

Sneak Peek

Dissolution Testing and Biowaivers



Dr Mark Powell

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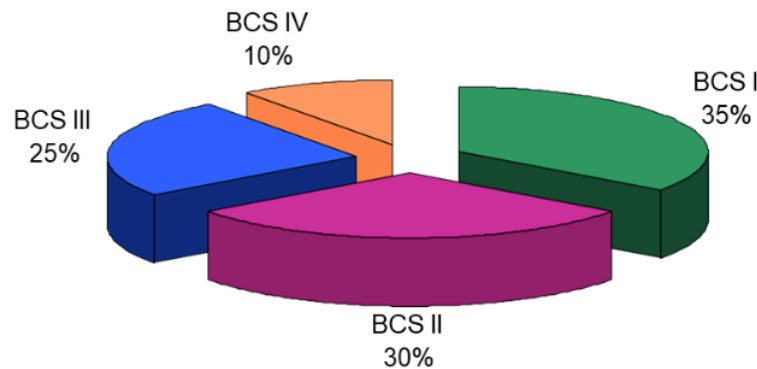


SYMMETRIC

Drug Solubility and Bioavailability

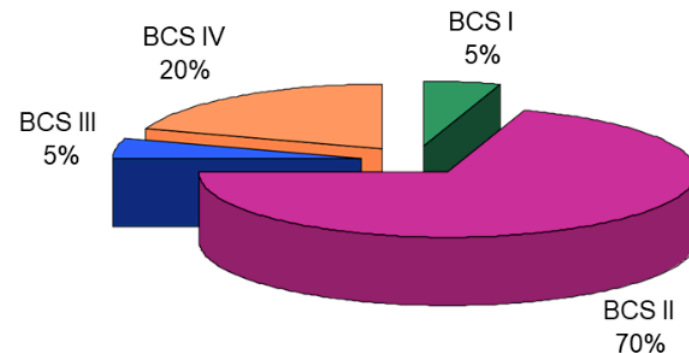
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Top 200 marketed products (US)



The majority of drugs in development, as well as a large proportion of marketed drugs, are classified as poorly soluble according to the Biopharmaceutics Classification System (BCS)

New chemical entities



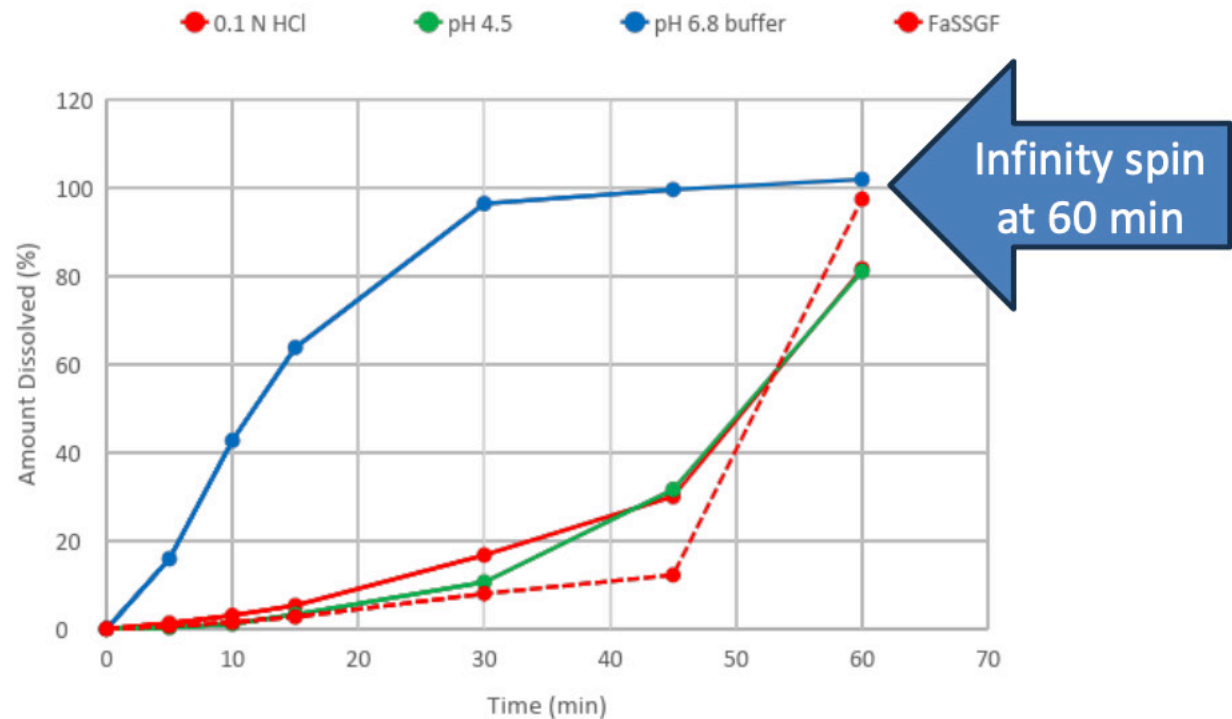
Benet LZ (2006), *Bulletin technique. Gattefossé* 99: 9-16

Dissolution Test Requirements



- Regulatory authorities expect dissolution test methods for poorly-soluble and extended-release drugs to be:
 - Discriminating
 - Robust
 - Adequately precise
- Dissolution must be essentially complete at the end of the test

