

## Tablet Statistical Analysis Lab – Instructor’s Version

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Date of Experiment:

### OBJECTIVES

- Students will perform a basic statistical analysis applied to an over-the-counter drug
- Students will learn about pharmaceutical engineering, including key terms and concepts

### INTRODUCTION

In the pharmaceutical industry, drugs are manufactured, produced, and marketed for therapeutic use. The industry has been one of the highest earning industries of the last decade, with 791 billion dollars in worldwide sales in 2010. The majority of these sales were in North American companies, totaling 335 billion dollars<sup>1</sup>.

A pharmaceutical product is not just one specific chemical, but many chemicals combined together to make a final product. Tablets, which the students will be working with in this lab, are composed of a few chemicals mixed together and then compressed. The therapeutic ingredient is known as the active pharmaceutical ingredient (API). The API is what causes the desired effect of the drug. The rest of the ingredients that remain inert are known as the excipients.

Excipients can have different functions, which is why there are sub-categories of excipients found in pharmaceuticals. For example, a filler is a type of excipient used to make up the volume of a medicine so that it can be taken in the form of a pill. In some cases, excipients known as binders are used to act as glue and make sure the ingredients stick together. Lubricants and glidants are used in combination since they reduce wall friction and interparticle friction, respectively. This prevents the tablet from clumping and sticking to equipment. Excipients may also be flavors or colors, which will mask any unpleasant tastes that the other ingredients have and improve the appearance of the product.

In any engineering field, statistical analysis is an important tool. In the pharmaceutical industry, statistics can be used in various ways. For example, statisticians use statistics to create trials for experimental drugs. A chemical engineer might use statistics in order to figure out a new process that creates more product for less. In these cases, statistics play an important role in analyzing data in order to come to a conclusion.

In this lab, the students will be looking at two different over the counter medications that contain the API ibuprofen, a known pain reliever and fever reducer. The rest of the inactive ingredients in the tablets are binders, fillers, or any other kind of excipient. This lab will consist of a statistical analysis on the difference in mass between the ibuprofen tablets, and also the difference in the mass of a generic brand and the trademarked brand Advil®. An introduction to creating a flow diagram will also be incorporated into this experiment.

## MATERIALS NEEDED

- Container of Advil® tablets (minimum of 10 tablets)
- Container of generic ibuprofen tablets (minimum of 10 tablets)
- Weigh boat
- Tweezers
- Bench scale (accurate up to 1/1,000 g).

## SAFETY CONSIDERATIONS

Always wear laboratory safety glasses when working in the lab.

## PROCEDURE

1. Make sure that the bench scale is turned on, and that the scale is set to measure weight in grams.
2. Take the Advil package and note where they list the active and inactive ingredients. Record all of the ingredients that are listed as non-active ingredients.

