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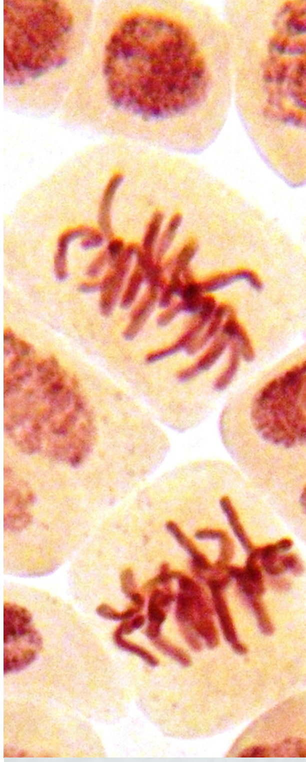

Teacher's Manual

STEM Investigations: Engineer and Explore Your Own Enteric Coated Drugs

IS3401

221 Rochester Street
Avon, NY 14414
Phone: (585) 226-6177
Fax: (585) 226-6919
www.aldon-chem.com

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Next Generation Science Standards

MS-LS1-3. Use argument supported by evidence for how the body is a system of interacting subsystems composed of groups of cells.

[Clarification Statement: Emphasis is on the conceptual understanding that cells form tissues and tissues form organs specialized for particular body functions. Examples could include the interaction of subsystems within a system and the normal functioning of those systems.]

LS1.A: Structure and Function

- In multicellular organisms, the body is a system of multiple interacting subsystems. These subsystems are groups of cells that work together to form tissues and organs that are specialized for particular body functions.

MS-LS1-7. Develop a model to describe how food is rearranged through chemical reactions forming new molecules that support growth and/or release energy as this matter moves through an organism.

[Clarification Statement: Emphasis is on describing that molecules are broken apart and put back together and that in this process, energy is released.]

LS1.C: Organization for Matter and Energy Flow in Organisms

- Within individual organisms, food moves through a series of chemical reactions in which it is broken down and rearranged to form new molecules, to support growth, or to release energy.

MS-ETS1-1. Define the criteria and constraints of a design problem with sufficient precision to ensure a successful solution, taking into account relevant scientific principles and potential impacts on people and the natural environment that may limit possible solutions.

ETS1.A: Defining and Delimiting Engineering Problems

- The more precisely a design task's criteria and constraints can be defined, the more likely it is that the designed solution will be successful. Specification of constraints includes consideration of scientific principles and other relevant knowledge that are likely to limit possible solutions.

MS-ETS1-2. Evaluate competing design solutions using a systematic process to determine how well they meet the criteria and constraints of the problem.

ETS1.B: Developing Possible Solutions

- There are systematic processes for evaluating solutions with respect to how well they meet the criteria and constraints of a problem.

MS-ETS1-3. Analyze data from tests to determine similarities and differences among several design solutions to identify the best characteristics of each that can be combined into a new solution to better meet the criteria for success.

ETS1.B: Developing Possible Solutions

- There are systematic processes for evaluating solutions with respect to how well they meet the criteria and constraints of a problem.
- Sometimes parts of different solutions can be combined to create a solution that is better than any of its predecessors.

ETS1.C: Optimizing the Design Solution

- Although one design may not perform the best across all tests, identifying the characteristics of the design that performed the best in each test can provide useful information for the redesign process—that is, some of those characteristics may be incorporated into the new design.

MS-ETS1-4. Develop a model to generate data for iterative testing and modification of a proposed object, tool, or process such that an optimal design can be achieved.

ETS1.B: Developing Possible Solutions

- A solution needs to be tested, and then modified on the basis of the test results, in order to improve it.
- Models of all kinds are important for testing solutions.

ETS1.C: Optimizing the Design Solution

- The iterative process of testing the most promising solutions and modifying what is proposed on the basis of the test results leads to greater refinement and ultimately to an optimal solution.

HS-LS1-2. Develop and use a model to illustrate the hierarchical organization of interacting systems that provide specific functions within multicellular organisms.

[Clarification Statement: Emphasis is on functions at the organism system level such as nutrient uptake, water delivery, and organism movement in response to neural stimuli. An example of an interacting system could be an artery depending on the proper function of elastic tissue and smooth muscle to regulate and deliver the proper amount of blood within the circulatory system.]

