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Analysis of Over-the-Counter Drugs

Student Laboratory Kit

Introduction

Learn to analyze and identify over-the-counter (OTC) drugs including common pain relievers such as aspirin and acetaminophen, and antacids such as Alka-Seltzer®. Test physical and chemical properties of actual OTC drug samples and then use test results to analyze unknown pain reliever and antacid samples.

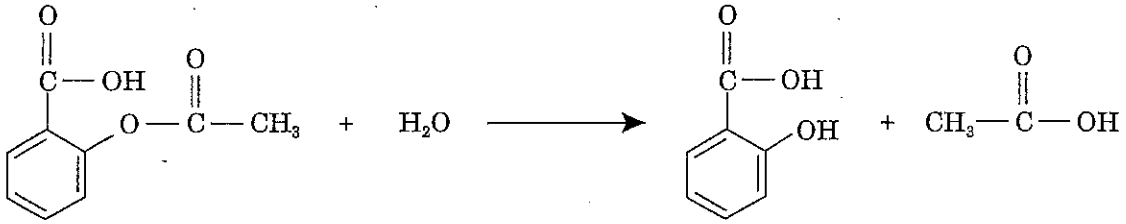
Chemical Concepts

- Qualitative analysis detection techniques
- Physical properties of OTC drugs
- Chemical reactions of OTC drugs

Background

A *drug* is a chemical used medicinally for treating diseases and injuries. The term "drug," however, often carries with it the connotation of narcotics, addiction, and crime. Many drugs or medicines are entirely legal, readily available, and are sold as over-the-counter medications without the need for a prescription. *Over-the-counter (OTC) drugs* include categories of drugs such as pain relievers, antacids, alcohol, caffeine, and vitamins. While these OTC drugs are sold legally they, like controlled or prescription drugs, have the ability to cause accidental or purposeful poisoning and even death if taken improperly. Thus it is important that dosage information and precautions printed on the label are strictly followed in order to prevent accidental injury or harm.

The first class of OTC drugs tested will be pain relievers—specifically aspirin, acetaminophen, ibuprofen, Bufferin®, and Excedrin®. Aspirin, the common or trade name for acetylsalicylic acid, is today's leading commercial pain reliever. Aspirin acts as an *analgesic* (pain reliever), an *antipyretic* (fever reducer), and an *anti-inflammatory agent* (inflammation reducer). Aspirin is a fairly acidic compound which reacts slowly with moisture from the air to undergo hydrolysis, forming salicylic acid and acetic acid (vinegar), as shown in Equation 1.



Acetylsalicylic Acid + Water → Salicylic Acid + Acetic Acid

Equation 1

Thus if aspirin is to be stored for several months, it should be kept dry. If the tablets pick up moisture, they may begin to smell like vinegar and become even more acidic. This increased acidity can be very irritating to the lining of the stomach and intestines, causing side effects such as upset stomach, gastrointestinal bleeding, and various allergic reactions. Furthermore, aspirin, as with any drug, must get into the bloodstream in order to do its work. The time it takes for the acetylsalicylic acid in tablet form to enter the blood is limited by the rate at which the tablet disintegrates in the stomach, which is dependent on pH. The higher the pH (less acidic), the faster the tablet disintegrates.

For these reasons, some people opt to take a buffered aspirin, which contains aspirin and one or more weak bases. Bufferin® is a brand of buffered aspirin containing aspirin, calcium carbonate, magnesium oxide, and magnesium carbonate. The combination of aspirin and weak bases increases the pH, thus helping with the disintegration of the tablet and hence the absorption of the

acetylsalicylic acid into the blood stream. The weak bases in buffered aspirin reduce the acidity that results from the hydrolysis of aspirin in the acidic juices of the stomach; thus, buffered aspirin is found to be less irritating to the stomach lining than aspirin.

The acetylsalicylic acid (aspirin) molecule has an ester side chain group, as shown in Figure 1 below. The ester group hydrolyzes in the presence of water, leaving an alcohol group (–OH) on the benzene ring, or a phenol compound. A chemical test to detect the presence of the phenol group is seen in the reaction with ferric nitrate. When a phenol group is present, a distinct violet-colored complex is formed. Therefore ferric nitrate is commonly used as a positive indicator test of the phenol group (and thus for aspirin which easily undergoes hydrolysis).

