Instructor's Notes on Thin Films Project
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Objectives

This set of experiments is designed to expose students to pharmaceutical engineering concepts over the course of a 15 week semester through the creation, testing, and analysis of dissolvable thin films. General engineering educational objectives are included in the course; this includes concepts such as proper laboratory safety, how to design experiments, and project-based learning. The goal of this set of experiments is to have students develop an interest in the pharmaceutical field in addition to engineering in general. Throughout this course, students will complete assessments to demonstrate their knowledge and give instructors feedback involving the effectiveness of these experiments.

The novelty of this experiment is to have students work with a new drug delivery device that is still being researched for medical and pharmaceutical applications. These strips were initially designed as a candy, but the uses evolved toward more practical applications such as vitamins, breath fresheners, supplements, and more recently for drug delivery. The strips can be loaded with and active pharmaceutical ingredients (API) to treat allergies, dry mouth, mild dementia, and even cancer[1, 2].

By the end of this course, students should be able to create and test dissolvable film strips based on experiments provided to them as well as experiments they designed. The students should be able to explain concepts of drug delivery, pharmaceutical manufacturing, and design of experiments by the end of this course. Students will demonstrate their knowledge gained over the semester by taking a midterm and a final exam. A final presentation can also be used.

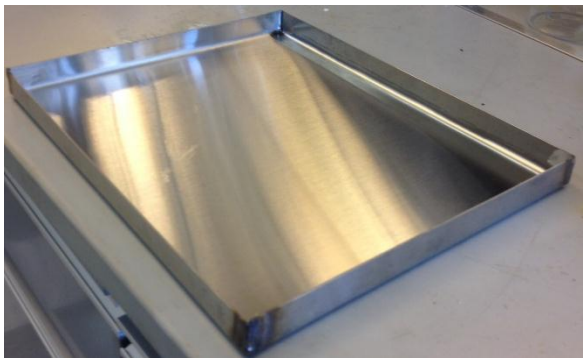
Safety Considerations

MSDS of each chemical used in the lab is documented and can be found in the lab. In addition, the students will be required to research the MSDS of each chemical. The main safety procedure in the laboratory will be to wear eye protection and safety gloves.

Equipment

Apparatus

- Stainless steel container



- Dimension: 12'' x 10'' x ¾''

The stainless steel container will be premade for the students to use. You will have to talk to the machine shop technician to have these made. The steel itself is 304 grade, 0.048 inches wide stainless steel with a vinyl coated brush. The stainless steel can be cut out using a water jet with 0.125 inches of tolerance for each the width and length. The sides can be bent up to form the container's shape, and then the corners will be welded together to seal the container. The edges should be grinded down, so that they will not be sharp.

Procedure Equipment

All chemical materials are available through Fisher Scientific®. All equipment needs are considered standard laboratory material.

- 1000 mL beaker
- Hot plate with mixer
- Magnetic stir bar
- Dropper
- Deionized water
- 3 mL syringe
- 2 Büchner (vacuum) flasks
- Funnel
- Fine mesh screen (approximately 0.0076 in opening)
- Vacuum tubing
- Vacuum source
- Spatula
- Petri Dish
- Analytical scale (Accuracy 0.001)
- Tubing and stoppers

You may need other materials based on the experiment. For more information on the individual needs of an experiment, please consult the instructor's version of the individual laboratory procedure.

Materials

Material	Vendor	Catalog #	Grade
Carboxymethyl Cellulose	Spectrum	CA194	U.S.P.
Sucrose	Spectrum	SU103	N.F.
Poloxamer 188	Spectrum	P1169	N.F.
Citric Acid	Duda Diesel	N/A	U.S.P/F.C.C.
Sodium Lauryl Sulfate	Spectrum	S1332	F.C.C.
Vegetable Glycerol	Duda Diesel	N/A	U.S.P.
Blue Dye	McCormick Culinary	N/A	Commercial
Peppermint Oil	NOW Foods	N/A	Commercial

U.S.P. – United States Pharmacopeia

N.F. – National Formulary

F.C.C. – Food Chemicals Codex

"**USP, NF and FCC**—Chemicals that conform to the requirements of the United States Pharmacopeia (USP), the National Formulary (NF), and the Food Chemicals Codex (FCC). These products are regulated by the Food and Drug Administration. All meet the requirements necessary for their use in pharmaceutical processing and prescription compounding (USP and NF) and for use in food processing operations (FCC)."[3]

Outline

The following is a sample timeline for a course using these sets of experiments. Changes can be made to this outline to better fit any differences in scheduling. Labs can be omitted at the instructor's discretion.

For all of the film labs, blue food dye is used as a substitute for the API and peppermint oil is added for aroma and flavor. However, different dyes and different flavors may be used to add more interest and customization to the labs.

Week 1: Syllabus

Week 2: Lab Tour/ safety

Week 3: Viscosity and Commercial Products Lab

Week 4: Degradation of Dissolvable Strips Lab

Week 5: Creation of Dissolvable Strips Lab

Week 6: Computer Modeling Lab

- You will need to reserve computer space for this lab.

Week 7: Initial versus Final Heights Lab

- This lab should be used in conjunction with the Computer Modeling Lab. This lab has questions whose answers relate back to the Computer Modeling Lab.

Week 8: Midterm

Week 9: Spring Break

Week 10: Hydro-properties Lab

Week 11: D.O.E. Lab #1

Week 12: D.O.E. Lab #1

- Note: You may omit this lab by providing groups with results that we provided. You may need to do this if the schedule does not permit for final examinations and final presentations.

Week 13: D.O.E. Lab #2

Week 14: D.O.E. Lab #2

Week 15: Final Exam/Final Presentations

References

1. Aggarwal Jyoti, Singh Gurpreet, Saini Seema, Rana A.C. "Fast Dissolving Films: A Novel Approach to Oral Drug Delivery." *International Research Journal of Pharmacy* 2011, 2 (12), 69-74.
2. Misao Nishimura et al. "*In vitro* and *in vivo* Characteristics of Prochlorperazine Oral Disintegrating Film." *International Journal of Pharmaceutics* 368 (2009) 98–102.
3. http://www.avantormaterials.com/Pages/Technical/Grade-Definitions.aspx