May 2012: (Updated to May 15, 2012)

Standardization and qualification/validation of the crescent shape spindle

Current practices of dissolution testing are not about developing or evaluating products anymore, they have become campaigns to continue using the flawed apparatuses with made-up qualification and validation approaches.

April 2012:

Consider the following ten facts before using the paddle/basket apparatuses for dissolution testing.

The issue of validation/qualification of dissolution apparatuses

MQ (Mechanical Qualification) vs PVT (Performance Verification Testing) which one to choose and why?

Assessing and Generating Useful Drug Dissolution Profiles – A Practical and Bio-relevant Approach

Predicting Drug Concentration-Time (C-t) Profiles for Metoprolol Tartrate Tablet Products in Healthy Human Volunteers and a Sub-population Group

March 2012:

(Developing) a discriminatory vs bio-relevant test

Assessing Lack of (Trouble-Shooting) Bio-Relevancy in Drug Dissolution Testing

Method Validation: A Unique Problem Concerning the Drug Dissolution Testing

Prediction of blood drug concentration-time (C-t) profiles does not require a deconvolution step

Equilibration at 37 °C is better than de-aeration/de-gassing of a dissolution medium for reproducible and relevant dissolution testing

Sink Condition: Solely an in vitro (analytical chemistry) and not the in vivo or physiological requirement

February 2012:

Old traditions take a long time to die!

Predicting Blood Drug Concentration-Time (C-T) Profiles Using Convolution Technique – Valproic Acid

Predicting Blood Concentrations-Time (C-t) Profiles from Drug Dissolution Results without Developing an IVIVC – Validation

Drawing Conclusions from Dissolution Testing/Results – A Cautionary Note

Citing a Post

Developing Dissolution Methods for Pharmacopeial Purposes – Deficiencies

January 2012:

F2 – Similarity Factor (A Deficiency)

Some Thoughts on a Recent US FDA Document "Quality by Design for ANDAs: An Example for Modified Release Dosage Forms"

Can an Appropriate Dissolution Method Transfer Protocol be Developed?

Potentially Incorrect Interpretation of In Vitro Dissolution Characteristics of Products – Glimepiride

Physiological Considerations for Drug Dissolution Testing

December 2011:

Two-Tier System for Setting Tolerances – (PVT vs Products)

Where does 20% of the drug go?

Pharmacokinetic (PK) Parameters Values for Estimating Blood Drug Concentration-time (C-t) Profiles

November 2011:

Lack of Objectivity and Relevancy of Current Practices

Use of Dissolution Testing During the Product (Tablet/Capsule) Development Stage

Setting Clinically Relevant Tolerances for IR Products – A Simple and Rationale Approach

October 2011:

Assay and Content Uniformity (CU) based on dissolution testing (Poster Presentation)

Simplifying Pharmacopeial Tolerances – An Example Based on USP Tolerances for Diltiazem ER Capsules

Estimation of blood levels – Example: 120 mg diltiazem ER capsules

Defining a dissolution apparatus

September 2011:

Multiple vs Single-Point Tolerances

Faster Dissolution Results Do Not Necessarily Mean A Loss Of Discriminatory Power

August 2011:

Developing a Dissolution Method – What is Required?

Are soluble and poorly soluble drugs classifications appropriate?

Choosing an Apparatus: Paddle vs Basket

July 2011:

A Concern Which Requires Urgent Attention

Considering IVIVC – requires caution

Clarification:

Currently suggested dissolution testers/methods may not be capable of determining dissolution characteristics of drug products.

Drug Dissolution Testing Using Simple and Common Experimental Conditions

June 2011:

In Vitro-to-In Vivo Profiling (IVIVP)

Has BCS (Biopharmaceutics Classification System) been a Futile Exercise?

Dissolution method development – a practice which causes confusion and hinders in product evaluation

Concept of "quality" in drug dissolution testing

Apparatus Calibration or Performance Verification: Misleading Conclusions and False Comfort

In Vivo vs In Vitro Bioequivalence

Lack of faith in obtaining physiologically relevant dissolution results. There is a reason for it.

Drug dissolution testing for phase I clinical trials/studies

May 2011:

Recent exchange of thoughts

Are current practices of dissolution testing just to meet the regulatory requirements?

A bio-relevant dissolution test?

A discriminating dissolution test

Different IVIV Relationship Terminologies

Simplification to a "universal" dissolution test

April 2011:

Dissolution-Absorption Link

Drug Dissolution Testing Mosaic

Dissolution Test For Nicotine Polacrilex Lozenges

Operating principle of a dissolution tester (Paddle/Basket)

Dissolution method precision – The way I see it

Obtaining bio- (physiologically) relevant dissolution results

March 2011:

Drug dissolution testing: Mixing by peristaltic motions vs stirring

IVIVC – Conflict between practices and objective/intent

Product dependent dissolution testing – a scientifically invalid practice

Selecting an RPM for dissolution testing

A recent article

February 2011:

Paddle and Basket Apparatuses require validation

Mechanical and/or chemical calibration – why bother?

Dissolution testing for products development?