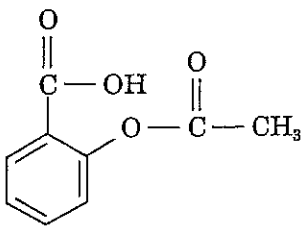


Figure 1.
Acetylsalicylic Acid
Aspirin

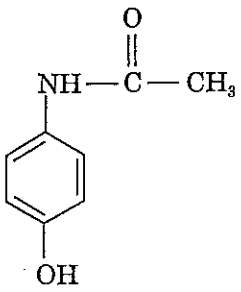


Figure 2.
Acetaminophen
Tylenol®

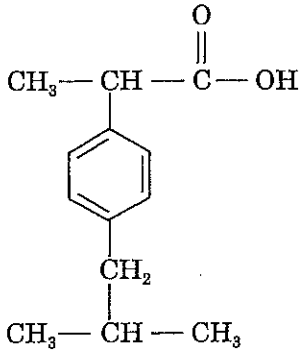


Figure 3.
Ibuprofen
Advil®

Acetaminophen, a non-aspirin headache remedy, is another important OTC pain reliever. Acetaminophen, which is an acylated aromatic amine as shown in Figure 2 above, is the active ingredient in Tylenol. Compare Figures 1 and 2 and notice the similarities and differences between the chemical structures of the two pain relievers. Notice that acetaminophen has an alcohol group (–OH) on the benzene ring, also known as a phenol group. Thus, in the presence of ferric nitrate, a distinct violet-colored complex is produced due to the reaction of ferric nitrate with the phenol group. Acetaminophen acts as a mild analgesic and antipyretic, but lacks anti-inflammatory properties. Acetaminophen is a less acidic alternative to aspirin for those who have an allergic reaction or who find that aspirin produces stomach disorders. Excedrin is a combination OTC pain reliever, consisting of equal amounts of aspirin and acetaminophen, and a small amount of caffeine. The caffeine is added as a stimulant to the nervous system and heart, providing a heightened sense of awareness that some people want in a pain reliever.

Ibuprofen, another commonly used pain reliever, is the active ingredient in Advil. Ibuprofen, shown in Figure 3 above, is another non-aspirin OTC drug. However, like aspirin, ibuprofen acts as an analgesic (pain reliever), an antipyretic (fever reducer), as well as an anti-inflammatory agent (inflammation reducer). Compare Figures 1, 2, and 3, noticing the similarities and differences among the chemical structures of the three molecules.

The second class of OTC drugs tested will be antacids—specifically Alka-Seltzer, Rolaids, and a generic antacid containing calcium carbonate. *Antacids* are chemicals that relieve over-acidity by neutralizing excess acid in the stomach. This excess acid can produce discomforts commonly called "acid indigestion" or "heartburn", and possibly gastric ulcers. Antacids promise to provide "prompt relief" of the unpleasant effects of these stomach distresses. Most antacids will not dissolve completely in water and are made to dissolve slowly in the acidic juices of the stomach so that carbon dioxide will be given off gradually as the antacid neutralizes excess acid.

The stomach's digestive juices, or gastric juices, contain hydrochloric acid (HCl), which serves to promote digestion of food proteins by the enzyme pepsin in the gastric juices and kill bacteria that enters our digestive system. The stomach lining of a normal adult produces two to three liters of dilute HCl each day to aid in digestion, with a normal stomach pH ranging from 1.0 to 3.0. While the stomach produces a small amount of acid all the time, it can be stimulated to produce more acid in the presence of food. Too much food, certain types of food, or high levels of stress may cause the stomach to respond with an outpouring of acid, thus lowering the stomach pH to the point of discomfort.