LS1.A: Structure and Function

- Multicellular organisms have a hierarchical structural organization, in which any one system is made up of numerous parts and is itself a component of the next level.

HS-ETS1-2. Design a solution to a complex real-world problem by breaking it down into smaller, more manageable problems that can be solved through engineering.

ETS1.C: Optimizing the Design Solution

- Criteria may need to be broken down into simpler ones that can be approached systematically, and decisions about the priority of certain criteria over others (trade-offs) may be needed.

Aligned to the Next Generation Science Standards (NGSS)*

Engineer and Explore Your Own Enteric Coated Drugs

IS3401

INTRODUCTION

Our digestive system is one of the most important aspects of the everyday function of our bodies. Every little bit of food we eat or anything we ingest in general has to be broken down into nutrients that can be absorbed by the body, which is why it takes hours to fully digest food. In humans, protein must be broken down into amino acids, starches into simple sugars, and fats into fatty acids and glycerol. Even the water in our food and drinks is absorbed into the bloodstream to provide the body with the fluid it needs. This means that our body will try to break down and absorb everything that is ingested, even if it is not a food, such as medication. Many medications can be dangerous if absorbed in the wrong part of the body or if they are absorbed in the wrong dosage. That is why for years scientists and engineers have been trying to perfect the production of medications so they are safe and effective when they enter the digestive system and the human body.

What is the Digestive System?

Simply, the digestive system is a group of organs working together to convert food into energy and basic nutrients to feed the entire body. Food starts at the mouth and passes through a long tube inside the body known as the alimentary canal or the gastrointestinal tract (GI tract). As stated before, every little bit of food we eat or anything we ingest in general has to be broken down in order for any nutrients or, in the case of medications, active ingredients to be absorbed. This process in which food is broken down and converted into substances that can be absorbed and assimilated by the body is known as digestion.

The first step in the human digestive process occurs in the mouth. Food begins to be ground up by the teeth and there is a flow of saliva set in motion by a brain reflex when we sense food or even think about eating. The digestive enzymes in saliva, such as amylase, also start to break down some of the carbohydrates in the food. From here, food is swallowed using muscle movements in the tongue and mouth, moving the food into the throat, or pharynx. A flexible flap of tissue called the epiglottis reflexively closes over the windpipe when we swallow to prevent choking. From the throat, food travels down a muscular tube in the chest called the esophagus. This digestive movement is carried out by waves of involuntary muscle contractions called peristalsis that force food down through the esophagus to the stomach.

The human stomach is a J-shaped, sac-like organ that is hollow and muscular and is one of the principal organs of digestion, located in between the esophagus and the small intestine. The churning and squeezing actions of the stomach break the food into even smaller, digestible pieces and mix it with the gastric acid secreted by the stomach lining. Gastric acid is the main digestive secretion in the stomach and consists of hydrochloric acid, mucin and several enzymes. Glands in the stomach lining produce about 3 quarts of these digestive juices each day. The environment of the stomach needs to be acidic so that food can react with the various enzymes present. The acid also helps to break down food to a certain degree. The acidic stomach environment has a pH of about 1.5, which is due to the low pH of gastric acid. While some nutrients are absorbed in the stomach, most nutrients are absorbed later in the small intestine.

The small intestine is the long, narrow, coiled section of the intestine that extends from the stomach to the beginning of the large intestine. Nutrients from food are absorbed into the bloodstream from the small intestine. In mammals, the small intestine is composed of the duodenum, jejunum and ileum. Food leaves the stomach in the form of a thick liquid called chyme and enters the small intestine. Here, food is mixed with a variety of new excretions including bile. Bile is a bitter, greenish liquid secreted by the liver, which aids in the absorption and digestion of food, especially fats. Bile is alkaline in nature, meaning it is basic, and therefore it neutralizes the gastric acid and chyme, further breaking down the food. It also creates a basic environment in the small intestine with a pH ranging from 7-9. Most of the nutrients your body needs for survival are absorbed from the food during this process. After passing through the small intestine, the remaining food waste passes through the large intestine and eventually out of the body through the rectum and anus.