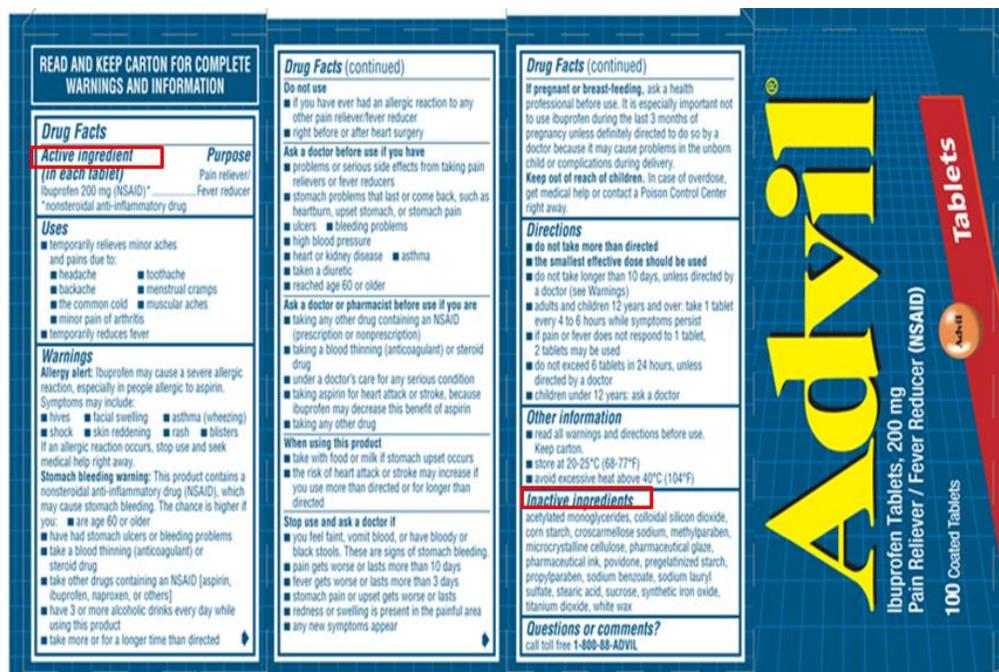


Figure 1. Where to find the active and inactive ingredients

3. Place the weigh boat on the bench scale. Record the weight, and then tare the instrument. The bench scale should now read 0 grams.
4. Open the box of Advil<sup>®</sup>, and with tweezers, place one tablet in the weigh boat. You may use the table provided below, but you should also record your findings in your lab notebook.
5. Once the mass has been recorded, tare the scale again.
6. Repeat the two previous steps until you have weighed ten Advil tablets. Empty your weigh boat, place it back on the bench scale, and tare the instrument. You should now have the Advil<sup>®</sup> portion of the data table filled out.
7. Now, look at your generic brand. Record all the non-active ingredients.
8. Open the container, and using the tweezers, place one tablet in the weigh boat. Once again, tare the instrument after recording the mass.
9. Repeat until you have collected ten measurements of the generic brand. You should now have the generic brand portion of the data table filled out.
10. Once all measurements have been completed, dispose of the measured tablets and the weigh boats. Return the containers to their respective boxes.

**Table 1. Empty table for recording the mass of the tablets**

Trial Number	Name Brand Mass (grams)	Generic Brand Mass (grams)
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

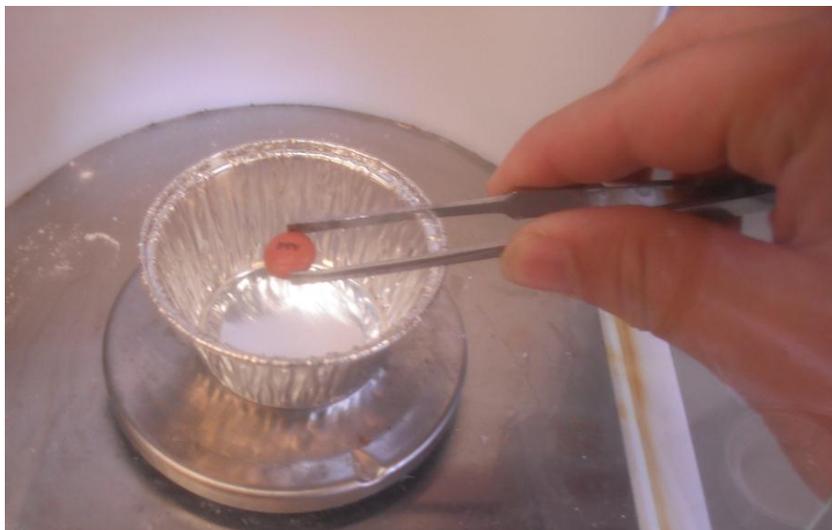


Figure 2. Proper technique for weighing tablets

## STATISTICAL ANALYSIS

You will need your calculator to do the following calculations. You must show all work to receive credit.

1. First, take the average of each set of data. Use the equation below, with  $i$  being the trial number (given in the data table),  $n$  being the total number of trials (10), and  $x$  being the mass recorded for the specific trial number. Record this in your lab notebook and include in your results.

$$\bar{x} = \frac{\sum_{i=1}^{10} x_i}{n} \quad (1)$$

2. Standard deviation is defined as the variation from the average. In other words, it is the average of the difference between each value obtained and the average value obtained. So, in this case, it would be important to know the standard deviation of the mass of the tablets for the trademarked brand and also the generic brand. To calculate the standard deviation, use the equation below, with  $i$  once again being the trial number,  $n$  being the total number of trials, and  $x$  being the mass recorded.

$$\sigma = \sqrt{\frac{\sum_{i=1}^{10} (|x_i - \bar{x}|^2)}{n}} \quad (2)$$

3. Now, we will look for any outliers in our data. An outlier can be defined as a data point significantly different than the mean of the data. In other words, an outlier is a datum point that significantly distant from other points. To do this, find the median data point in both sets of data. To find the median, list the data in order from lowest value to highest value, and find the point that resides in the middle. If you have an even number of data points, the median is found by averaging the two middle data points. From now on, this median (the median of the entire data set) is known as **overall median**. From here, find the first and third quartiles. These values are found by splitting the list of data in half. In this case, we now have two sets of five data points; one with the lower data points, and the other with the higher data points. The **first quartile** can be found by taking the median of the lower data points. The **third quartile** is the median of the higher data points. Lastly, we state that the overall median is the **second quartile**. Using the equations below, calculate if any of your data points are *outliers*.