Most common antacids contain weak bases such as sodium bicarbonate, calcium carbonate, magnesium hydroxide, aluminum hydroxide, or various combinations of these. The basic compounds in the antacids serve to neutralize excess HCl as well as to affect the functioning of the enzyme pepsin. An *acid–base neutralization reaction* occurs between the base and the acid in the stomach. An effective antacid does not bring the pH of the stomach fluid to complete acid–base neutrality (pH of 7) as this would

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completely shut down digestion and promote "acid rebound"—an automatic response which floods the stomach with fresh acid. Instead, an effective antacid neutralizes some of the HCl in the gastric juices—enough to relieve the pain and discomfort, yet still allowing for the continuation of normal digestive processes.

Carbonate-containing antacids, such as sodium bicarbonate, react with stomach acid to produce a neutral salt and carbonic acid. Carbonic acid is a much weaker acid than HCl and decomposes readily to yield carbon dioxide and water, as shown in Equation 2. Hydroxide-containing compounds, such as magnesium hydroxide, react with the acid to produce its neutral salt and water, as shown in Equation 3.

$$NaHCO_3 + HCl \rightarrow NaCl + \underset{\text{carbonic acid}}{H_2CO_3} \rightleftarrows CO_2 + H_2O \qquad \textit{Equation 2}$$

$$Mg(OH)_2 + 2HCl \rightarrow MgCl_2 + 2H_2O \qquad \textit{Equation 3}$$

Alka-Seltzer is a popular antacid and pain relief medicine, containing aspirin, citric acid, and sodium bicarbonate (baking soda). When the tablet is dropped into water, the bicarbonate and the citric acid dissolve, producing the familiar "fizz" from the chemical release of carbon dioxide. Rolaids® is another common antacid, containing a combination of calcium carbonate and magnesium hydroxide. The generic antacids provided in this laboratory are formulated with only calcium carbonate, as are other popular antacids such as Tums®. Individuals with high blood pressure are advised to avoid excess sodium and may choose to use an antacid without sodium bicarbonate. People with osteoporosis or those who need a calcium supplement may choose an antacid formulated with calcium carbonate. Calcium carbonate, however, if used over long periods of time tends to cause constipation. Thus some antacids contain a combination of calcium carbonate and magnesium hydroxide. This combination tends to overcome the constipation as magnesium hydroxide produces an opposite laxative effect. Magnesium hydroxide, while effective in controlling ulcer pain, has a lower neutralizing capacity and can cause trouble if taken too frequently by people with kidney impairment. In any case, each OTC drug must be taken with caution, and dosage information printed on the label should be strictly followed.

In this laboratory activity, two classes of over-the-counter drugs will be analyzed—pain relievers and antacids. Known samples will be tested, and then unknown samples will be identified by comparison with the known samples. This process of determining the identities of unknown substances by comparison to known substances is called *qualitative analysis*. This can be contrasted to *quantitative analysis*, the process of determining how much of a given component is present in a sample. Qualitative analysis procedures involve using physical and/or chemical tests, both of which will be performed here.

Materials (for each student group)

OTC Drug Samples—Pain Relievers, 1 of each tablet

- Acetaminophen tablet
- Aspirin tablet
- Bufferin® tablet
- Excedrin® tablet
- Ibuprofen tablet
- Unknown OTC pain reliever sample

OTC Drug Samples—Antacids

- Alka-Seltzer® tablet, one-half of a tablet
- Antacid generic tablet, one tablet
- Rolaids® tablet, one tablet
- Unknown OTC antacid sample

Other Chemicals/Materials Needed

- Hydrochloric acid solution, HCl, 0.5 M, 100 drops
- Ferric nitrate solution, $Fe(NO_3)_3$, 0.2 M, 100 drops
- pH indicator paper, 10 pieces
- Universal indicator solution, 40 drops
- Universal indicator color chart
- Water, distilled or deionized, H_2O
- Beral-type pipets, 4
- Cotton swabs (for cleaning wells)
- Mortar and pestle
- Reaction plate, 24-well
- Sheet of white paper
- Spatula
- Test tubes, 5
- Toothpicks (for stirring), 10

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Safety Precautions

Do not ingest any of the over-the-counter drug samples during this laboratory. The samples are for laboratory use only, have been stored with other non-food-grade laboratory chemicals, and are not meant for human consumption. Hydrochloric acid solution is toxic by ingestion and inhalation and is corrosive to skin and eyes. Ferric nitrate solution may be a skin/tissue irritant. Universal indicator solution is a flammable, alcohol-based solution. Avoid contact of all chemicals with eyes and all body tissues. Wear chemical splash goggles, chemical-resistant gloves, and a chemical-resistant apron. Wash hands thoroughly with soap and water before leaving the laboratory.

