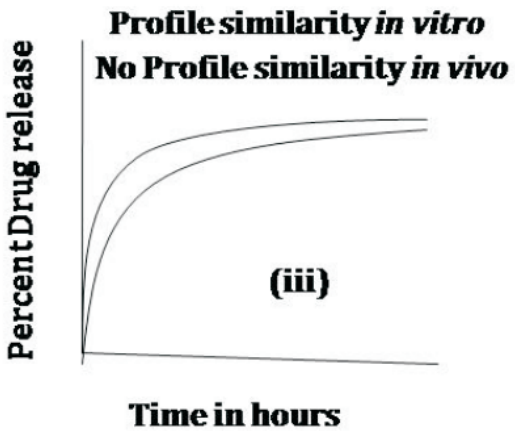
ii) Formulation X bioequivalent to product P shows dissolution profile different from P

iii) Formulation Y bioinequivalent to product P shows dissolution profile same as P

iv) Formulation Y bioinequivalent to product P shows dissolution profile different from P.







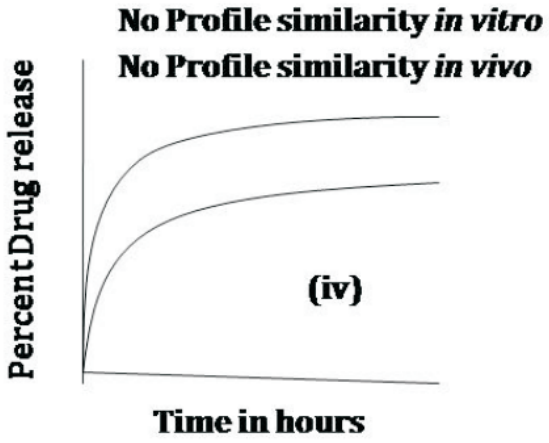


Fig 2: Drug release patterns of Formulation X and Y when compared with standard product P

Out of the above four results, (i) and (iv) can be considered as accurate as the *in vivo* behavior is clearly exhibited by *in vitro* results.. However only result (iv) can be considered for predictive for the discriminating test as it aids to differentiate the two formulations based on the *in vivo* behavior of the formulation and product. Result (i) can be utilized for tolerance determinations for acceptable products. Result (ii) and (iii) can be considered as false and can be called as *over-discriminating* and *under-discriminating* respectively.

The relevance of a discriminatory test can be established only if the test is able to give good correlation with *in vivo* environment and is able to give an idea about *in vivo* release characteristics. Establishment of a discriminating test comprises of utilizing different dissolution testing assemblies in order to generate dissolution environment conducive in generating accurate drug release profiles. Generation of stirring and mixing conditions in the dissolution process that closely mimic *in vivo* conditions can be utilized to create discriminating media with applicability for multiple types of formulations. The main purpose of generating discriminating media is to differentiate between formulations and hence a discriminating test should be able to differentiate between Immediate Release (IR) and Extended Release

(ER) products which show wide differences in drug release profiles and performances.

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Two day Professional Development Certification Course V on QbD in Dissolution Method Development by SOCIETY FOR PHARMACEUTICAL DISSOLUTION SCIENCE in association with Bombay College of Pharmacy, Kalina on 4th and 5th July 2016

The two day course entitled **'QbD in Dissolution Method Development: QTTP, Critical Method Attributes, Discriminatory Method, DOE's, Method Finalization** was conducted by Mr. Vijay Kshirsagar, CEO and Director, TRAC Consulting, Mumbai. The course was chaired by Dr Padma V. Devarajan, Professor of Pharmaceutics, Institute of Chemical Technology, Mumbai,, Mumbai. The course partner for this Series is Sotax India Pvt. Ltd. The inaugural session was presided over by Dr. L Ramaswamy, Hon. General Secretary, SPDS and Managing Director, Sotax India Pvt. Ltd, Mumbai. Speaking on this occasion, the Chief Guest, Dr N. Sivaprasad, President, Indian Pharmaceutical Association (Maharashtra State Branch), Governing Body of Bombay College of Pharmacy. expressed his happiness at the progress made by the Pharmacy profession and the role of SPDS in promoting a culture of inquisitiveness in young pharmacists. Mr Kshirsagar elaborated on various aspects of QbD including PAT, DoE, QTTP, CQA. The changing face of regulatory requirements was very well explained by him with the help of real life examples. Around 100 delegates from Academia and Industry participated in this Certificate course and went back highly impressed with the technical quality of the session.

The forthcoming events organized by SPDS include

International Annual Symposium on Dissolution Science to be held at Ahmedabad on 26th and 27th July 2016

International Conference on Dissolution Science to be held at Bucharest, Romania, on 20th and 21st October 2016.

For further details and for becoming a member, log on to www.spds.in

Dignitaries in dias (seated L-R) : Prof. Padma V Devarajan, Vijay Kshirsagar, Dr. N. Sivaprasad, Dr. L. Ramaswamy

Delegates

Dr. Ramaswamy lighting the lamp

Dr. N. Sivaprasad addressing the audience

Vijay Kshirsagar during the session

Vijay Kshirsagar lighting the lamp

Vijay Kshirsagar and SPDS committe with the delegates

Romanian Academy
Section of Medical Sciences

Romanian Society for
Pharmaceutical Sciences

University of Medicine and
Pharmacy "Carol Davila" Bucharest

Society for Pharmaceutical
Dissolution Science (SPDS)

Society for Pharmaceutical Dissolution Science(SPDS)
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Announces…

DISSO EUROPE - ROMANIA 2016
INTERNATIONAL
CONFERENCE

Date : 20th & 21st Oct. 2016
Venue : Bucharest, Romania

International Conference
on Dissolution Science