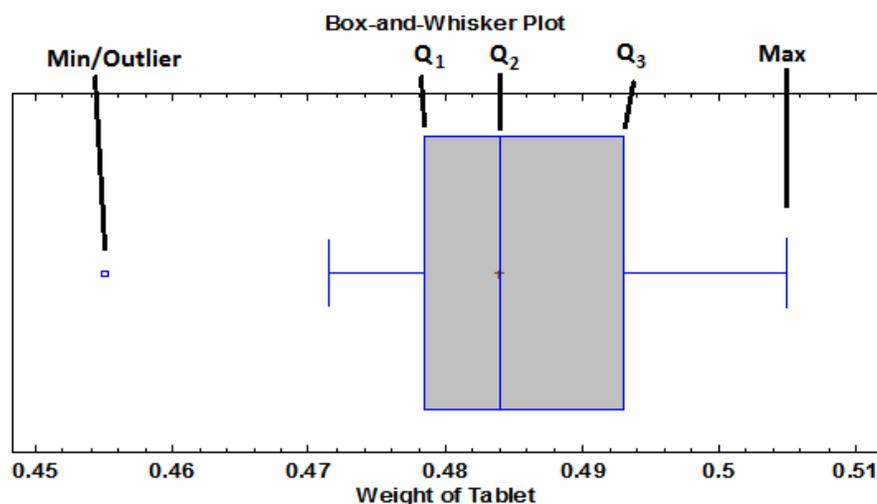
$$O_L = Q_1 - 1.5(Q_3 - Q_1) \quad (3)$$

Where,  $O_L$  is the low-value outlier cutoff,  $Q_1$  is the first quartile, and  $Q_3$  is the third quartile.

$$O_H = Q_3 + 1.5(Q_3 - Q_1) \quad (4)$$

Where,  $O_H$  is the high-value outlier cutoff,  $Q_3$  is the third quartile, and  $Q_1$  is the first quartile.

Are any weights you measured above  $O_H$  or below  $O_L$ ? If so, they are outliers. Arrange your findings in a box-and-whisker plot as described in the diagram below.



**Figure 3: A typical box-and-whisker plot.**

## RESULTS

Be sure to record all findings for this lab. Answer any questions that might have been asked in the procedure section of the lab.

## QUESTIONS

1. During the statistical analysis section, you were asked to find the standard deviation of the trademarked and the generic brand. Explain what this value tells you. Compare the two standard deviations you calculated, and determine what this means.
  
2. Now, you will determine whether or not these two brands are different from each other. To do this, you will use a statistical analysis technique known as an F-test. An F-test is used to compare two samples. This test can become difficult if the samples are not done in a similar manner. In this case, the number of measurements taken in each sample is similar, so this makes the F-test much simpler. To conduct an F-test, do the following:
  - a. Find the variance of the two samples. The variance of a sample is defined as the average of the squared difference of the means. An equation of what this would look like is shown below:

$$\text{Variance} = s = \frac{\text{sum of the squared differences from the average value}}{\text{number of measurements taken}} \quad (5)$$

$$s = \frac{\sum(x_i - \bar{x})^2}{n} \quad (6)$$

Another way of looking at the variance is it's relation to the standard deviation of a sample. The relation of the variance of a sample to the standard deviation of a sample is shown below:

$$s = \sigma^2 \quad (7)$$

If you compare the equation of variance to the equation of standard deviation, you can see how this is true. Use the relation between standard deviation and variance to find a value of variance for the two samples.

- b. Now, find the F-value for your experiment. To find your F-value, use the following equation:

$$F_{exp} = \frac{s_1^2}{s_2^2} \quad (8)$$

For this equation, the variance in the numerator "s<sub>1</sub>" has to be the larger of the two variances.

- c. Now, compare this value to a critical value. This is known as the F-critical value. The F-critical value is dependent on the number of measurements taken in each sample, and the percent confidence that is desired. The percent confidence is another way of saying how accurate one wishes to be in their experiments. The higher the percent confidence, the more certain one is in their experiments. In this case, you will use a standard percent confidence of 95%. So, you will need an F-critical value which corresponds to a 95% percent confidence, a variance based on 10 measurements in the numerator, and a variance based on 10 measurements in the denominator. Usually, these would be looked up in tables, as seen in appendix A Figure 1. However, below you will find an critical F value for your calculations<sup>3</sup>:

$$F_{crit} = 3.18$$

If the F value you calculated in part b of this problem is larger than the critical value given, then the two samples are significantly different. If the F value you calculated in part c of this problem is smaller than the critical value given, then the two samples are not significantly different. State whether or not there is significant difference between the two samples .

3. Research suggests that one ibuprofen tablet should have a mass of 480 mg.<sup>2</sup> Do you think there is significant difference between the values you obtained and this literature value for a typical formulation? To answer this, you will use another statistical test known as the t-test. There are several different types of t-tests used in statistics. In this case, you will be using a one-sample t-test, which compares a single mean to a fixed value. So for this test, the fixed value will be the 480 mg. You will conduct a t-test on both samples. In order to conduct this analysis, do the following:

- a. For a t-test, you will need to find a t-value. The t-value for an experiment relates the average, standard deviation, and number of measurements to a given value. Using the symbols found previously in this experiment, the equation for the t-value is as follows:

$$t_{exp} = \left| \frac{\bar{x} - \mu_o}{\frac{\sigma}{\sqrt{n}}} \right| \quad (9)$$

In this case,  $\mu_o$  will be the mass found in research (480 mg).

