

Class & Group	Seat	Name	Student number	Date	Handout Number

**Pre-reading thinking question:**

What is an in vivo study?

What is an in vitro study?

**Reading**

At the middle of the century, emphasis started to shift to the examination of the effects of dissolution behavior of drugs on the biological activity of pharmaceutical dosage forms. One of the earliest studies with this purpose in mind was conducted by **J. Edwards** in 1951 on aspirin tablets. Based on his findings, Edwards reported that "because of its poor solubility, the analgesic action of aspirin tablets would be controlled by its dissolution rate within the stomach and the intestine." No *in vivo* studies, however, were conducted by Edwards to support his postulate. About eight years later, **Shenoy et al.** proved the validity of Edward's suggestion of the *in vitro/in vivo* correlation by demonstrating a direct relationship between the bioavailability of amphetamine from sustained release tablets and its in vitro dissolution rate. Other studies, especially those reported by **Nelson, Levy and Hays**, confirmed beyond doubt, the significant effect of the dissolution behavior of drugs on their pharmacological activities. Because of the novelty and importance of these findings, dissolution testing began to emerge as a dominant topic within both the pharmaceutical academia and the drug industry.

In the late sixties biopharmaceutics were established as an important discipline in the pharmaceutical sciences and dissolution testing became a mandatory USP requirement for several dosage forms. Dissolution, however, is still far from being understood perfectly. In spite of the reported success of several *in vitro/in vivo* correlation studies, dissolution is not a predictor of therapeutic efficiency. Rather, it is a qualitative tool which can provide valuable information about the biological availability of a drug as well as batch to batch consistency. Another area of difficulty is the fact that the accuracy and precision of the testing procedure is dependent to a large extent on the strict observance of so many subtle parameters and detailed operational controls. In spite of these shortcomings, dissolution is considered today as one of the most important quality control tests performed on pharmaceutical dosage forms.

**Post-reading question:**

Why dissolution is not a predictor of therapeutic efficiency?

**Translation:**


---



---



---



---



---



---



---