Assay of Sodium Bicarbonate tablet commercially available in Bangladesh.

By

Mehdi Zaman Rumman
19146049

A thesis submitted to the School of Pharmacy in partial fulfillment of the requirements for the degree of Bachelor of Pharmacy (Hons.)

School of Pharmacy
BRAC University
July 2025

Declaration

It is hereby declared that

1. The thesis submitted is my/our own original work while completing degree at BRAC University.
2. The thesis does not contain material previously published or written by a third party, except where this is appropriately cited through full and accurate referencing.
3. The thesis does not contain material which has been accepted, or submitted, for any other degree or diploma at a university or other institution.
4. I have acknowledged all main sources of help.

Mehdi Zaman Rumman
19146049

Approval

The thesis/project titled "Assay of Sodium Bicarbonate tablet commercially available in Bangladesh" submitted by Mehdi Zaman Rumman – 19146049 of Spring, 2025 has been accepted as satisfactory in partial fulfillment of the requirement for the degree of B.Pharm on 2025.

Examining Committee:

Supervisor:
(Member)

_____

Eshaba Karim
Lecturer ,School of Pharmacy
Brac University

Departmental Head:
(Chair)

_____

Raushanara Akter, PhD
Professor and Acting Chairperson, School of Pharmacy
Brac University

Acting Dean:
(Chair)

_____

AFM Yusuf Haider, PhD
Acting Dean, school of pharmacy
Brac University

Ethics Statement

This study does not involve any human and animal trial

Abstract

The quality of Pharmaceutical products need to be strictly maintained to ensure safety. The USP provides strong guidelines checking and ensuring quality of pharmaceutical products. In this study the potency of commercially available sodium bicarbonate tablets was determined and their quality was evaluated. Out of four brands that were assessed three met specifications set by USP. This study demonstrates their high quality of the products manufactured by pharmaceutical companies in Bangladesh and identifies scope of future studies.

Keywords: Potency, Titration, Sodium bicarbonate tablets,

Acknowledgement

First and foremost, I would like to express my gratitude to the Almighty Allah for his endless gifts, which have been given to me in an effort to provide me with the strength and determination to complete this project. It is my genuine pleasure to offer my heartfelt appreciation to my academic supervisor, Eshaba Karim (Lecturer at Brac University's School of Pharmacy), for her invaluable guidance and encouragement during this research. Through the course of my education and project writing, she was a true source of advice and support for me. I am quite grateful to her for her valuable comments and ideas during my study, which helped me much in completing me project work in a timely manner.

Finally, I'd like to convey my thanks to my parents, who never cease to inspire me to push myself beyond my comfort zone. I would not have made it this far without the daily prayers and unconditional love of my family and loved ones. I'd also want to express my gratitude to all of the folks who, whenever they were called upon, went above and beyond to assist me.

Table of Contents

List of Tables

List of Figures

Chapter 1 Introduction

The remarkable growth and resilience of the pharmaceutical industry of Bangladesh contributes noticeably to monetary growth, employment, and technological advancement. The past two decades have seen the rise of the pharmaceutical industry of Bangladesh. It has undergone transformative developments that gave it the position as a leader among the developing countries. Advancing from promising administration guidelines, regulatory support, and a highly capable workforce, the pharmaceutical sector of Bangladesh has become self-sufficient and has been able to meet over 98% of domestic pharmaceutical demands. This self-sufficiency has made it possible for Bangladesh to expressively increase its pharmaceutical exports in over 150 countries across Asia, Europe, Africa, and the Americas.(Asia Pharma Expo 2025 Boosts Bangladesh Pharma Industry, n.d.) The achievement of the pharmaceutical sector in Bangladesh is due to the viable manufacturing proficiencies, cost-effective production practices, and compliance to international quality standards.

Previous studies have evaluated the quality of pharmaceutical products in Bangladesh. One such study examines the dissolution profile, potency, and hardness of four diclofenac sodium tablet brands available in Bangladesh. The samples met USP and BP standards, confirming satisfactory quality and bioavailability (Sultana et al., 2017).

However not all studies reported products meeting quality standards. In one such study a cross-sectional investigation was conducted to investigate the potency of vital drugs from small pharmaceutical companies in Bangladesh. The outcome revealed common substandard products, particularly for amoxicillin and diclofenac sodium, signifying a demanding necessity for regulatory initiatives in the rural drug markets of Bangladesh(Hossain ASMM & Abm, 2017).

Another study was about the evaluation of the potency, dissolution, and physical parameters of paracetamol and ranitidine brands that are available in Bangladesh. Although most samples met BP/USP standards, some showed failures in potency, dissolution, and weight variation, suggesting the existence of inferior items (Rahman et al., 2003).