- b. You will now compare this value to a critical value. This is known as the critical t-value. Like the F-critical value, the critical t-value is dependent on the percent confidence that is desired and the number of measurements taken in the sample. Again, you will use a percent confidence of 95%. For an example of a t-Table, see Appendix A Figure 2. The critical t-value you will be using is given below<sup>3</sup>:

$$t_{crit} = 2.262$$

Just like with the F-test, if the critical t-value is higher than the value obtained earlier, then there is no difference between your sample and the value from literature. If the t-value calculated earlier is higher than the critical t-value, then there is a significant difference between the sample

and the value obtained from literature. State whether or not there is significant difference between the value obtained from experiments and the value obtained from literature.

- c. Repeat this process for whichever sample you did not already conduct the analysis on.
4. It has been estimated that the world production of ibuprofen is in the vicinity of 15,000 tons per year.<sup>4</sup> It has also been estimated that the average price for one ibuprofen tablet is roughly 0.12 USD.<sup>5</sup> Using this information, calculate the total price of ibuprofen production for a year.
5. Remember that you listed the inactive ingredients from each of the brands. Research the first three ingredients from both brands and state what type of excipient you believe them to be (i.e. filler, preservative, lubricant, etc.).
6. It is your first day on the job working for Pfizer and you are told to do an experiment on the Advil production line. A new tablet press has been installed and your boss wants to know if it is producing tablets with consistent weight. To start your experiment, you pull a sample of 20 tablets off of the line and weigh them. The data is arranged in a table below. Your boss tells you that each pill must be 90% to 110% of the mean tablet size, which is 0.485 g. Do any pills in your sample fall outside of these bounds? Furthermore, did you find any outliers in your sample? What does this say about the consistency of the new pill press?

**Table 2: Experimental data from production line**

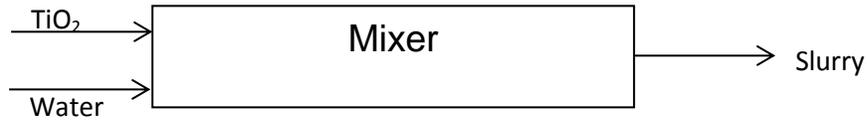
<b>Advil Sample - 20 Tablet weights (g)</b>			
0.4850	0.5435	0.4686	0.4837
0.5198	0.4448	0.5211	0.5895
0.5048	0.4668	0.4863	0.5227
0.4857	0.4465	0.4217	0.4662
0.4786	0.4835	0.4481	0.5101

7. You will now have an introduction to creating process flow diagrams. These diagrams are an important part of engineering, as they are used in most plants. A process flow diagram indicates the major equipment used in a process. In this case, a box with a label will be acceptable as a piece of equipment. An example is shown below:

A heater heats water from 10°C to 50°C:



If you have more than one stream entering or exiting a process, multiple lines can be drawn. For example, if a mixer blends water and titanium dioxide to make a slurry the process flow diagram would look like:



- a. Make a process flow diagram for the creation of the ibuprofen tablets as described by the steps below:
  - i. Mix the powder (maize starch) for 15 minutes at high speed. Add 10.67 g of cold water and check weight (theoretical weight, 58.00g). If required adjust with hot water. Record the quantity of extra water added.
  - ii. Mix this binding solution with Mixture 1 (Ibuprofen and maize starch).
  - iii. Collect and spread the granules onto the trays, one third the thickness of the tray.
  - iv. Load the trolley into the oven and dry the granules in the trays and change the position of the trays for uniform drying.
  - v. Mix stearic acid and corn starch separately and add to the granules before sending them to a compressor. Compress into 330-mg tablets, using 10-mm convex punches at 4 to 9 kPa.
  - vi. Put the tablets into the coating and rolling pan.
- b. Make another process flow diagram that shows the coating of the ibuprofen tablets as described by the steps below:
  - i. Make sugar coating:
    1. Heat 72.0 g of item 6 (purified water) in mixer to boiling.
    2. Dissolve 168.0g of item 4 (sucrose) and then cool to 25°C.
    3. Filter the syrup through a 180- $\mu$ m stainless steel sieve.

4. Dispense item 5 (titanium dioxide) into the sugar syrup from the previous step and homogenize.
  5. Check for evenness of the dispersion.
- ii. Apply Sugar Coating to tablets in coating pan by rolling tablets and slowly adding the sugar solution over 30 minutes.
  - iii. Make gloss solution
    1. Melt items 1 - 3 (bee's wax, polyethylene glycol, carnauba wax) in a steam-heated vessel by gentle heating to 70°C or in a stainless steel container on a hotplate heater.
    2. Mix thoroughly.
    3. Pass the mixture through a homogenizer.
    4. Store the polishing emulsion in a closed container at room temperature.
  - iv. Apply gloss solution to tablets in coating pan by rolling tablets. Once the desired polish appears, stop rolling the pan.
  - v. Dry the tablets in the pan at 30°C for 30 minutes. Final tablet weight should be 480 mg.