Pre-Lab Activity

1. Read the background information provided in this handout.
2. On Data Tables 1 and 2, fill in the list of active ingredients that are found in each of the known over-the-counter drugs that you will be testing. This information can be found in the *Background* section of this handout, or on the bottle containing the OTC drug.

Procedure

Part Ia. Known OTC Drug Testing—Pain Relievers

1. Place a 24-well reaction plate on a sheet of white paper on the lab bench. Label the sheet of paper as indicated in Data Table 1.
2. Use a mortar and pestle to grind up a single tablet of the first pain reliever, aspirin.
3. Use a spatula to add a **few granules** of powdered aspirin to each of the four wells of Column 1 of the well plate. Save the remaining powdered aspirin in a labeled test tube—in case a test needs to be repeated later.
4. Clean the mortar and pestle by wiping both with a dry paper towel.
5. Repeat steps 2–4 for the remaining four OTC pain reliever tablets. Place a **few granules** of powdered acetaminophen in each well of Column 2 of the well plate, ibuprofen in Column 3, Bufferin in Column 4, and Excedrin in Column 5. Leave Column 6 empty—this will be used for the unknown pain reliever sample.

Row A—Appearance/Solubility

6. Make detailed observations about the appearance of each powder, noting the color and consistency of each. Record observations of appearance in Row A of Data Table 1.
7. Using a dropper pipet, add 10–15 drops of distilled or deionized water to each of the five powders across Row A.
8. Observe any physical or chemical changes that occur, e.g., fizzing or dissolving. Record observations in Row A of Data Table 1.
9. Stir each well of Row A with a toothpick. Observe and record the solubility of each powdered OTC pain reliever in Data Table 1. Use the following guidelines to determine the solubility of each
   - If the resulting solution is *clear,* then the drug is *soluble.*
   - If the resulting solution is *cloudy,* then the drug is *slightly soluble.*
   - If the powder remains unchanged and there is a *thick white precipitate,* then the drug is *insoluble.*

Note: To avoid contamination while stirring, use five toothpicks—one toothpick for aspirin, one for acetaminophen, etc.-.-.-.

Row B—Acidity/pH

10. Using a dropper pipet, add 10 drops of distilled or deionized water to each of the five powders across Row B. Stir.
11. Using a different dropper pipet, add 3–4 drops of universal indicator solution to each well of Row B. Record the color of each solution in Row B of Data Table 1. Be very specific when describing the color so as to distinguish between the wells. Note the approximate pH of each solution by comparing the color to the universal indicator color chart.
12. Determine an accurate pH of each OTC drug by dipping one end of a strip of 1–12 pH paper into each of the corresponding wells of Row B. Save resources by using each end of the pH paper for a different well. Use the color chart on the pH paper tube to determine the pH. Record the pH of each in Row B of Data Table 1. *Note*: Monitor the color in the wells of Row B as the lab progresses. Watch for any changes in color over time. For any wells that do change color, be sure to retest the pH using a fresh pH strip and record data in Data Table 1.

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Row C—Reaction with HCl, "Simulated stomach acid"

13. Using a dropper pipet, add 10 drops of 0.5 M HCl "simulated stomach acid" solution to each well of Row C.
14. Stir each well of Row C with a toothpick. Observe any reactions that occur as noted by fizzing (slight or vigorous) or dissolving (insoluble, slightly soluble, or fully soluble). Record detailed observations in Row C of Data Table 1.
15. Determine the pH of each OTC pain reliever in the "stomach" by dipping one end of a strip of 1–12 pH paper into each of the corresponding wells of Row C. Save resources by using each end of the pH paper for a different well. Use the color chart on the pH paper tube to determine the pH. Record the "stomach" pH of each in Row C of Data Table 1.