Another study used spectrophotometric analysis to assess the pharmaceutical quality of 43 brands of ranitidine tablets marketed in Bangladesh by testing for potency, weight fluctuation, and disintegration time. Among these eight did not meet USP guidelines. these were judged to be substandard or imitations. (Sarker et al., 2016)

Another study assessed the potency of ten commercially available amoxicillin dry suspensions marketed in Bangladesh. The initial potencies ranged from 80.52% to 121.68%. While most samples met the USP specification , one sample (SH6) was found to be substandard , and two samples exceeded the upper limit (Shabbir Haider et al., n.d.)

Sodium bicarbonate ($NaHCO_3$) has a range of applications from being an active pharmaceutical ingredient (API) to an effective excipient in numerous medicinal formulations. Sodium bicarbonate is used for the alkalinizing properties, proving its effectiveness in the treatment of conditions, such as metabolic acidosis, that can occur in various renal diseases, uncontrolled diabetes, or circulatory inadequacy for shock or serious dehydration. It is also specified for acidosis during cardiac arrest and for alkalinizing urine to increase the excretion of certain drugs or toxins (Karen Whalen, n.d.).Additionally, sodium bicarbonate is a key component for the formulation of antacids that provides relief in acidity, indigestion, and heartburn through neutralizing excess gastrointestinal acid. Several prominent pharma companies in Bangladesh manufacture and supply sodium bicarbonate in various available forms. For instance, Radiant Pharmaceuticals Ltd. offers "Alkalina" tablets containing 600 mg of sodium bicarbonate, while UniMed UniHealth Pharmaceuticals Ltd. provides "Renocarb" tablets with the same dosage. “Sodibar” tablet

is offered by Square Pharmaceuticals PLS with the dose of 600mg and Popular Pharmaceuticals Ltd offers “ Sodicard ” with the dose of 600mg. “Sodinate” tablet is offered by Opsonin Pharma Ltd with similar dose. Additionally, intravenous formulations such as "Sodib" (7.5% solution) are available through Jayson Pharmaceutical Ltd .

In Bangladesh quality and purity of drugs are vital to guarantee the efficacy, safety, and compliance with regulatory standards. To sustain consistency in pharmaceutical use, global pharmacopeias, for example the United States Pharmacopeia (USP) and British Pharmacopoeia (BP), provide strict rules for the assay of Sodium bicarbonate tablets to regulate the purity and concentration ((United States Pharmacopeial Convention [USP], 2011; British Pharmacopoeia Commission [BP], 2022). The USP assay of Sodium bicarbonate tablets is based on a direct acid-base titration method. Here Sodium bicarbonate reacts with hydrochloric acid and forms sodium chloride , carbon dioxide, and water . The endpoint is detected using an indicator called methyl orange. The percentage of Sodium bicarbonate is calculated based on the volume of acid needed for neutralization. According to USP standards, Sodium bicarbonate tablets must exhibit a potency of 95.0% to 105.0% .(United States Pharmacopeial Convention [USP], 2011). Correspondingly, BP assay employs a back- titration or acidimetric method, where an additional amount of HCl is added to react with sodium bicarbonate, and the remaining unreacted acid is titrated against sodium hydroxide (NaOH).

In this study, the assay of sodium bicarbonate tablets was performed in order to determine the potency and evaluate their quality as per USP standards.

Chapter 2 Material & Methods:

2.1 Materials.

Sodium bicarbonate tablets were purchased from a retail pharmacy outlet. The details of the brands are given below:

Table 1: Details of tablets

Brand Name	Tablet A	Tablet B	Tablet C	Tablet D
Dosage form	Tablet	Tablet	Tablet	Tablet
Batch number	1241924E1026	5A02207	24K0673	441
Expiry date	10/26	12/26	10/27	09/26

37% concentrated HCL and Sodium Carbonate was provided by the School of Pharmacy, BRAC University.

Table 2 : Details of reagents

Reagent	**HCL details:**	**Na_2CO_3 details:**
Manufacturer	Merck Specialties' Private Limited	Merck (EMSURE® grade)
Lot number / Batch number	CA5C657111	SC2023A01
CAS number	1.93001.2521	1.06392.0500
Expiry date	May 2027	Dec. 2027

2.2 Methods.

Standardization of Hydrochloric Acid (HCl) Solution:

10 mL of 0.5 N sodium carbonate solution was taken in a clean 100 mL conical flask. The solution was titrated with standard 0.5 N hydrochloric acid solution using methyl orange as the indicator. The titration was continued until the yellow-orange color was changed to red. The initial and final burette readings were recorded. The process was repeated. The average volume of titrant consumed was taken and the strength of the titrant (HCl) was determined.

