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Quality Control of Aspirin: Experimental Synthesis Versus Industrial Formulations

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Abstract: The objective of this study was to synthesize aspirin (acetylsalicylic acid) in the laboratory and thereafter evaluate its quality in comparison to aspirin tablets marketed by two distinct pharmaceutical corporations. In an acidic environment, salicylic acid and acetic anhydride were utilized to synthesize the chemical. Then, it was cleaned up by recrystallization. We checked the product's physical qualities, such as its melting point and yield. The yield was supposed to be 11.72 g, however it was only 8.5 g, which means the percentage yield was 72.5%. This is a good outcome for a synthesis at the academic level. The melting point of the synthesized aspirin was 140 °C, which is close to the normal range of 135–136 °C. This suggests that it was really clean. The melting points of commercial aspirin from British and Egyptian companies were substantially different, though (120 °C and 220 °C). This could suggest that the aspirin is breaking down or that it has additives in it. The study highlighted how crucial quality control is in drug development and how helpful it is for students to acquire hands-on experience producing and evaluating pharmacological compounds. It also underlined how important it is to use correct analytical procedures and maintain a close eye on the conditions of synthesis. In conclusion, lab-made aspirin was just as excellent as the criteria specified by the pharmacopeia and was cleaner than certain samples sold in stores. The research demonstrates the significance of include both synthesis and analytical assessment in pharmaceutical science curricula.

Keywords: Aspirin, laboratory synthesis, melting point, pharmaceutical quality and commercial comparison are all important words
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1. Introduction

A lot of people take aspirin (acetylsalicylic acid) because it helps with pain, fever, and swelling (S. D. Inc, 1989). It is also highly crucial for heart health since it stops platelets from sticking together. Even though it's crucial, the fact that the quality and stability of aspirin might change from store to store can make it less effective as a treatment. Not a lot of research has been done to see how the pharmaceutical quality of lab-made aspirin compares to that of commercial aspirin. It is crucial to close this gap for patients' safety and for pharmacy education to include hands-on training. This study pertains to both public health and educational outcomes. It helps pharmacy students learn how to make pharmaceuticals, how to check their quality, and how to think critically about how industrial processes affect the quality of drugs. Aspirin is manufactured from salicylic acid, which is a substance that is naturally found in the bark of the willow tree. In 1899, the German drug company Bayer created aspirin in a form that was easier to use for medical purposes. Aspirin lowers the quantity of prostaglandins generated by permanently inhibiting the cyclooxygenase enzymes (COX-1 and COX-2). Prostaglandins are responsible for pain, inflammation, and fever ("Global Aspirin Market 2025–2034," n.d.). Low-dose aspirin therapy (typically 75–100 mg daily) is often administered to people who are at risk of atherosclerotic events because it helps stop blood clots from forming. It keeps platelets from adhering together, which lessens the chance of blood clots[1]. But using aspirin for a long period might create difficulties including stomach irritation and bleeding, especially in elderly persons or those who already have stomach problems[2]. Aspirin is still one of the most significant and strong drugs in modern medicine since it can be used for so many different things and is easy to find. It can be used to stop and treat sicknesses. The purpose is to see how well lab-produced aspirin works and how it compares to aspirin pills made by two different drug companies. Goals: To use common esterification procedures to manufacture aspirin in the lab. - To learn about and compare the melting points and yields of both synthetic and commercial aspirin. - To understand what the differences in pharmaceutical quality mean. understanding of the processes used to create pharmaceuticals and check their quality (British Pharmacopoeia, 2023; USP, 2022; Vogel, 1989). Three primary categories of literature are distinguished in this chapter: stability, content analysis, and synthesis and comparison. Aspirin dosage and degradation rate can vary by brand, according to Oyetunde et al[3]. In terms of TLC and melting point, laboratory-produced aspirin closely resembles commercial brands, according to Kumar and Rao[4] (2018). In order to show disparities in quantity, which suggest uneven quality control, Ahmed used HPLC analysis[5]. Aspirin breaks down more easily at higher temperatures and humidity levels, according to Chakraborty et al[6,7]. There is a gap that this study fills because none of these studies specifically examined changes in melting point in conjunction with possible excipients or degradation indication.

2. Materials and Procedures

2.1.Design of Research: There is a comparative component to this experimental study. In order to compare it with aspirin

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from two commercial sources (British and Egyptian companies), aspirin was synthesized under controlled conditions. To guarantee traceability, tablets were chosen from batches that were properly labeled.

2.2 Safety and Flow Diagram : To provide a visual summary of the synthesis steps, a process diagram was included. When handling acid, safety measures included wearing lab coats, gloves, goggles, and fume hoods.

2.3 Resources : Aspirin was synthesized in a lab using the following materials and tools:

2.3.1 Chemicals: concentrated sulfuric acid (H_2SO_4) or phosphoric acid (H_3PO_4) as a catalyst; distilled water; ethanol (optional, for recrystallization); salicylic acid ($C_7H_6O_3$); acetic anhydride ($C_4H_6O_3$); ice.

2.3.2. Glassware and Equipment: Conical flask (100 mL), beaker (100 mL, 250 mL), measuring cylinder, dropper or pasteur pipette, glass rod, Bunsen burner or hot plate, water bath, filter paper and funnel, watch glass, analytical balance, thermometer, melting point apparatus, and desiccator.