#### ANSWER KEY

#### PROCEDURE

2. Take the Advil package and note where they list the active and inactive ingredients. Record all of the ingredients that are listed as non-active ingredients  
**Ans:** On the container of a bottle of Advil purchased November 2012, the inactive ingredients listed were acetylated monoglycerides, colloidal silicon dioxide, corn starch, croscarmellose sodium, methylparaben, microcrystalline cellulose, pharmaceutical glaze, pharmaceutical ink, povidone, pregelatinized starch, propylparaben, sodium benzoate, sodium lauryl sulfate, stearic acid, sucrose, synthetic iron oxide, titanium dioxide, and white wax.
7. Now, look at your generic brand. Record all the non-active ingredients.  
**Ans:** This answer will vary depending on the generic brand that was purchased for this experiment. For a bottle of CVS Pharmacy® brand ibuprofen tablets purchased November 2012, the non-active ingredients are carnauba wax, corn starch, and fumed silica gel, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, red iron oxide, sodium starch glycolate, stearic acid, and titanium oxide.

## STATISTICAL ANALYSIS

These calculations were done using the following table of data.

**Table 3. Sample data used for the answer key section of this guide.**

Trial Number	Name Brand Mass (grams)	Generic Brand Mass (grams)
1	0.4784	0.3354
2	0.4837	0.3300
3	0.4715	0.3296
4	0.5019	0.3280
5	0.4840	0.3383
6	0.4842	0.3284
7	0.5050	0.3307
8	0.4930	0.3365
9	0.4804	0.3272
10	0.4845	0.3362

1. First, take the average of each set of data. Record this in your lab notebook and include in your results.

**Ans:** The average for the Advil data was found to be 0.487g. The average for the generic brand was found to be 0.332g.

2. Standard deviation is defined as the variation from the average. In other words, it is the average of the difference between each value obtained and the average value obtained. So, in this case, it would be important to know the standard deviation of the mass of the tablets for the trademarked brand and also the generic brand.

**Ans:** The standard deviation for the Advil data was found to be 0.010g. The standard deviation of the generic brand was found to be 0.004g.

3. Are any weights you measured above  $O_H$  or below  $O_L$ ? If so, they are outliers. Arrange your findings in a box-and-whisker plot as described in the diagram below. (*Omitted from solutions, see above for diagram.*)

**Ans:** FOR THE ADVIL<sup>®</sup> BRAND:

$$Q_2 = \frac{(0.4840+0.4842)}{2} = 0.4841 \text{ g} ; Q_3 = 0.4930 \text{ g} ; Q_1 = 0.4804 \text{ g}$$

$$O_L = 0.4804 - 1.5(0.4930 - 0.4804) = 0.4615 \text{ g}$$

Since the minimum value in this data set is 0.4715 g, a low-value outlier does not exist.

$$O_H = 0.4930 + 1.5(0.4930 - 0.4804) = 0.5119 \text{ g}$$

Again, all data points are less than this number, so a high-value outlier does not exist. A Box-and-Whisker plot of this is shown below.

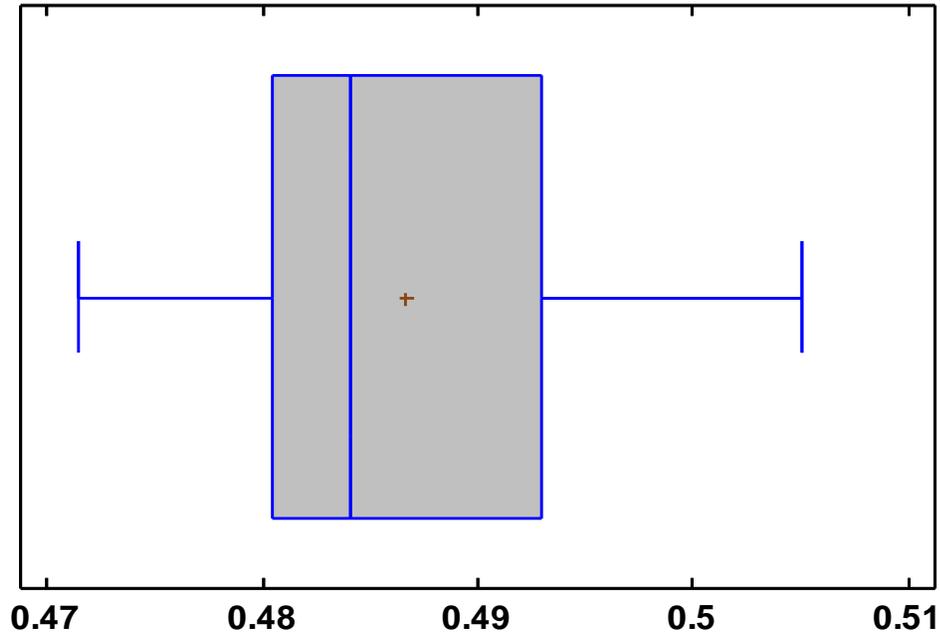


Figure 4. Box-and-Whisker plot for the Advil® brand. The x-axis here is the mass of the ibuprofen tablets in grams.