Row D—Reaction with Ferric Nitrate

16. Using a dropper pipet, add 10 drops of 0.2 M $Fe(NO_3)_3$ solution to each well of Row D.
17. Stir each well of Row D with a toothpick. Observe any reactions that occur as noted by fizzing or color changes. Record detailed observations of each solution in Row D of Data Table 1. Be very specific when describing the color so as to distinguish between the wells.
18. Repeat any tests that gave unclear results using the remaining pain relievers that were saved earlier. Go on to Part Ib—testing an unknown OTC pain reliever. Do not rinse out the well plate until Part Ib is completed.

Part Ib. Unknown OTC Drug Testing—Pain Relievers

19. Obtain an unknown powdered sample of an OTC pain reliever from your instructor. Record the unknown letter in Data Table 1.
20. Use a spatula to add a **few granules** of the powdered unknown OTC drug sample to each of the four wells of Column 6 of the well plate. Save the remaining amount of sample for later use—in case a test needs to be repeated.
21. Repeat steps 6–9 for Row A of the reaction plate. Record observations in Data Table 1.
22. Repeat steps 10–12 for Row B of the reaction plate. Record observations in Data Table 1.
23. Repeat step 13–15 for Row C of the reaction plate. Record observations in Data Table 1.
24. Repeat steps 16–17 for Row D of the reaction plate. Record observations in Data Table 1.
25. Compare your results from the unknown to each of the five known pain reliever samples in Columns 1–5. Record observations.
26. Rinse out the reaction plate in the sink, using plenty of tap water. Use a cotton swab to clean the individual wells. Tap the plate dry for use in Part IIa. Empty the test tubes containing the excess powdered pain relievers into a solid waste container. Use these test tubes for Part IIa.

Part IIa. Known OTC Drug Testing—Antacids

1. Place a 24-well reaction plate on a sheet of white paper on the lab bench. Label the sheet of paper as indicated in Data Table 2.
2. Use a mortar and pestle to grind up a single tablet of the first antacid, Alka-Seltzer.
3. Use a spatula to add a **few granules** of powdered Alka-Seltzer to each of the four wells of Column 1 of the well plate. Share the powdered Alka-Seltzer with another lab group as these tablets are large in size. Save the remaining powder in a labeled test tube—in case a test needs to be repeated later.
4. Clean the mortar and pestle by wiping both with a dry paper towel.
5. Repeat steps 2–4 for the remaining two OTC antacid tablets. Place a **few granules** of powdered Rolaids in each well of Column 2 of the well plate and the powdered generic antacid in Column 3. Column 4 will be used for your unknown antacid sample.

Row A—Appearance/Solubility

6. Make detailed observations about the appearance of each powder, noting the color and consistency of each. Record observations of appearance in Row A of Data Table 2.
7. Using a dropper pipet, add 10–15 drops of distilled or deionized water to each of the three powders across Row A.
8. Observe any physical or chemical changes that occur as noted by fizzing or dissolving. Record observations in Row A of Data Table 2.

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9. Stir each well of Row A with a toothpick. Observe and record the solubility of each powdered OTC antacid in Data Table 2. Use the following guidelines to determine the solubility of each
   - If the resulting solution is *clear*, then the drug is *soluble.*
   - If the resulting solution is *cloudy*, then the drug is *slightly soluble.*
   - If the powder remains unchanged and there is a *thick white precipitate*, then the drug is *insoluble.*

   Note: To avoid contamination while stirring, use three toothpicks—one for Alka-Seltzer, one for Rolaids, etc. . . .

Row B—Acidity/pH

10. Using a dropper pipet, add 10 drops of distilled or deionized water to each of the three powders across Row B. Stir.
11. Using a different dropper pipet, add 3–4 drops of universal indicator solution to each well of Row B. Record the color of each solution in Row B of Data Table 2. Be very specific when describing the color so as to distinguish between the wells. Note the approximate pH of each solution by comparing the color to the universal indicator color chart.
12. Determine an accurate pH of each OTC drug by dipping one end of a strip of 1–12 pH paper into each of the corresponding wells of Row B. Save resources by using each end of the pH paper for a different well. Use the color chart on the pH paper tube to determine the pH. Record the pH of each in Row B of Data Table 2.