Assay of Sodium Bicarbonate Tablets:

For each brand, tablets were weighed and powdered. 1.25 g of the powder was transferred into a conical flask and marked as the sample. 50 mL of distilled water was added to it. The solution was titrated with a standardized 0.5 N HCl solution employing methyl orange as the indicator. The initial and final burette readings were recorded. The process was repeated twice.

Figure 1: Preparation of tablet solutions

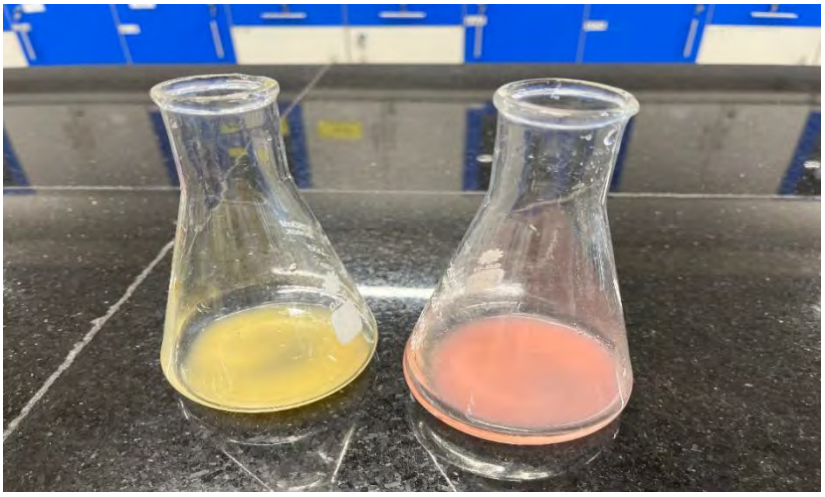

Figure 2: Assay of tablets

Chapter 3 Result

3.1 Preparation of Sodium carbonate solution.

To prepare 0.5N sodium carbonate solution, 1.3394g of sodium carbonate was dissolved with distilled water in a 50 mL volumetric flask.

Table 3: Preparation of Sodium carbonate solution

Weight of Sodium carbonate	1.3394 g
MW of Sodium carbonate	106 g
Equivalent weight of Sodium carbonate	53 g
Number of eq. wt in 50mL	0.02527
Normality	0.5054 N

The concentration of the solution was 0.5054 N.

3.2. Standardization of HCL.

HCl solution was prepared to carry out the assay, to prepare 0.5N HCL, 4.25 mL was diluted to 100 mL with distilled water of 37% w/w.

HCl solution was standardized with the prepared Sodium Carbonate Solution.

Table for the results of the titration are given below:

Table 4: Standardization of HCl

Initial reading (ml)	Final reading (ml)	Volume (ml)	Average (mL)
7.6	17.3	9.7	10.0
17.5	27.6	10.1	
27.7	37.9	10.2	

Concentration of HCL solution was calculated to be 0.5054 N.

3.3 Assay of tablets.

Tablet solutions were made by grinding two tablets. The weight of the tablets and the powders used to make the solution is given in the following table.

Table 5 : Weight of tablet powder

Brand name	**Weight of two tablets**	**Weight of tablet powder used in assay**
Tablet A	1.6289	1.2218
Tablet B	2.0132	1.2550
Tablet C	1.6403	1.2872
Tablet D	1.9427	1.2669

Tablet solutions were titrated. The results are given in the table below:

Table 6 : Assay of tablets

Brand Name	**Initial volume (mL)**	**Final volume (mL)**	**Difference (mL)**	**Average (mL)**
Tablet A	7.4	12.4	5	4.567
	12.4	17.1	4.7	
	17.2	21.2	4	
Tablet B	10.3	14.1	3.8	3.7
	14.2	17.9	3.7	
	17.9	21.5	3.6	
Tablet C	21.2	25.6	4.4	4.633
	25.8	30.6	4.8	
	30.7	35.4	4.7	
Tablet D	35.5	39.1	3.6	3.767
	39.2	43.0	3.8	
	43.1	47.0	3.9	

1 mL 1N HCl solution is equivalent to 84.0 mg sodium bicarbonate. Since the concentration of the prepared HCl solution was 0.5054N, 1 mL of this solution is equivalent to 42.4536 mg sodium bicarbonate.

For each brand, the amount of sodium bicarbonate in 10 mL solution was calculated using the average volume of HCl required in the assay. This was used to calculate the weight of sodium bicarbonate in 50 mL tablet solution. Since this corresponds to the weight of tablet powder used for the assay, the amount of sodium bicarbonate that would be present in two tablets was calculated.