Engineering Connection

An engineer is someone who uses their understanding of science and math to create things for the benefit of our world and humanity. One specific branch of engineering is biomedical engineering. This field blends traditional engineering techniques with the biological sciences and systems, as well as medicine, to improve the quality of human health and life. Biomedical engineers design artificial body parts, medical devices, diagnostic tools, and medical treatment methods. Some of these devices directly help the injured and infirm, such as prosthetic limbs or insulin pumps. In other cases, these devices help indirectly by simulating different life processes so that researchers can better understand how the body works. This will help them experiment with new treatment ideas and create the best possible therapeutic technologies and devices for certain problems and diseases.

Recently, biomedical engineers created the world's first artificial stomach. It mimics many of the activities that take place in your body and can even throw up! It may seem strange to spend countless hours creating a fake digestive system simply to watch and clean up vomit on occasion. In reality, this machine is expected to be very beneficial to scientists, doctors and pharmacists who want to know more about how our bodies work. What happens to food or medicine after it is swallowed? How does your body absorb food or medicine? This is very important information to know. Biomedical engineers are continually researching and designing new types of medical devices to help doctors and other medical professionals help people. Many of the most revolutionary medical devices were developed by biomedical engineers.

What Are Polymers?

The simple answer to the above question can be found in the word “polymer” itself. Polymer is derived from the Greek words *poly* for many and *meros* meaning parts. So on a basic level, a polymer is something made from many parts. Beyond that, a polymer is actually a macromolecule. Macro is a prefix meaning large, meaning a polymer is a large molecule. What makes a polymer different from other large molecules is that it is constructed from many little molecules linked together which are the same, or similar, in structure. A chain is a good analogy as a chain is composed of many links. The individual links (molecules) are the same and the more links that are hooked together, the larger the chain (macromolecule).

Some polymers are naturally-occurring. For example, cellulose is a naturally occurring substance found in plants that is called a polysaccharide. A saccharide is a sugar, so a polysaccharide is a material composed of many sugars. Other polymers are synthetic, or man-made. Plastics are probably the most familiar example of synthetic polymers. While there are many different types of plastics, they are generally composed of a couple of simpler, smaller molecules that are linked together into larger chains to form a particular plastic.

Sodium Alginate/Shellac

Sodium alginate is a naturally-occurring polymer isolated from seaweed. The alginate chains are composed of sugars so it can also be referred to as a polysaccharide. Sodium alginate may be added to foods as a thickener, used in the preparation of some medications, or found in cosmetics, just to list a few examples of it's many uses. When mixed with water, sodium alginate dissolves and forms a viscous solution. Shellac is a resin secreted by the female lac bug, on trees in the forests of India and Thailand. It is also a natural bioadhesive polymer and is chemically similar to synthetic polymers, and thus can be considered a natural form of plastic. When dissolved in denatured alcohol, shellac yields a coating of good durability and hardness. Because of its acidic properties, shellac-coated pills are often used for a timed enteric release in medications, which will be discussed more in depth later.

Due to the adhesive and viscous properties of shellac and sodium alginate, when a salt such as sodium alginate is added to a solution containing shellac, the alginate molecules undergo cross-linking. Cross-linking is a process in which many polymer molecules are linked, or bound, to each other. The molecules within the shellac react with the alginate molecules and cause cross-linking between the alginate molecules. This results in the formation of a gel. The longer the alginate molecules remain in the shellac solution, the more cross-linking that occurs and therefore the more rigid the gel becomes.

Connecting engineering and the digestive system

As explained before, biomedical engineers are important because they create applications that help us better understand the human body and even try to fix problems. To test certain theories, they often create simulations, which are experiments in which one is imitating the behavior of some situation or process, especially for the purpose of study or experimental testing. Because of its complexity, biomedical engineers have studied the digestive system thoroughly and created many simulations to better understand how it works in order to design medications and other devices that work to their full potential.

