Establishing quality of pharmaceutical products: Addressing some serious illusions!

Saeed A. Qureshi, Ph.D.
Principal @ PharmacoMechanics

Senior Research Scientist (Ret'd)
Therapeutics Products Directorate

Presentation at:
Faculty of Pharmacy,
University of Montreal, Montreal
March 21, 2017

Outline (Summary)

The quality feature of the pharmaceutical products has never been defined; however, manufacturers as well as regulatory authorities make claims of achieving it – thus illusions. This presentation will focus on defining the quality of a drug product, based on tablet/capsule products as an example, and will provide simple approach for establishing it to streamline product development and manufacturing practices, and regulatory requirements.

Let us start with a question!

What is quality of a pharmaceutical product *or* what is a quality product?

Is this a quality product, Why?

Is this a quality *product*, Why?

This is an approved product, *not* necessarily a quality product!

Is this a quality *product*, Why?

At present, no one can define a quality product, thus cannot develop or manufacture one!

Do not confuse products with drugs?

These are two different things!

Do not confuse products with drugs?

Drug/Medicine

Product

These are two different things!

Drugs vs Products

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PHARMACEUTICAL SCIENCE UPDATE

✓ *Drug Product*

2017-03-15

Lawmakers Revise Bill to Speed Generic Drug Approvals ✗

ANDA (Abbreviated New Drug Application) Is it a correct terminology? Maybe not!

In reality, ANDAs deal only with OLD drugs, not the new drugs as the title indicates, to provide new PRODUCTS. A more appropriate terminology should be NPA (new product application) reflecting accurately objective and content of the application. If the title/objective is revised and proper, it is highly likely that submitted material would be more concise and relevant which would help in manufacturing of PRODUCTS efficiently by focusing only on necessary expertise and regulations.

Something to think about!

Quality

Drug/Medicine

= safe,
efficacious
& pure

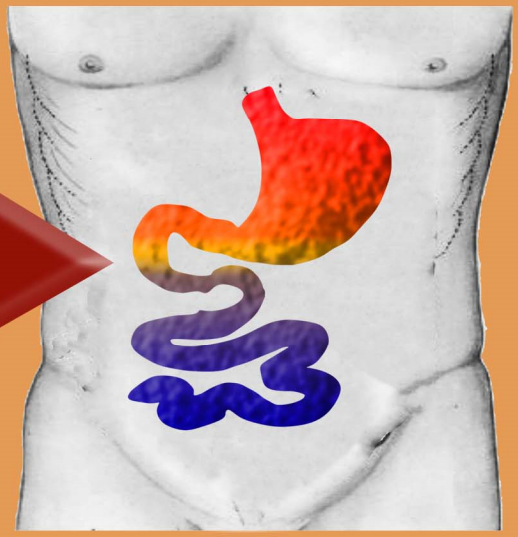
Product

Ability to release drug as expected

Quality Metric

Ability to release drug* as expected

*Active Ingredient



It is scientifically valid, measurable and enforceable.

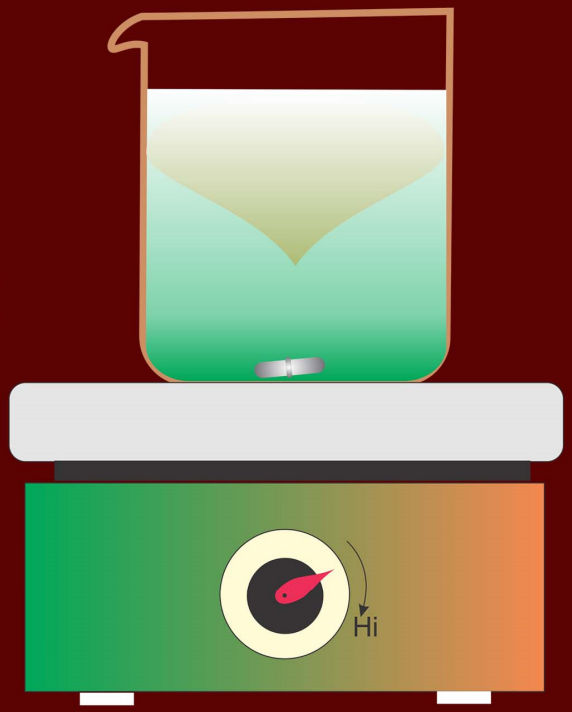
www.pharmacomechanics.com

A drug release test, commonly known as *drug dissolution test*, is the only test which can establish the drug release, thus quality of a product, at the *manufacturing stage*.