FOR THE GENERIC BRAND:

$$Q_2 = \frac{(0.3307+0.3300)}{2} = 0.3304 \text{ g} ; Q_3 = 0.3362 \text{ g} ; Q_1 = 0.3284 \text{ g}$$

$$O_L = 0.3284 - 1.5(0.3362 - 0.3284) = 0.3167 \text{ g}$$

Since the minimum value in this data set is 0.3272 g, a low-value outlier does not exist.

$$O_H = 0.3362 + 1.5(0.3362 - 0.3284) = 0.3479 \text{ g}$$

Again, all data points are less than this number, so a high-value outlier does not exist. The Box-and-Whisker plot is shown below.

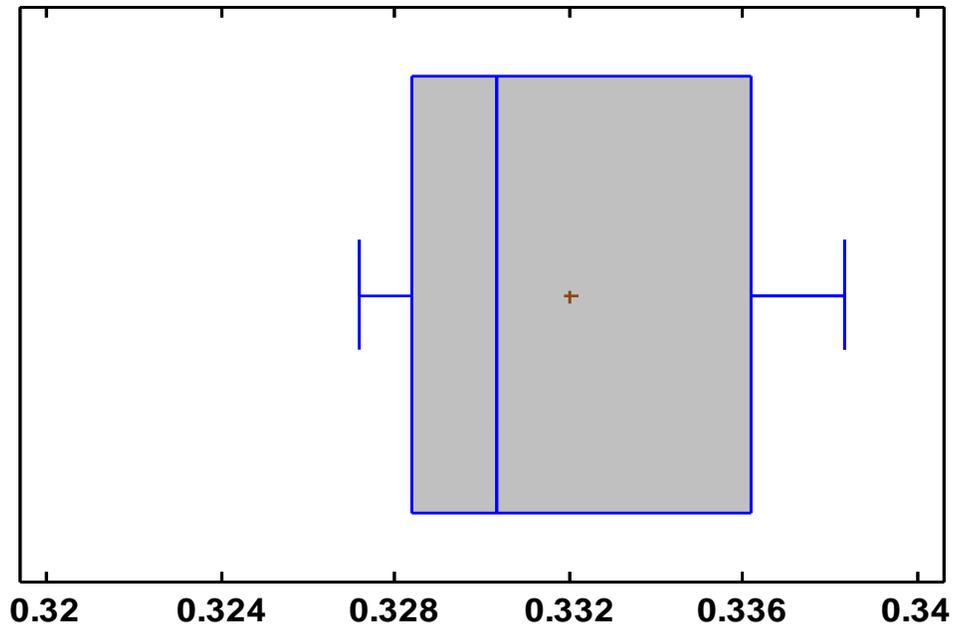


Figure 5. Box-and-Whisker plot for the generic brand. The x-axis here is the mass of the ibuprofen tablets in grams.

## QUESTIONS

1. During the statistical analysis section, you were asked to find the standard deviation of the trademarked and the generic brand. Explain what this value tells you, and why it is important. Compare the two standard deviations you calculated, and determine what this means. **Ans:** As stated in this lab, the standard deviation of the variation from the average. This shows the precision of each of the brands. If a brand has a lower standard deviation, then it is more precise. From the statistical analysis section, the generic brand had a smaller standard deviation. This means that the process used to make the generic brand is more precise.
2. Now, you will determine whether or not these two brands are different from each other. To do this, you will use a statistical analysis technique known as an F-test. **Ans:** The answers for each piece are as follows:
  - a) The variance for the Advil<sup>®</sup> brand was found to be 9.72E-05, while the generic brand was found to have a variance of 1.52E-05.
  - b) The F-value was found to be 40.63.