One specific simulation that biomedical engineers have performed countless times is a study of the pH levels in the stomach and intestines. An understanding of how these pH levels work has helped engineers design specific medications, such as aspirin, that will not be damaged or cause damage to the digestive system, and also will dissolve in the specific location in which they are needed. One such medication is enteric-coated aspirin. *Enteric* means relating to or occurring in the intestines. Therefore, enteric-coated aspirin is aspirin that has been treated to pass through the stomach unaltered and dissolve in the intestines. Enteric tablet film coatings are designed to be resistant to stomach acid, and will not dissolve until the tablet reaches the small intestine, which has a basic pH of about 7-9. These pH dependant tablet coatings dissolve at a pH of around 5.5-6.0, therefore they can protect the stomach from an acidic active pharmaceutical ingredient (API), protect an acid-sensitive API from gastric fluid, and target delivery of the drug to the intestines. The time required for an enteric-coated dosage form to reach the intestine mostly depends on the presence and type of food in the stomach. It varies from 30 minutes up to 7 hours, with an average time of 6 hours.

Materials used for enteric coatings include fatty acids, waxes, plastics, plant fibers, and polymers such as cellulose acetate phthalate, sodium alginate, and shellac, as well as many others. Surprisingly, much design goes into developing pill tablet coatings and the systems that apply these coatings. Varying the material or thickness of a coating can dramatically affect a medication's effect on the body. For example, different ratios and combinations of polymers such as sodium alginate and shellac can affect how fast the body reacts with the coating and medication. The combination of alginate and shellac result in a coating showing “enteric” characteristics, which neither material showed independently. Engineers play an integral role in the process of finding a “perfect” ratio to create better medications for specific purposes, from developing and testing chemicals for coatings to designing the complex systems used to mass produce uniformly-coated pills.

Objectives

- Define simulation and explain its importance in the science and engineering fields in regards to testing the reactions in the human body.
- List several ways in which engineers can directly and indirectly help people with medical problems.
- Learn the basic structures and pathway of the digestive system.
- Understand the different functions of the stomach and the small intestine in regards to digestion.
- Investigate how the properties of different enteric coatings react in different sections of the digestive system.
- Explore the purpose of an enteric coating and make a simulated “coating."
- Engineer a coating most suitable for certain pharmaceutical needs.

Materials Included in the Kit

2	Enteric-coated aspirin tablets
2	Uncoated aspirin tablets
50	Plastic cups
30	Plastic pipettes
45	Plastic beads
100	Cover slips
15	Well plates
200 mL	99% Isopropyl Alcohol
34 g	Shellac dry flakes
4 g	Sodium alginate
2x25mL	Hydrochloric acid,10M
150ml	Sodium hydroxide, 10M

Materials Needed but not Supplied

Electronic balance
Graduated cylinders
Beakers
Stirring rods (or similar)
Distilled (or deionized) water
Stopwatch

Safety

Goggles
Gloves
Lab apron

Pre-Lab Preparation

Do not prepare the sodium alginate more than three days prior to performing the exercise. If the solutions are prepared more than a day prior to performing the exercise store refrigerated until needed. Remove the solutions far enough in advance to allow them to come up to room temperature prior to performing the exercise.

Prepare 1.0M Sodium Hydroxide

1. In a large beaker, or similar, add approximately 1000ml of distilled or deionized water.
2. While stirring, SLOWLY add the entire contents of the bottle of 10M sodium hydroxide.
3. Using distilled or deionized water bring the volume of the solution up to 1500ml.

Prepare 1.0M Hydrochloric Acid

1. In a large beaker, or similar, add approximately 300ml of distilled or deionized water.
2. While stirring, SLOWLY add the entire contents of both bottles of 10M hydrochloric acid.
3. Using distilled or deionized water bring the volume of the solution up to 500ml.

Prepare 2% Sodium Alginate Solution

1. Add 200ml of distilled or deionized water to a beaker, place on a stir plate, and set stirring to medium. Add the entire contents of the bottle containing the sodium alginate powder to the beaker. Add the contents of the bottle slowly while stirring to prevent the formation of clumps.
2. Mix until completely dissolved.

Note: *The sodium alginate takes some time to fully dissolve. Be sure to prepare far enough in advance prior to performing the activity. Heating the solution to approximately 60-70 degrees C will reduce the amount of time required to prepare the solution.*

Prepare Shellac Solution

1. Add the 99% isopropyl alcohol to a beaker, place on a stir plate, and set stirring to medium. Add the entire contents of the bottle containing the shellac flakes to the beaker.
2. Mix until completely dissolved.