Similarity of Operation

Dissolution Tester

=



Conducting a dissolution test!

Given is a sample of a simple tablet product containing a highly water soluble drug. Requirement is of dissolution samples only as quantitation of the samples will be done independently. The analyst must provide specific details of the dissolution method along with its qualification/validation documentation.

Please respond!

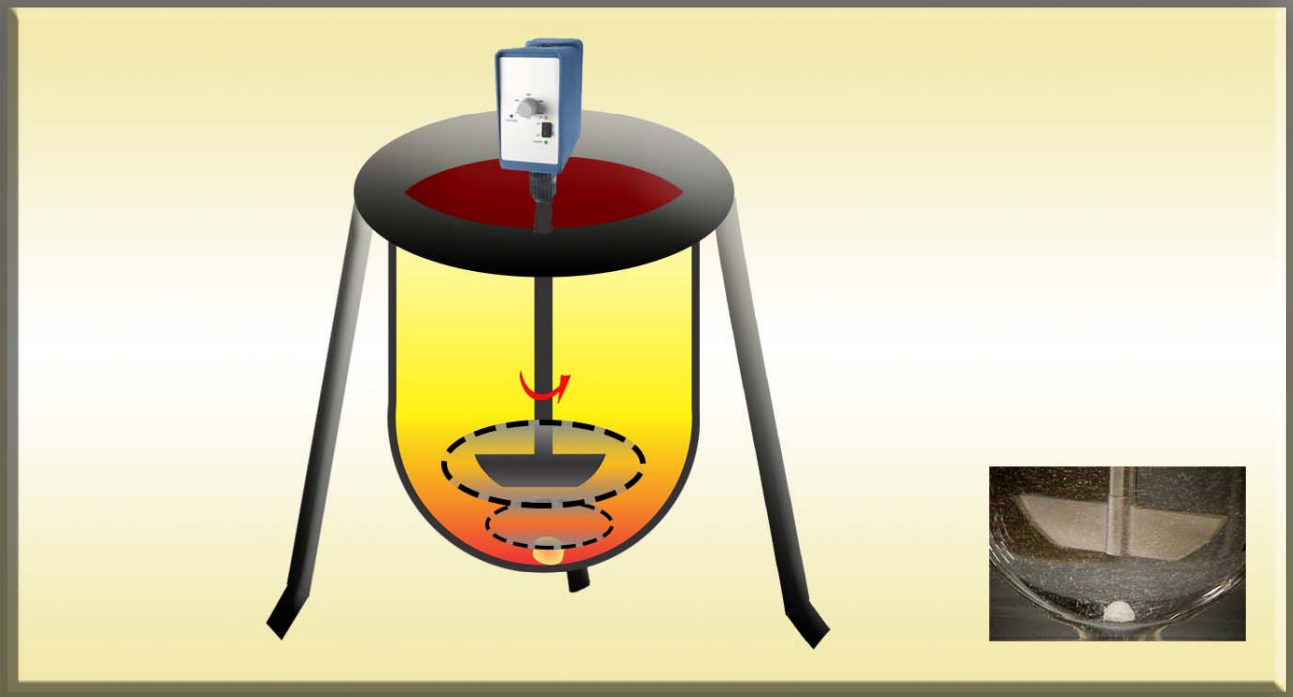
Conducting a dissolution test!

Given is a sample of a simple tablet product containing a highly water soluble drug. Requirement is of dissolution samples only as quantitation of the samples will be done independently. The analyst must provide specific details of the dissolution method along with its qualification/validation documentation.

Please respond!

At present, no one can!

Reason #1: Never validated or qualifiled for the intended use!