- c) Since the F-value calculated was higher than the F-critical value given, there is significant difference between the two brands at 95% confidence.
3. Research suggests that one ibuprofen tablet should have a mass of 480 mg.<sup>2</sup> Do you think there is significant difference between the values you obtained and this literature value for a typical formulation? To answer this, you will use another statistical test known as the t-test. **Ans:** The answer for each piece are as follows:
- For the Advil<sup>®</sup> brand, the experimental t-value was found to be 2.14.
  - Since the critical t-value is higher than the experimental t-value, there is no significant difference between the literature value and the Advil<sup>®</sup> brand.
  - For the generic brand, the experimental t-value was found to be 119.79. Since this value is considerably higher than the critical t-value, there is significant difference between the value obtained from literature and the generic brand value.
4. It has been estimated that the world production of ibuprofen is in the vicinity of 15,000 tons per year.<sup>4</sup> It has also been estimated that the average price for one ibuprofen tablet containing 200 mg of ibuprofen is roughly 0.12 USD.<sup>5</sup> Using this information, calculate the total price of ibuprofen production for a year. **Ans:** To determine the price of ibuprofen production, this was done:

$$15000 \frac{\text{tons}}{\text{year}} * 0.12 \frac{\text{USD}}{\text{tablet}} * \frac{\text{tablet}}{200 \text{ mg}} * 1000 \frac{\text{kg}}{\text{ton}} * 1000 \frac{\text{g}}{\text{kg}} * 1000 \frac{\text{mg}}{\text{g}}$$

$$= 9.0 * 10^9 \frac{\text{USD}}{\text{year}}$$

5. Remember that you listed the inactive ingredients from each of the brands. Research the first three ingredients from both brands and state what type of excipient you believe them to be (i.e. filler, preservative, lubricant, etc.). **Ans:** The answer to each of the ingredients is as follows:
- FOR THE ADVIL<sup>®</sup> BRAND:**
- The first listed inactive ingredient was acetylated monoglycerides. According to Lipid Technologies and Applications, this ingredient is often used as a coating ingredient.<sup>6</sup>
  - The second inactive ingredient, colloidal silicon dioxide, is also known as silicon dioxide or silica. In nature, it is also known as sand or quartz. According to Pharmaceutical Dosage Forms: Tablets, a compendium of information on tablets, colloidal silicon dioxide is often used as a glidant.<sup>7</sup>
  - The third inactive ingredient listed was corn starch. As described in the excipients catalog on PharmaHUB.org, corn starch consists of the starch

granules separated from the mature grain of corn. This excipient can fit into many categories, including binders, diluents, and disintegrants.<sup>8</sup>

FOR THE GENERIC BRAND:

- 1) The first listed non-active ingredient listed on the CVS® brand was carnauba wax. Carnauba wax is also known as palm wax or Brazil wax, and comes from the leaves of a palm tree grown only in Brazil. According to About.com, carnauba wax is often used as a coating agent for candies and also for cars. Likewise, it is most likely used to coat the tablet.<sup>9</sup>
  - 2) The second listed non-active ingredient was corn starch. As stated in number 3) of the Advil section of this answer, it is used as a disintegrant, binder, or diluent.<sup>8</sup>
  - 3) The third non-active ingredient listed was fumed silica gel. What makes fumed silica gel unique is that it has a rather large surface area. Fumed silica gel has many applications, but in this case, it is probably used as a thickening agent, or a thickener.<sup>10</sup>
6. Do any pills in your sample fall outside of these bounds? Furthermore, did you find any outliers in your sample? What does this say about the consistency of the new pill press?

**Ans:** By taking the percent error of each data point from the average point of 0.4850 grams, we find that three tablets are out of the speculated range. The equation used and the percent error for each point is shown below.

$$\% \text{ Error} = \frac{|Data \text{ Point} - 0.4850 \text{ g}|}{0.4850 \text{ g}} * 100\%$$

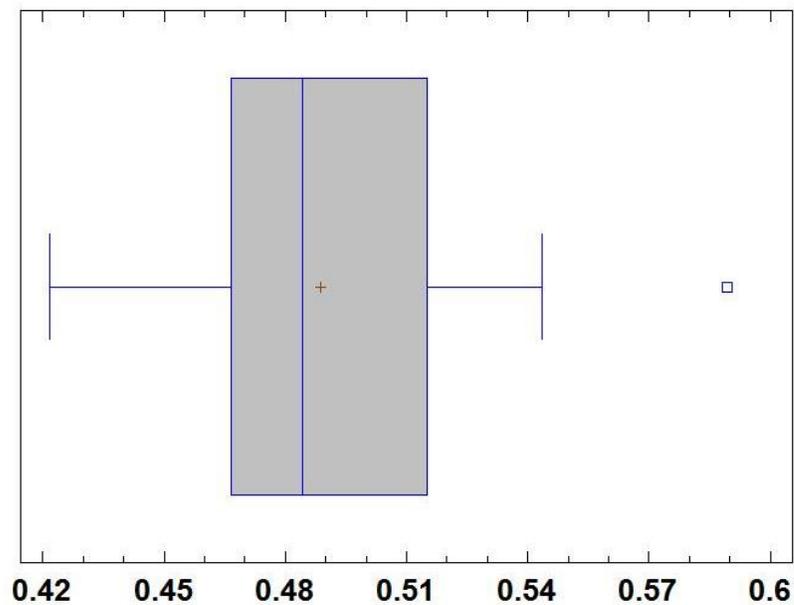
**Table 4. Percent error of each of the mass samples. The rows and columns correspond to the same points as seen in the questions section.**