2.4. Preparation Method.

• We used a standard esterification procedure to create aspirin (Vogel, 1989):

• Mixing and Weighing:

• Fill a dry conical flask with approximately 9.0 g of salicylic acid.

• Adding Acetic Anhydride: The flask containing salicylic acid received 18.0 mL of acetic anhydride.

• Catalysis: To serve as a catalyst, I cautiously added 15 to 16 drops of pure sulfuric acid. The mixture was gently swirled with a glass rod.

• Heating: To facilitate esterification, the reaction mixture was placed in a water bath that was heated to 70–80°C for 15–20 minutes. Cooling and Crystallization: After being taken off of the heat source, the mixture was left to cool. To break down extra acetic anhydride and cause aspirin to crystallize, 20 milliliters of cold distilled water were gradually added.

3. Results and Discussion

3.1 Aspirin Synthesis

This study demonstrates how to calculate the theoretical and actual yield of aspirin (acetylsalicylic acid) based on laboratory production. The calculation is based on the reaction between acetic anhydride and salicylic acid. The balanced chemical equation is :

$$C_6H_6O_3 + C_4H_6O_3 \rightarrow C_9H_8O_4 + CH_3COOH$$

3.2 Aspirin Quantum Yield Percentage Calculations.

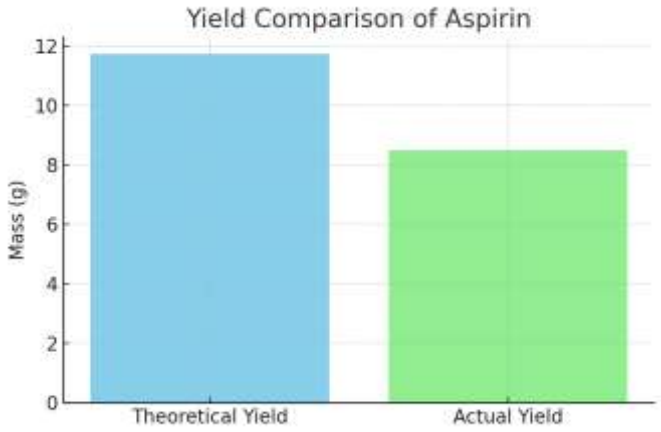
table 1 : Shows the measurements required for the quantum yield measurements of aspirin produced at Al Rayyan University.

Sample Data

Mass of salicylic acid used	9 g
Molar mass of salicylic acid	138.12 g/mol
Moles of salicylic acid	9 / 138.12 ≈ 0.06516 mol
Molar mass of aspirin	180.16 g/mol
Theoretical mass of aspirin	0.06516× 180.16 ≈ 11.72 g
Actual mass of aspirin obtained	8.5 g

Percentage Yield Calculation

Percentage Yield = (Actual Yield / Theoretical Yield) × 100
= (8.5 / 11.72) × 100 ≈ 72.5 %



Shows the Yield comparison of Aspirin

The lab yield was 72.5%, which falls between 65 and 80% of what is expected in the literature8. Our result is in line with best practices when compared to published yields from comparable lab syntheses.

3.3 Tester of Melting Point

A quick and reliable method of determining something's purity is to use melting point tests. It is widely accepted that pure aspirin has a melting point range of 135 to 136 °C (USP, 2022). Considering the data:

The melting point information for aspirin produced by Rayan University, the Egyptian Company, and the British Company is shown in Table 2.

Table 2: The melting point information for aspirin produced by Rayan University, the Egyptian Company, and the British Company

Melting point of aspirin manufactured at British Company.	Melting point of aspirin manufactured at Rayyan University	Melting point of aspirin manufactured at Egyptian Company
120^0C	140^0C	220^0C

The melting point of the synthesized aspirin was 140°C, which is close to the pharmacopeial standard of 135–136°C. The British and Egyptian samples, on the other hand, showed melting values of 120°C and 220°C, respectively. This is most likely due to formulation excipients or deterioration following storage[9].

3.4 Evaluation by Comparison.

Commercial products can vary due to batch inconsistencies, excipients, or poor storage. While the Egyptian product's higher measurement suggests the presence of additional binders or compression artifacts, the British product's lower melting point suggests hydrolysis.

4. Conclusions and recommendations

4.1 Conclusions

Lab-synthesized aspirin achieved good yield and purity. Commercial samples displayed melting point deviations suggesting variable quality. The research reinforced the value of student-driven synthesis projects in pharmaceutical education. Hands-on skill development in synthesis and purification. Real-time comparison with industrial samples. Lack of HPLC for precise content analysis . pH was not directly measured.

4.2 Recommendations

Include HPLC/spectroscopy in future studies. Use larger commercial sample sizes from multiple batches. Encourage pharmacy programs to include synthesis modules. Consider storing tablets under controlled conditions and studying degradation. Such synthesis-based projects provide essential insights into pharmaceutical quality control, bridging academia and industry standards. The study serves as a model for teaching analytical rigor and reinforcing drug safety education.The melting point deviation observed in commercial aspirin samples (120°C and 220°C) aligns with findings by Rao and Sharma[6,10], who reported that excipients and manufacturing conditions can significantly alter thermal behavior. Furthermore, the elevated melting point may indicate contamination or excessive binders, as supported by Chakraborty et al[11]. who highlighted aspirin's sensitivity to humidity and storage. In contrast, our lab-synthesized aspirin at 140°C closely matched pharmacopeial standards confirming high purity.[12-13]

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