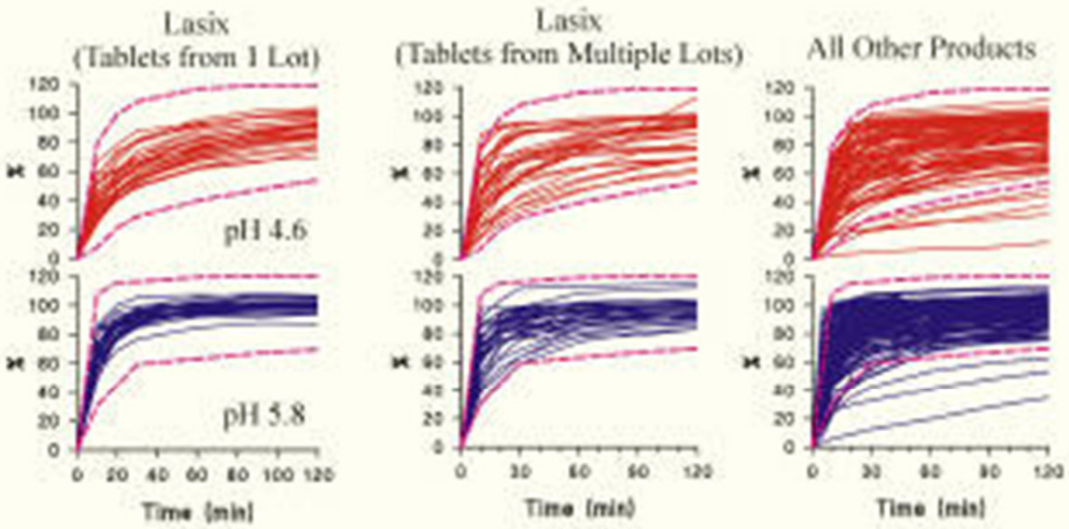


Reason #2: Poor hydrodynamics within vessel!

Expected variability in dissolution results!

Dissolution Profiles of Furosemide Products

(Using Paddle Apparatus at 50 rpm)

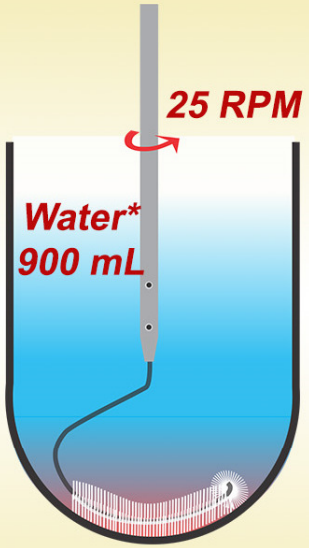


Qureshi & McGilveray. *Drug. Develop. Ind. Pharm.* 1998.

Universal Dissolution Test/Tester
(Using Crescent-shape Spindle)

Simple, scientifically valid, product independent, bio-relevant, and much more! Based on 25+ years of research.