Table 7 : Potency of tablets

Brand Name	**Mean volume of HCl (ml)**	**Amount of Na_2CO_3 / 10 ml**	**Amount of Na_2CO_3 / 50 ml**	**Amount of Na_2CO_3 in two tablets (mg)**	**Potency**
Tablet A	4.567 ml	193.9 mg	969.5 mg	1292.53 mg	107.71%
Tablet B	3.7 ml	157.102 mg	785.51 mg	1226.36 mg	105.005 %
Tablet C	4.633 ml	196.72 mg	983.6 mg	1260.07 mg	104.45 %
Tablet D	3.767 ml	159.95 mg	799.75 mg	1253.41 mg	102.20 %

Potency was determined using the formula,

$$\%\text{potency} = \frac{amount\ found}{amount\ claimed} \times 100\%$$

Chapter 4 Discussion

In this study, four brands of sodium bicarbonate tablets were assayed to evaluate their quality as per USP standards. The four brands included were Tablet A, Tablet B, Tablet D, and Tablet C. As per the United States Pharmacopeia (USP) and the British Pharmacopoeia (BP) specifications, Sodium bicarbonate tablets must fulfill established potency specifications in order to ensure the effectiveness of therapy. The USP requires the potency to be within 95.0% to 105.0% of the labeled amount. This confirms that each tablet contains the required amount of sodium bicarbonate needed on the label, allowing a ±5% variation to account for manufacturing and analytical tolerances. In this study, 3 out of 4 brands met the potency specification of USP. The potency of Tablet B is 105.005%, Tablet C is 104.45%, and Tablet D is 102.20%. These are within the range of potency standards of USP . The potency of Tablet A is 107.71%, which exceeds the maximum range of the potency standard. Previous studies which evaluated the quality of pharmaceutical products manufactured in Bangladesh have reported mixed results. Our study also found that three out of four brands of sodium bicarbonate tablets complied with USP specifications.

Chapter 5 Conclusion

This present study evaluated the potency compliance of four marketed brands of sodium bicarbonate tablets available in Bangladesh are Tablet A, Tablet B, Tablet D, and Tablet C. Potency was compared with specifications set in USP . The results that were acquired were satisfactory. Among the four brands, three met the accepted potency range. This demonstrates that major local manufacturers are proficient in producing quality-compliant formulations. These findings reflect an overall improvement in pharmaceutical manufacturing standards, particularly in commonly used agents like sodium bicarbonate, which is very important in managing acid-base imbalances and other clinical conditions.

This study is focused solely on assay-based potency analysis. However, there are other critical parameters, such as hardness test, disintegration test, dissolution behavior, stability under variable environmental conditions, impurity profiling, and bioequivalence assessments which were beyond the scope of this work. These could be scopes for future study. Furthermore, expanding the study to include a wider range of manufacturers and geographical sampling would provide a more comprehensive view of market consistency. In this study, we did the potency test of four available brands, but there are a few more brands, The study is based on the brands of Bangladesh, but globally available brands could be assayed and their potency could be compared. The batch differences may also be investigated.

References

Hossain ASMM, A., & Abm, F. (2017). Potency Determination of Essential Drug Samples Manufactured By Small and Medium Pharmaceutical Industries in Bangladesh. In *Bangladesh Med Res Counc Bull* (Vol. 43).

Karen Whalen. (n.d.). *Lippincott Illustrated Reviews: Pharmacology* (7th ed.). Lippincott Williams & Wilkins.

Rahman, G. M. S., Ahmed, F., Shill, M. C., Karmakar, U. K., Khaleq, T., & Alam, S. M. M. (2003). POTENCY AND STABILITY STUDIES OF MARKETED PARACETAMOL AND RANITIDINE HCl PREPARATIONS IN BANGLADESH. *Khulna University Studies*, 49–53. https://doi.org/10.53808/kus.2003.5.2.0310-l

Sarker, M. M. R., Rashid, M. S., Raju, A. A., Rana, M., Karim, M. F. Bin, Akter, R., Howlader, A. N. M. A. N., Ming, L. C., & Ismail, N. E. (2016). Evaluation of the pharmaceutical quality of different brands of ranitidine tablets manufactured in Bangladesh: A pharmaceutical and public health prospective. *Journal of Applied Pharmaceutical Science*, *6*(1), 055–061. https://doi.org/10.7324/JAPS.2016.60109

Shabbir Haider, S., Nasrin, N., Sarker Apu, A., & Asaduzzaman, M. (n.d.). *Accelerated stability and antimicrobial sensitivity studies of amoxicillin dry suspensions marketed in Bangladesh*.

Sultana, T., Didaruzzaman Sohel, M., Hassan Kawsar, M., & Banoo, R. (2017). In Vitro Dissolution Study and Assay of Diclofenac Sodium from Marketed Solid Dosage form in Bangladesh. *J Bioanal Biomed, an Open Access Journal*, *09*(3), 3. https://doi.org/10.4172/1948-593x.1000164ï