Drug Dissolution Testing and Establishing Plasma Drug Levels in Humans

Date : Apr 19, 2018 - 08:30 AM - Apr 20, 04:30 PM

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Organizer : MetricStream, Inc.

Venue : To Be Announced

Location : 1, Main St
San Diego, CA, USA, ZIP: 00000

Drug Dissolution Testing and Establishing Plasma Drug Levels in Humans

Drug dissolution testing is an essential and critical step for appropriate and efficient product development such as tablet and capsule. A number of approaches are used to conduct dissolution testing using different apparatuses and methods. Making a choice for an appropriate apparatus and method has always been confusing and challenging. This seminar will provide relevant pharmacokinetics and physiological background so that making this choice becomes easier and instinctive. No prior knowledge of pharmacokinetic and/or physiology is required; however, these will be explained in very simple terms to help attendees in selecting or developing a dissolution method. This seminar will describe in detail the theoretical aspect of the drug dissolution testing including method development. Pros and cons of different approaches will be explained in detail.

Furthermore, drug dissolution testing is also conducted to provide an estimate/prediction of expected drug levels in humans. Commonly, concepts of convolution/deconvolution and in vitro-in vivo correlation (IVIVC) are described in this respect, unfortunately with limited success. Difficulties and limitations of the currently suggested approaches will be highlighted. This seminar will provide details of the underlying scientific principles involved in convolution, deconvolution and IVIVC techniques with simple practical examples. In this regard, a unique and simple approach based on convolution technique using spreadsheet software, along with hands-

on exercises, will be described.

This is a unique in-depth seminar on the subject not available anywhere else with unmatched coverage of scientific details and addressing regulatory and compendial requirements yet extremely simple to understand.

Seminar Fee Includes:
Lunch
AM-PM Tea/Coffee
Seminar Material
USB with seminar presentation
Hard copy of presentation
Attendance Certificate
$100 Gift Cert for next seminar
DOWNLOAD BROCHURE

Seminar Instructor Dr. Qureshi has extensive (30+ years) working experience, as a research scientist, with a regulatory agency (Health Canada). He is an internationally known expert on the subject and maintains a full command in the areas of drug dissolution testing, pharmacokinetics, biopharmaceutics and analytical chemistry as related to animal and human studies for developing and evaluating pharmaceutical products.

Learning Objectives:

Physiological and Pharmacokinetic Principles:

- Related physiological terms: GI tract environment, drug absorption, permeation.
- Pharmacokinetic principles including terminologies of plasma drug concentration-time profiles/curves, rates of absorption and elimination, Cmax, Tmax, half-life, AUC, apparent volume of distribution, bioavailability/bioequivalence, etc.
- Defining and differentiating drugs/medicines and drug/medicinal products
- Defining quality of drugs/medicines and drug/medicinal products.

Drug Dissolution Testing:

- Theoretical concepts
- Drug Dissolution Testing vs Solubility determination
- Drug Dissolution vs Drug Release Testing – Is there a difference?
- Apparatuses: compendial vs non-compendial
- Apparatus/instruments qualification/calibration
- Results Interpretation and tolerance
- Dissolution Method Developments
- Apparatus and agitation rate

- Selection of dissolution medium
- Sampling and run times
- QC method, bio/clinical relevant methods
- Discriminatory vs non-discriminatory methods
- Product dependent vs product independent methods
- Dissolution method validation vs analytical (quantitation) method validation
- (Specificity, Linearity/range, Accuracy/recovery, Precision, Robustness)

Linking Dissolution Results to Plasma Drug Levels:

- Concepts of convolution, deconvolution and in vitro in vivo correlation (IVIVC)
- Requirements for appropriate and relevant dissolution results
- Convolution vs deconvolution methods which one to use and why?
- Predicting plasma drug levels (theoretical background)
- Practical hands-on interactive demonstration of predicting/estimating of plasma drug levels using Excel spreadsheet software. Attendees should bring their computers for hands-on practice.

Who will Benefit:

Anyone working as bench chemist/analyst, supervisor, managers, director or vice president in pharmaceutical manufacturing facilities, including laboratories and associated contract organizations, of innovator and generic companies for human and animal products, in the following areas:

- Pharmaceutical Development
- Setting up analytical methods (pharmacopeial, regulatory or in-house developed)
- R & D, both analytical and formulation
- Project Management
- Quality Control
- Quality Assurance
- Regulatory Affairs

AGENDA

DAY 01(8:30 AM - 4:30 PM)

- 8:30 am – 9:00 am: Registration, Meet & Greet.
- Session 1: Physiological and Pharmacokinetic Principles (90 Mins)
- Coffee Break
- Session 2: [Continue] Physiological and Pharmacokinetic Principles (60 Mins)
- Question/Answer/discussion (30 Mins)
- Lunch Break

- Session 3: Drug Dissolution Testing (90 Mins)
- Coffee Break
- Session 4: [Continue] Drug Dissolution Testing (60 Mins)
- Question/Answer/discussion (30 Mins)

DAY 02(8:30 AM - 4:30 PM)

- Session 1: Linking Dissolution Results to Plasma Drug Levels (90 Mins)
- Coffee Break
- Session 2: [Continue] Linking Dissolution Results to Plasma Drug Levels (90 Mins)
- Question/Answer/discussion (30 Mins)
- Lunch Break
- Session 3: Practical hands-on interactive demonstration of predicting/estimating of plasma drug levels using Excel spreadsheet software (90 Mins)
- Coffee Break
- Session 4: Practical hands-on interactive demonstration of predicting/estimating of plasma drug levels using Excel spreadsheet software (60 Mins)
- Wrap-up (15 Mins)

SPEAKER

Saeed Qureshi
Principal, PharmacoMechanics (Former Senior Research Scientist at Health Canada)
Dr. Saeed Qureshi has extensive (30+ years) working experience, as a research scientist, with a regulatory agency (Health Canada). He is an internationally known expert on the subject and maintains a full command in the areas of drug dissolution testing, pharmacokinetics, biopharmaceutics and analytical chemistry as related to animal and human studies for developing and evaluating pharmaceutical products. His areas of expertise include: (1) Quality assessment of pharmaceutical products based on pharmacokinetic studies (e.g. bioavailability/bioequivalence) in humans and animals, including validation of in vitro results with in vivo (bioavailability) studies. (2) In vitro drug release characterization of pharmaceutical products in particular oral and dermal using dissolution and/or diffusion (absorption/penetration through skin) techniques. (3) Analytical methods development/validation for drug disposition evaluation in humans and animals using chromatographic (e.g. HPLC, GC, TLC) and

spectroscopic (e.g. UV, MS) techniques. (4) Data analysis using sophisticated (SAS) and general-purpose (e.g. MS Excel) software.

Dr. Qureshi has extensively published in peer-reviewed journals and given numerous national and international presentations on the subject. Dr. Qureshi is very well known for his innovative but simple and practical ideas. Since 2010, he has been contributing and moderating a weblog (www.drug-dissolution-testing.com) which has become a popular source of new and thought provoking ideas for addressing the issues of product evaluations.

Please contact the event manager Marilyn (marilyn.b.turner(at)nyeventslist.com) below for:
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