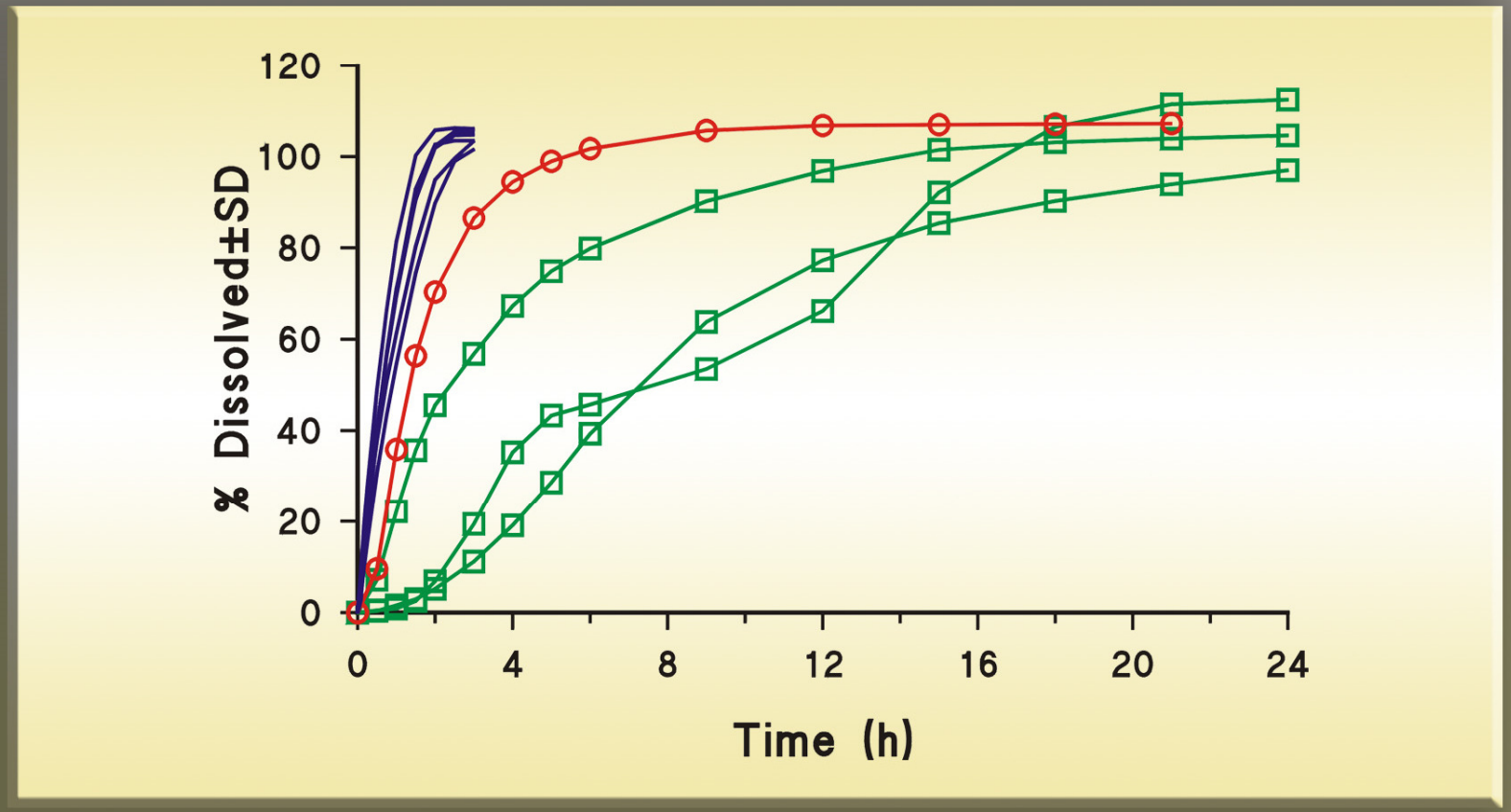
The same test may also be used for determining potency (assay) and content uniformity of a drug product.