0.000	12.062	3.381	0.268
7.175	8.289	7.443	21.546
4.082	3.753	0.268	7.773
0.144	7.938	13.052	3.876
1.320	0.309	7.608	5.175

Through outlier testing, one outlier was found. Through the use of the quartiles, the following values were calculated:

Median	0.4844
First Quartile	0.4665
Third Quartile	0.5150
O <sub>L</sub>	0.3938
O <sub>H</sub>	0.5876

Through these values, we find one outlier. The data point 0.5895 is larger than the O<sub>H</sub> value, and therefore an outlier to the series. A Box-and-Whisker plot was developed, and shown below.



**Figure 6. Box-and-Whisker plot for Problem 6. The x-axis here is the mass of the ibuprofen tablets in grams. One outlier is clearly visible in this plot.**

This tells us that this pill press is not consistent enough for the product specifications and is not precise enough to produce no outliers.

- For this exercise, read the following description on the creation of ibuprofen tablets, and then create a process flow diagram of the process.

**Ans:** After reading the description, the following flow diagrams were made:

a.

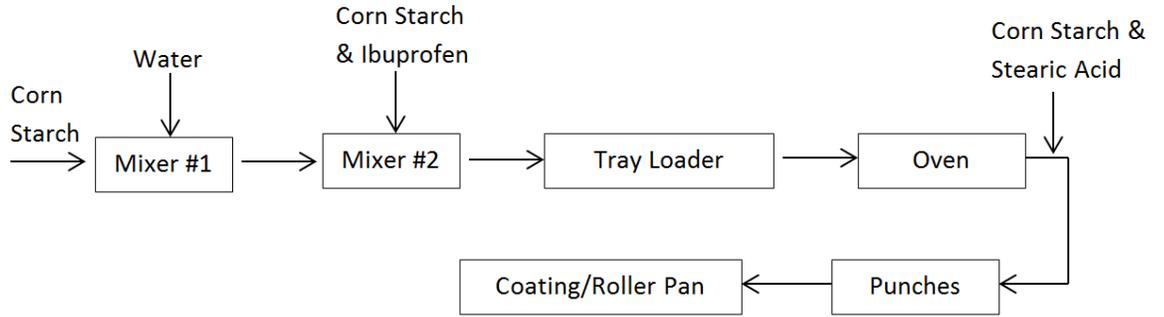


Figure 7. Solution to part a) of Question 7.

b.

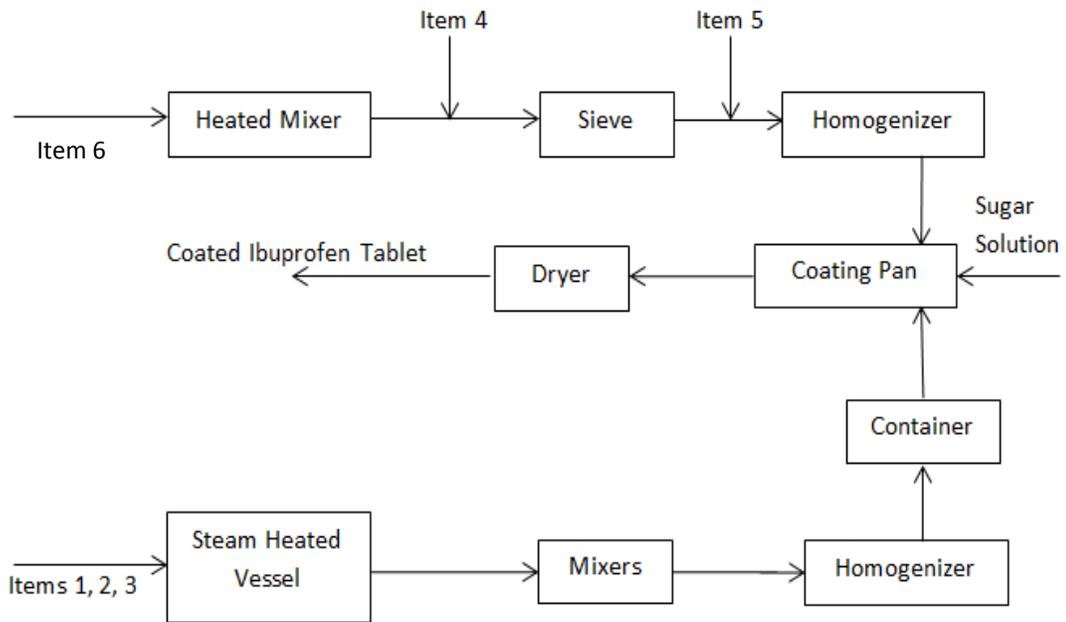


Figure 8. Solution to part b) of Question 7.

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