Note: *The shellac takes some time to fully dissolve. Be sure to prepare far enough in advance prior to performing the activity.*

Prelab Demonstration:

After introducing what engineers do and what simulations are, ask students to brainstorm and come up with examples of specific parts of the body that biomedical engineers might want to simulate in order to learn more about how the human body works. Possible examples include:

1. Simulating blood flow around a blocked artery
2. Simulating the digestion of food or medication
3. Simulating the absorption of a poison or harmful substance through skin
4. Simulating the mending of a broken bone or a healing wound
5. Simulating how the heart pumps blood, how the lungs move air, or how any other specific body system works start to finish

After this exercise, introduce the digestive system as well as enteric coatings on medications and demonstrate how a biomedical engineer might use simulations to better understand how medication, specifically aspirin, is processed in the body. Aspirin has an irritant effect on the stomach. However, by coating it with an enteric coating that can not dissolve in the low pH of the stomach (1.5 - 3), the drug will not be digested until after it has passed through the stomach and into the small intestine. This will protect the gastric mucosa in the stomach from the irritating effects of the aspirin. Since most enteric coatings dissolve at a pH of around 5.5, when the drug reaches the neutral or alkaline environment of the small intestine, the coating will breakdown, and then the active ingredients of the actual aspirin can also dissolve and become available for absorption into the bloodstream.

To help simulate this create a simple model of the digestive system. The stomach is represented by a cup filled with hydrochloric acid and the small intestine by a cup filled with sodium hydroxide. We use hydrochloric acid to represent the stomach because it is an acid similar to the gastric acid that breaks down food in the stomach. We use sodium hydroxide to represent the small intestine because it is a base similar to bile, which aids in absorption and digestion in the small intestine.

Materials Needed:

1 uncoated aspirin tablet
1 enteric-coated aspirin tablet
2 clear plastic cups
20 mL hydrochloric acid 1.0M
20 mL sodium hydroxide 1.0M

Demo procedure:

1. Fill a clear plastic cup with 20 mL of hydrochloric acid. Fill a second clear plastic cup with 20 mL sodium hydroxide.
2. Show students the difference between the regular, uncoated aspirin tablet and the enteric-coated aspirin tablet. Then drop both tablets into the cup containing hydrochloric acid.
3. Explain that this represents the digestion that occurs in our stomachs, because the acidity of hydrochloric acid is similar to that of stomach acid. Expect the uncoated aspirin tablet to dissolve in about 10 seconds, and the enteric-coated tablet to remain relatively unchanged.
4. After a short amount of time has passed, and it is evident that the enteric-coated aspirin is not going to dissolve in the hydrochloric acid, take it out and place it in the cup of sodium hydroxide. Explain that this represents the movement of broken down food and the gastric acid mix from the stomach to the small intestine.
5. Carefully swirl the sodium hydroxide solution in the plastic cup, or stir using a stirring rod. The outside coating of the aspirin tablet should begin to slowly dissolve as the acidic coating reacts with the basic sodium hydroxide. Continue to stir or swirl the solution every 30-60 seconds until the outside coating has fully dissolved or separated itself from the tablet (it may take up to 10 minutes for the coating to fully dissolve/separate). Explain that the sodium hydroxide represents an environment similar to that of the small intestine.

Pre-lab Questions:

1. How is this demonstration similar to the human digestive system?

This demonstation shows a pill dissolving, like what would happen in the digestive system. The hydrochloric acid is similar and acts the same as the stomach and the stomach's gastic acid. The sodium hydroxide is similar and acts the same as the small intestine and the bile it contains.

2. After watching this demonstration, where in the body would you expect each tablet to be most likely to dissolve? And why?

Expect the uncoated aspirin to dissolve in the stomach in the acidic environment; expect the coated aspirin to not dissolve in the stomach, but later, past the stomach, in the small intestine.