**Dissolution medium (water) may require small amount of solublizer for low solubility drugs.*

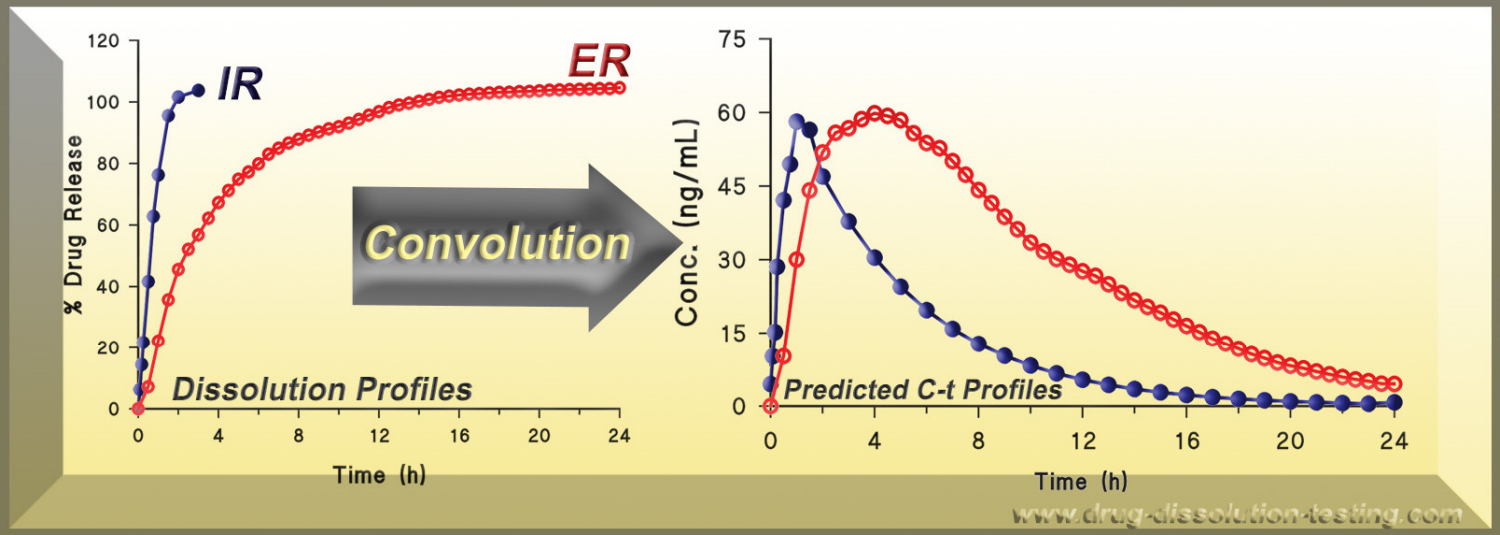
Universal Dissolution Test/Tester

(Using Crescent-shape Spindle-Diltiazem Products)



Universal Dissolution Test/Tester
(Using Crescent-shape Spindle)

Predicting Plasma Drug Levels Using Excel Spreadsheet



Drug Dissolution Testing

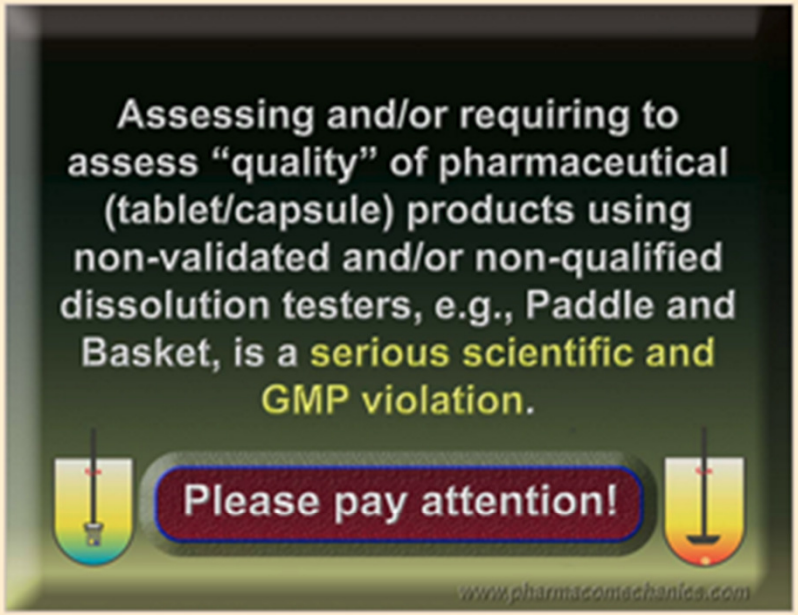
- For Simple and Practical Ideas -

« Guidance Documents – Deficiency

Drug Dissolution Testing – Illusion! »

Scientific and GMP violation!

March 1st, 2016 | Author: Saeed Qureshi



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Comments are closed.

Summary

Definition of a “quality product” is lacking (missing) thus, at present, it is not possible to develop and manufacture quality products.

To address this shortcoming a definition is suggested, which is scientifically valid, quantitatively measurable and enforceable.

Drug release or dissolution testing is the only test available to assess the quality of the products at the manufacturing stage.

Summary

Currently recommended dissolution testers, in particular paddle/basket, have never been qualified or validated for the intended purpose. In addition, because of their inherent flaws these apparatuses cannot provide relevant and reproducible results.

A simple approach, using crescent-shape spindle, with a common set of experimental conditions is suggested to alleviate current problems leading way for scientifically valid and efficient dissolution testing thus development and manufacturing of quality products.


Thank
you!