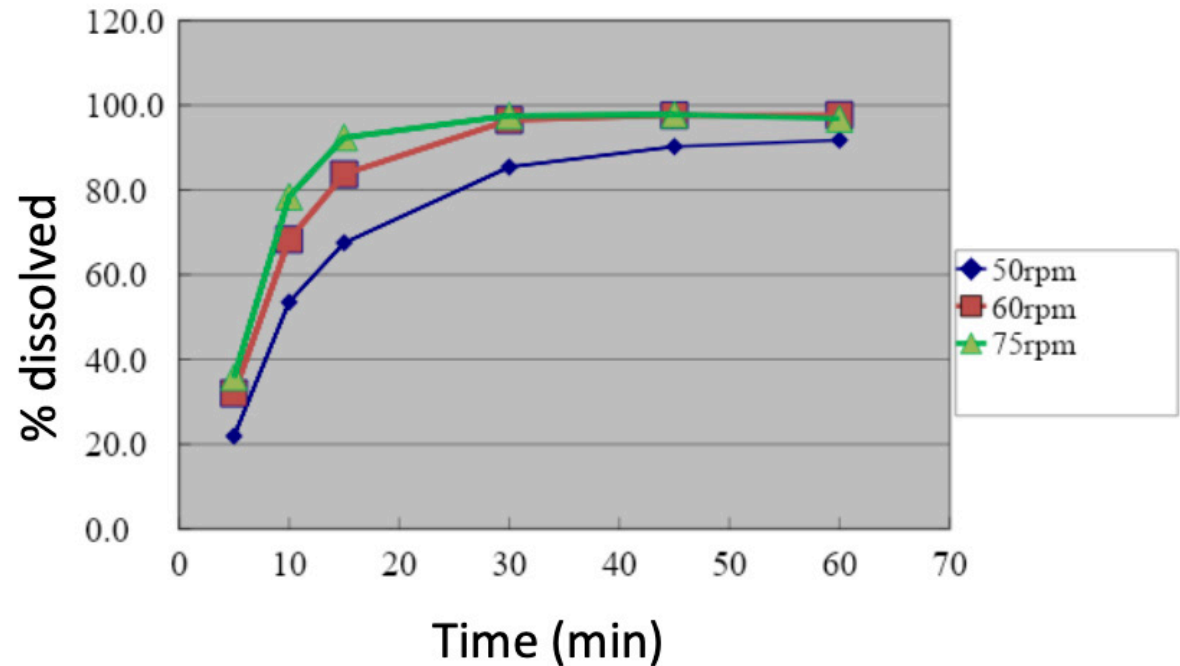
Highly-soluble drug demonstrating pH-dependent dissolution rate



Discriminating Ability



- Discriminating ability depends on many factors:
 - Dissolution medium (pH, ionic strength, surfactant type and concentration)
 - Apparatus
 - Agitation speed
 - Formulation factors
 - API solubility



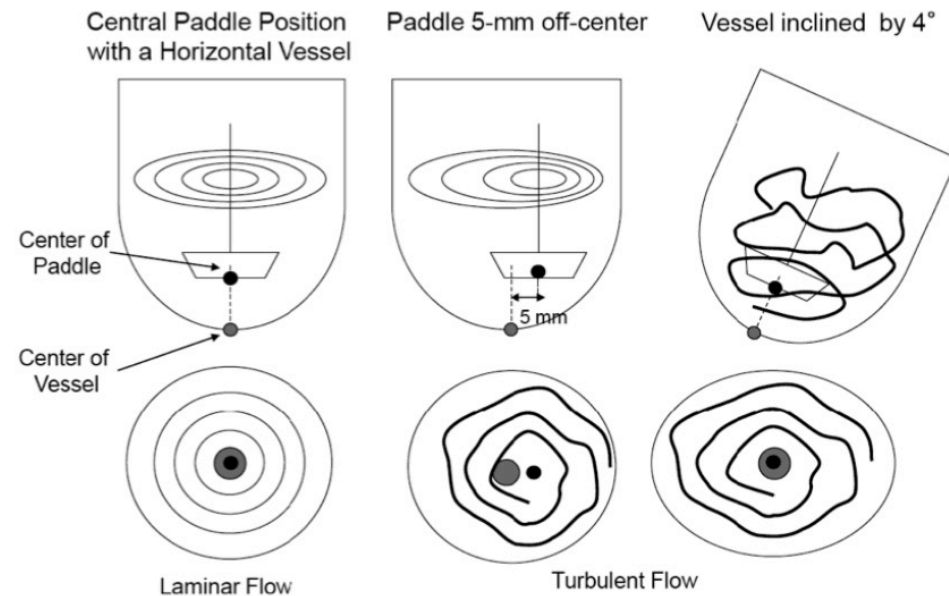
Formulation Factors

- Even if the dissolution conditions are otherwise appropriate, problems such as coning (with paddle apparatus) or delay to the rupture of gelatin capsules due to cross-linking can affect results



Mechanical Factors

- Mechanical factors such as vessel and shaft verticality, centring, vibration, paddle height and the surface finish of the vessels and stirring element can affect results



M. Fujimoto et al., Dissolution Technologies, May 2010, p.36

Understand the Science



- Success (and regulatory acceptability) in dissolution method development requires an understanding of dissolution science
- This course explains the theory of dissolution testing, regulatory expectations (including acceptable specification limits), how to approach method development and investigate unexpected results
- In addition, our trainer, Dr Mark Powell, would be very happy to answer any specific questions that you have

Registration

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