3. Why might it be a good idea to test new medicines in a simulated environment rather than on a real person?

If unsure of the results, it is never a good idea to test medications on a human as they could cause harm. For example, if testing a new enteric-coated aspirin, if it does not dissolve in the small intestine like it is intended and it dissolves somewhere else in the digestive system, the wall of the digestive system could be damaged from the active pharmaceutical ingredient (API), or an acid-sensitive API

in the pill could be damaged from gastric fluid or other fluids in the body. Either way

Procedure

Part I: Where is an Enteric-Coated Pill Digested?

Materials needed per group

3 plastic cups
2 plastic pipettes
3 plastic beads
4-5 cover slips
1 well plate
10 ml 2% sodium alginate solution
10 ml 17% shellac solution
20 ml hydrochloric acid 1.0M
80 ml sodium hydroxide 1.0M

Shared Materials

Graduated cylinders
Beakers
Distilled water
Stopwatch

Safety

Goggles
Gloves
Lab apron

As observed in the pre-lab demonstration, an enteric-coated pill acts differently than a normal pill due to its coating. In this part of the lab, you will create a simulated enteric-coated “pill” and observe how it acts in different parts of the digestive system.

1. Using a graduated cylinder, measure 10ml of 2% sodium alginate solution and place it in a beaker.

2. Using a graduated cylinder, measure 10ml 17% shellac solution and place it in another beaker.

3. Place your 3 beads in your well plate, separating them into 3 different wells.

4. Using one of your pipettes, add 5 drops of the 17% shellac solution to each of the 3 wells containing a bead.

5. Using your other pipette, add 5 drops of the 2% sodium alginate solution on top of the bead and shellac solution to each of the 3 wells containing a bead.

6. Observe what is happening to the sodium alginate as it is placed in the shellac solution.

7. Record your observations in the Data Analysis section of the lab.

8. Allow the mixture to harden into a coating around the bead for about 5 minutes, or until it is noticeably solidified.

9. Using graduated cylinders, measure out 20ml of 1.0 M hydrochloric acid, 20ml of distilled water, and 20ml of 1.0 M sodium hydroxide and pour these into your three separate plastic cups.

10. Pick up each bead, and with your thumb and forefinger, roll the bead around so the bead is coated equally all over.

11. Place a bead in each of the three plastic cups containing hydrochloric acid, distilled water, and sodium hydroxide.

12. Observe what is happening to the beads in each of the three liquids for 5 minutes, swirling the cups every 30 seconds.

13. Record your observations every 30 seconds in the Data Analysis section of the lab.

14. Dispose of your coated beads and rinse out the three plastic cups, drying them thoroughly for use in the next part of the lab.

Note to Instructor: *An actual enteric pill in the digestive system does not take 5 minutes to dissolve, the swirling is just to speed up the process for the purpose of this lab. After this amount of time, the enteric coated "pill" that students created should not dissolve at all in the acid, should dissolve slightly in the neutral water, and should dissolve almost completely in the base. In this lab, the shellac coating is often thick, so it may only fall off in the base instead of completely dissolve like the actual pill did in the prelab demonstation.*

Part II: Engineer the Best Pill

Now that you understand how an enteric-coated pill is created and how it works in the digestive system, you will focus on the small intestine. The objective of this part of the lab is to engineer your own shellac based enteric-coating that will dissolve in the small intestine, and once it enters the small intestine, it will dissolve between 5 to 6 minutes, no sooner, no later. For the purpose of this lab, you will test your different coatings on coverslips.

1. Using a graduated cylinder, measure out 20 ml of sodium hydroxide into each of your three plastic cups. You will use these to test your coating.

2. Using the same beakers of shellac and sodium alginate and their respective plastic pipettes from part 1, pipette different amount combinations of shellac and sodium alginate onto your coverslips, creating several ratios. Create ratios that you think will create a coating that will dissolve in 5 to 6 minutes.

3. Allow your coverslips to dry for about 5 minutes, or until your different coatings have all fully hardened.

4. Place the coverslips in the plastic cups containing sodium hydroxide and start your stopwatch. Observe how your different coating ratios react to the sodium hydroxide.

5. Record your observations for each of your coating ratios every 30 seconds until all of your coatings have dissolved or until time has reached 8 minutes.