Row C—Reaction with HCl, "Simulated stomach acid"

13. Using a dropper pipet, add 10 drops of 0.5 M HCl "simulated stomach acid" solution to each well of Row C.
14. Stir each well of Row C with a toothpick. Observe any reactions that occur as noted by fizzing (slight or vigorous) or dissolving (insoluble, slightly soluble, or fully soluble). Record detailed observations in Row C of Data Table 2.
15. Determine the pH of each OTC pain reliever in the "stomach" by dipping one end of a strip of 1–12 pH paper into each of the corresponding wells of Row C. Save resources by using each end of the pH paper for a different well. Use the color chart on the pH paper tube to determine the pH. Record the "stomach" pH of each in Row C of Data Table 2.

Row D—Reaction with Ferric Nitrate

16. Using a dropper pipet, add 10 drops of 0.2 M $Fe(NO_3)_3$ solution to each well of Row D.
17. Stir each well of Row D with a toothpick. Observe any reactions that occur as noted by fizzing or color changes. Record detailed observations of each solution in Row D of Data Table 2. Be very specific when describing the color so as to distinguish between the wells.
18. Repeat any tests that gave unclear results using the remaining antacids that were saved ealier. Go on to Part IIb—testing an unknown OTC antacid. Do not rinse out the well plate.

Part IIb. Unknown OTC Drug Testing—Antacids

19. Obtain an unknown sample of an OTC antacid from your teacher. Record the unknown letter in Data Table 2.
20. Use a spatula to add a **few granules** of the powdered unknown OTC drug sample to each of the four wells of Column 4 of the well plate. Save the remaining amount of sample for later use—in case a test needs to be repeated.
21. Repeat steps 6–9 for Row A of the reaction plate. Record observations in Data Table 2.
22. Repeat steps 10–12 for Row B of the reaction plate. Record observations in Data Table 2.
23. Repeat step 13–15 for Row C of the reaction plate. Record observations in Data Table 2.
24. Repeat steps 16–17 for Row D of the reaction plate. Record observations in Data Table 2.
25. Compare your results from the unknown to each of the three known antacid samples in Columns 1–3. Record observations.
26. Rinse out the reaction plate in the sink, using plenty of tap water. Use a cotton swab to clean the individual wells. Tap the plate dry. Empty the test tubes containing the excess powdered antacids into a solid waste container.

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Name: _____

Data Table 1 — Pain Relievers

OTC Drug: **Aspirin** **Acetaminophen** **Ibuprofen** **Bufferin®** **Excedrin®** **Unknown #** ____

Active Ingredients:

a. Appearance

b. Solubility in H_2O

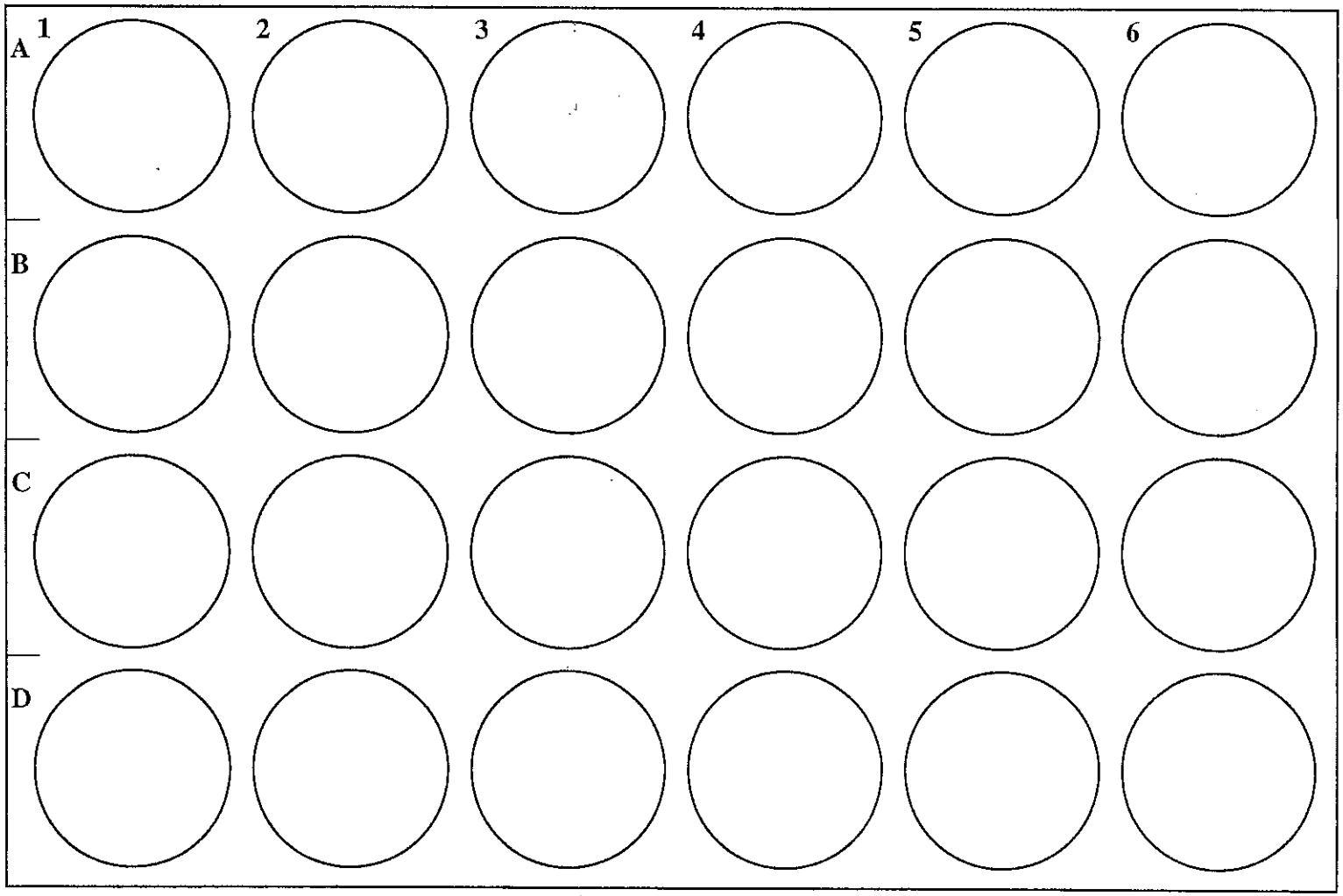
a. Color with universal indicator

b. pH

a. Reaction with 0.5 M HCl

b. pH

Reaction/color with 0.2 M $Fe(NO_3)_3$



Record detailed observations inside the circles on the table. Record all colors that form. Record whether any gases evolve. If no reaction at all occurs, use the abbreviation NR.

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Name: _____

Data Table 2 — Antacids

OTC Drug: **Alka-Seltzer®** **Rolaids®** **Generic** **Unknown # ____**

Active Ingredients:

a. Appearance

b. Solubility in H_2O

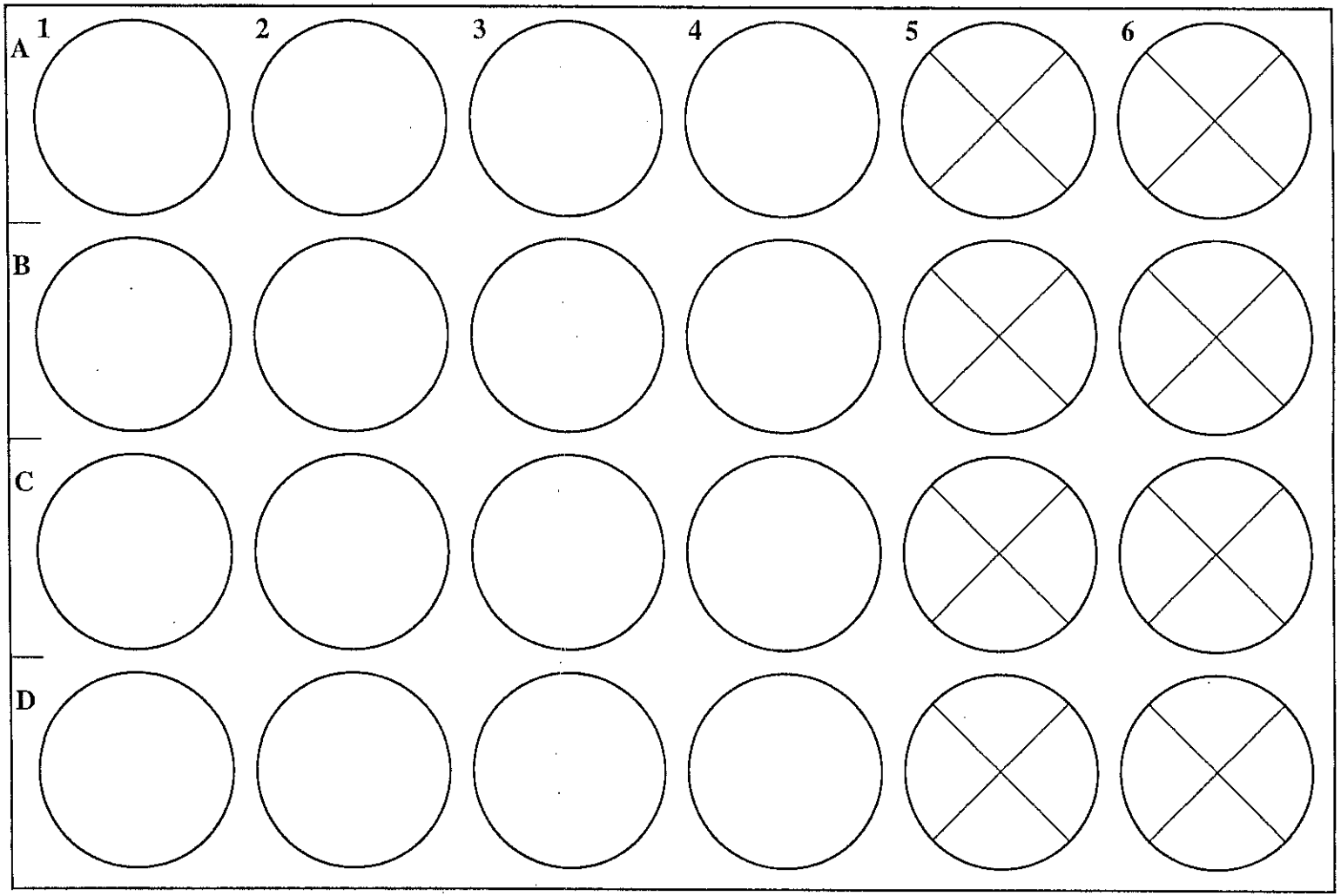
a. Color with universal indicator

b. pH

a. Reaction with 0.5 M HCl

b. pH

Reaction/color with 0.2 M $Fe(NO_3)_3$



Record detailed observations inside the circles on the table. Record all colors that form. Record whether any gases evolve. If no reaction at all occurs, use the abbreviation NR.

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Name: _____

Analysis Questions

Over-the-Counter Drugs

Part I. Questions

1. The unknown pain reliever for Part Ib was unknown # _____.
2. Based on your data, what is the identity of the unknown pain reliever? Analyze your data from Part I and list all evidence for choosing this pain reliever.
3. Which of the five pain relievers tested was the most acidic? Which was the least acidic?
4. Did the pH (acidity) of any of the pain relievers change over time? Which? Explain.
5. When the "simulated stomach acid" (0.5 M HCl) was added to the pain relievers, what happened to the pH? Did any pain relievers resist a drastic drop in pH? Explain.
6. Compare the structures of acetylsalicylic acid, acetaminophen, and ibuprofen from the background section. What similarities do you notice in terms of structure? What differences?

Part II. Questions

7. The unknown antacid for Part IIb was unknown # _____.
8. Based on your data, what is the identity of the unknown antacid? Analyze your data from Part II and list all evidence for choosing this antacid.
9. Why are most pain relievers (and antacids) fairly insoluble? *Hint*: Refer to the background section.
10. Compare the pH of the three antacids tested before adding HCl. Then compare the pH of the three antacids after adding HCl, "stomach acid". Which antacid(s) seem to be most effective? Which antacid(s) seem to be least effective? Explain.

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