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A challenge-based laboratory to explore drug delivery from swellable matrices

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ABSTRACT

This paper describes an experiment that introduces students to drug delivery from swellable matrices (tablets). Students produce hydrophilic polymeric tablets loaded with drug and measure the rate of release from the tablets for systems having different drug loading, polymer composition and polymer molecular weight. Transient concentration data are obtained from drug release studies and analyzed to characterize the release profile and to determine the predominant rate controlling mechanism. The purpose of the experiment is to provide engineering students with basic skills relevant to drug delivery while simultaneously introducing or reinforcing science principles; applications of science, math and engineering; the science and art of design, and data analysis. Students showed significant pre-post gains in several areas, and the gains for each objective between the pre- and post-test ranged from 48% to 60%. The average normalized gain between pre-test and post-test was 65%.

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1. Introduction

Controlled drug delivery is a burgeoning field that represents a major growth driver of the pharmaceutical industry today: the global drug delivery technology segment has grown from $15 billion in 2000 to $50 billion in 2008, representing an average compound annual growth rate of 18% in comparison with 10% for the overall pharmaceutical market (Pannelay, 2009). The field has grown tremendously, driven in part by the innovations of chemical engineers (Liechty et al., 2010) who play an important and expanding role in this exciting and inherently multidisciplinary field.

Controlled drug delivery systems are engineered to deliver a drug to the body at a predetermined rate for an extended time. Controlled release systems have expanded from traditional drugs to therapeutic peptides, vaccines, hormones, and viral vectors for gene therapy. These systems employ a variety of rate-controlling mechanisms, including matrix diffusion, membrane diffusion, biodegradation and osmosis (Langer, 1990). The interdisciplinary training of an engineer enables him/her to make a unique contribution to the development of novel drug delivery systems, where an understanding of drug transport, action, metabolism; materials science; and mathematical analysis are essential (Saltzman, 2001).

The chemical engineer plays a vital role in the development of new drug delivery systems, and examples of hands-on experiments to introduce chemical engineering students to drug delivery are emerging in the educational literature (Farrell and Hesketh, 2002; Farrell and Vernengo, 2012; Norman et al., 2011; Xu et al., 2010). This paper describes an experiment that introduces students to drug delivery system design, formulation and analysis from an engineering point of view. Students produce compressed tablets of hydrophilic polymer, obtain release data and analyze the rate of release from the tablets. They investigate the effect of drug loading, polymer composition, and polymer molecular weight on the release rate of the drug. Using Excel and Polymath, students compare their results to a mathematical model in order to determine

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the rate controlling mechanism of the release. Through this experiment students explore many concepts and tools that they will use throughout their engineering careers:

- Modeling of and application of chemical engineering principles (mass transport and materials)
- Concentration measurement
- Use of spreadsheets for calculating and graphing
- Identification of questions that guide data analysis
- Interpretation of the significance of results
- Design of solid dosage form drug delivery systems

This experiment has been implemented in the Freshman Engineering Clinic at Rowan University, and the impact on student learning has been evaluated using an instrument that maps concepts from the lesson to course and lab objectives and ABET objectives. While this paper describes the details of a freshman-level experiment, it may easily be adapted to more advanced courses such as materials science or a bioengineering/drug delivery elective course. A materials science course would focus on the changes in the morphological structure of the swellable tablets that occur with time and how this affects the release mechanism. In an elective course in which there is time for a course project, a factorial design could be used to design a formulation that meets a specific clinical challenge.

Rowan's Freshman Engineering Clinic is a required two-semester course sequence taken by all engineering students. Each section has students from all four engineering majors (Chemical, Civil and Environmental, Electrical and Computer, and Mechanical) who work together in multidisciplinary teams. The class meets twice per week: one 50-min class and one 3-h laboratory period. This experiment was part of a biomedical theme that was used to introduce engineering principles related to units and conversions, engineering measurements; analysis and representation of data; and modeling using linear, exponential and power law functions.

2. Background information

2.1. *Pedagogical framework*

The project was conducted in the context of the How People Learn (HPL) framework (Bransford et al., 2000). HPL has been used extensively in designing university bioengineering modules that enhance learning outcomes (Cordray et al., 2009; Greenberg et al., 2003; Roselli and Brophy, 2006; Vernengo and Dahm, 2012). The HPL framework comprises four pillars: knowledge-centeredness, learner-centeredness, assessment-centeredness, and community-centeredness. A learner-centered approach considers the knowledge, skills, attitudes and beliefs that students bring to their educational experience. A knowledge-centered approach promotes conceptual understanding and organization. An assessment-centered course gives frequent opportunities for constructive formative feedback, and a community-centered environment incorporates collaborative learning in a community of peers.

The structure of each laboratory was based on the approach described by Linsenmeier et al. (2008) in which the How People Learn (HPL) framework was applied to a human metabolism laboratory. A similar challenge-based approach was used in a sustainability project at our university previously (Farrell and Cavanagh, 2014a,b). In the drug delivery challenge were asked whether the rate control mechanism of drug from a tablet would change under different drug experimental conditions. Associated with the laboratory experiment was a pre-lab introduction in which students' prior conceptions were uncovered through discussion, and new concepts were connected and built upon this knowledge. The pre-laboratory class session introduced a motivating problem that would be explored during the experiment, helping students to organize their body of knowledge (knowledge-centered); in this case the problem was how to deliver a drug at a controlled rate from a tablet. The assessment-centered leg of the HPL framework was provided by the pre-laboratory quiz as well as lab notebook page reviews. During the pre-laboratory session, the in-class discussion provided formative feedback to both the students and the professor. The professor was able to assess students' pre-existing knowledge, disrupt misconceptions and facilitate students' construction of knowledge through linkages between prior knowledge and new concepts. The lab notebook pages were also reviewed by the instructor before the students left the laboratory, and formative feedback was given regarding accuracy and quality of the investigation and analysis. The course was community-centered in the use of in-class breakout groups for brainstorming and discussion, followed by whole-class discussion. Students worked collaboratively in teams of 3 throughout the project, with the team size chosen according to the recommendations set forth by Oakley et al. (2004).

2.2. *Oral drug delivery systems*

Oral drug administration offers many advantages over other routes of administration, for example, patient compliance, convenience, cost-effective manufacturing, and usually a long shelf life of the drug. Conventional, immediate-release formulations such as a liquid solution can offer effective therapy for many drugs administered orally, but not for all drugs. Among the challenges that confront oral delivery of certain drugs are (1) the need for frequent administration to maintain therapeutic effectiveness which often results in decreased patient compliance and/or unsteady pharmacodynamics responses, (2) acid or enzymatic degradation of some compounds in the stomach (3) side effects associated with peak levels of the drug and (4) location-dependent absorption windows within the GI tract. The advent of drug delivery technology has brought new options in oral delivery that overcome some of these challenges using novel strategies for spatial and temporal control of drug release to control the bioavailability of the drug. Controlled release delivery forms are designed to release a drug at a predetermined rate by maintaining a therapeutic drug level for a specific period of time. Drug targeting systems aim to deliver a drug preferentially to a desired location in the body to optimize its effectiveness and minimize side effects. The design of oral drug delivery systems optimizes the dosage form characteristics relative to the GI environment, considering aspects such as the physiology and of the GI tract and absorptive properties of the GI mucosa, pharmacokinetic considerations and biopharmaceutical considerations. With oral controlled drug delivery systems, the rate and extent of drug absorption is determined by the rate of release from the dosage form, but the bioavailability (fraction of the administered drug that enters the systemic circulation) is often be lower than in oral controlled release formulations, due to a variety of factors. These factors include, for example, incomplete drug release

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