6. Clean up all materials according to your instructor. Be sure to wash your hands before leaving the lab.

Note to Instructor: *The point of this part of the lab is for students to engineer an enteric coating that will dissolve in between 5-6 minutes after entering the small intestine (in this lab the solution of sodium hydroxide). Students should experiment with different ratios of shellac to sodium alginate to create a coating that does not dissolve before this time frame but is completely separated from the coverslip by the end of this time frame. A ratio of 20% shellac or below should dissolve within a minute and a ratio of 90% shellac or above should be completely intact for up to 10 minutes. A ratio of 50% shellac should separate from the coverslip in about 4 to 5 minutes and a ratio of 70% shellac should separate from the coverslip in about 6 minutes.*

Name:	Instructor:
Date:	Class/Lab Section:

DATA ANALYSIS

Part I: Where is an Enteric-Coated Pill Digested?

Observations (Sodium Alginate):

Time(min)	Hydrochloric Acid	Distilled Water	Sodium Hydroxide
.5			
1			
1.5			
2			
2.5			
3			
3.5			
4			
4.5			
5			

Name:	Instructor:
Date:	Class/Lab Section:

DATA ANALYSIS

Part II: Engineer the Best Pill

Time(min)	Ratio #1 ______	Ratio #2 ______	Ratio #3 _____
.5			
1			
1.5			
2			
2.5			
3			
3.5			
4			
4.5			
5			
5.5			
6			
6.5			
7			
7.5			
8			

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Name:	Instructor:
Date:	Class/Lab Section:

DATA ANALYSIS

Questions

1. Based on your observations, what reaction is occuring when sodium alginate and shellac mix? Why does this happen?

Crosslinking. This happens because the molecules within the shellac react with the alginate molecules and causes cross-linking between the alginate molecules. Shellac is a material highly likely to undergo crosslinking because it is a natural bioadhesive polymer and sodium alginate is because it is viscous in solution. Therefore, because of the adhesive and viscous properties of shellac and sodium alginate, crosslinking occurs and a gel is formed.

2. In part I, what do each of the three liquids you tested your coated beads in represent in respect to the digestive system? Explain how your beads reacted in each of these liquids and how this is similar to the digestion of an enteric-coated pill in regards to pH.

The hydrochloric acid represents the acidic environment of the stomach and gastric acid, the distilled water represents a neutral environment in the digestive system (such as the jejunum or large intestine), and the sodium hydroxide represents the basic environment of the small intesine and bile. The coated bead should not have reacted at all in the hydrochloric acid (no change the entire time), it should have reacted slightly in the distilled water (the coating might turn slightly red, small parts might fall off, but is still intact), and it should have almost completely reacted in the sodium hydroxide (the coating should have turned red within seconds, and over time break up more so that the whole coating detached from the bead). This is similar to the digestive system because enteric tablet film coatings are designed to be resistant to stomach acid (pH of 1.5), and will not dissolve until the tablet reaches the small intestine, which has a basic pH of about 7-9. These pH dependant tablet coatings dissolve at a pH of around 5.5-6.0, which is why there is some reaction in a neutral environment such as distilled water which has a pH of around 7.

Name:	Instructor:
Date:	Class/Lab Section:

DATA ANALYSIS

3. Define enteric. Why would you want a pill to be coated so that it will dissolve in a specific organ at a certain time?

Enteric means relating to or occurring in the intestines. Therefore, enteric-coated aspirin is aspirin that will not dissolve until in the intestines. This is good for situations where there is an acidic active pharmaceutical ingredient (API), which would affect the stomach lining. Another possibility is if the API is acid-sensitive, the coating will protect the API from being attacked by the gastric fluid in the stomach. Time is important because depending on the materials used for the coating, different absorption sites in the small intestive can be targeted to make the medication effects more effective and precise.

4. What ratio of shellac to sodium alginate worked best? Why?

Due to possible error in the lab, accept any answers in the range of 55-75% shellac. Shellac has acidic properties and is very durable and easily hardens in denatured alcohol. So, the more shellac there is, the longer it will take for the durable coating to break down. Also, too much sodium alginate cannot be used or else not enough crosslinking will occur (you need some shellac to crosslink) and the coating will not harden enough, making it easy to break down.