A COMPARATIVE STUDY OF HARDNESS AND FRIABILITY OF SELECTED ORAL PARACETAMOL TABLET BRANDS IN BANGLADESH

By

SANJITA RAHMAN MEGHLA
ID- 20346011
CHRISTINA CHAITY SARKAR
ID- 20346020
JANNATUL AFROZAH
ID- 20346028

A thesis submitted to the School of Pharmacy in partial fulfillment of the requirements for the degree of Bachelor of Pharmacy

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School of Pharmacy

BRAC University

Dedicated to our family and our respected faculty members.

Declaration

It is hereby declared that

1. The thesis submitted is 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. We have acknowledged all main sources of help.

Student's Full Name & Signature:

Sanjita Rahman Meghla
ID-20346011

Christina Chaity Sarkar
ID- 20346020

Jannatul Afrozah ID-
20346028

Approval

The thesis/project titled "A Comparative Study of Hardness and Friability of Selected Oral Paracetamol Tablet Brands In Bangladesh" submitted by Sanjita Rahman Meghla (20346011), Christina Chaity Sarkar (20346020) and Jannatul Afrozah (20346028) of Summer, 2020 has been accepted as satisfactory in partial fulfillment of the requirement for the degree of Bachelor of Pharmacy on January 2026.

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Supervised by: Eshaba Karim
Senior Lecturer, School of Pharmacy
BRAC University

Approved by:

_____

Dr. Sharmind Neelotpol, PhD
Chairperson: Professor and Chairperson, School of Pharmacy
BRAC University

_____

Dean: Professor A.F.M. Yusuf Haider, PhD
Acting Dean, School of Pharmacy
BRAC University

Ethics Statement

The study design does not involve any human participants or animal experimentation.

Abstract

Paracetamol is one of the most widely used over-the-counter analgesic and antipyretic drug in Bangladesh. Due to its extensive consumption, maintaining consistent tablet quality is essential to ensure therapeutic effectiveness and patient safety. This study aimed to comparatively evaluate the quality control parameters, specifically hardness and friability, of selected oral paracetamol tablet brands available in Bangladesh.

A total of fifteen commercially available brands were collected and analyzed using standard in vitro quality control methods. The obtained results were statistically analyzed using one- way ANOVA to assess significant differences among brands and formulations.

All tested brands complied with limits for friability and exhibited acceptable hardness values. Statistical analysis indicated no significant differences in hardness and friability between tablets of different doses of paracetamol and tablets with different drug combination ($p > 0.05$). These findings suggest that the evaluated brands demonstrate satisfactory mechanical integrity.

Keywords: Paracetamol, Hardness, Friability, Paracetamol, ANOVA

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List of Acronyms

- SPSS – Statistical Package for the Social Sciences.
- ANOVA – Analysis of Variance.
- API – Active Pharmaceutical Ingredient.
- HPLC – High-Performance Liquid Chromatography.
- WHO – World Health Organization.
- OTC – Over the Counter Drug.

Chapter 01 Introduction

1.1 Background

The pharmaceutical industry in Bangladesh has experienced remarkable growth over the past two decades, becoming one of the most technologically advanced and economically important sectors in the country. Following the Drug (Control) Ordinance of 1982, which promoted domestic drug production and reduced dependence on imports, the industry expanded rapidly. At present, approximately 97–98% of the nation's medicine demand is met by local manufacturers, producing a wide range of dosage forms including tablets, syrups, injectables, inhalers, and selected biotechnology products (*Bangladesh Pharmaceutical & API Industry*, n.d.). The sector is regulated by the Directorate General of Drug Administration (DGDA) under the Ministry of Health and Family Welfare, which oversees drug registration, factory licensing, quality control, inspections, and post-marketing surveillance. All pharmaceutical manufacturers in Bangladesh are required to comply with Good Manufacturing Practices (GMP) in accordance with World Health Organization (WHO) guidelines. The market comprises over 300 companies, with 30–40 major players dominating production.

Quality control testing is a fundamental aspect of pharmaceutical manufacturing, ensuring that medicines comply with established standards for safety, efficacy, and stability. *In vitro* testing of tablets involves evaluating the properties and performance of pharmaceutical tablets outside of a living organism, in a controlled laboratory environment. These tests are crucial for ensuring the quality, safety, and efficacy of the tablets before they are approved for use in patients. Several key *in vitro* tests are commonly conducted on tablets such as hardness test, friability test, weight variation test, disintegration test, dissolution test, potency test, Dose uniformity test etc. Among the many physical quality parameters, tablet hardness and

friability is particularly significant because they determine a tablet's mechanical strength, resistance to damage, and ability to disintegrate properly after administration. Tablets that are too hard may fail to disintegrate in a timely manner, whereas tablets that are too soft may break or crumble during handling, packaging, or transportation, ultimately affecting dose accuracy and patient outcomes (Allen & McPherson, 2023).

Tablet hardness is commonly assessed using a tablet hardness tester, which applies increasing force to a tablet until it fractures. A minimum hardness value of approximately 4 kg is generally considered acceptable for conventional tablets. Several factors influence tablet hardness, including compression pressure during tableting, granulation characteristics, binder concentration, and the nature of excipients used in the formulation (Allen & McPherson, 2023).

Friability testing, on the other hand, measures a tablet's resistance to abrasion and mechanical stress. This test is performed using a friabilator, in which tablets are rotated and allowed to fall repeatedly within a drum. The percentage weight loss after testing indicates the tablet's durability during handling and transportation. Pharmacopeial guidelines state that an acceptable tablet should not lose more than 1% of its weight during the friability test. Like hardness, friability is also affected by formulation variables and manufacturing conditions (Allen & McPherson, 2023)

There has been several studies which studied the hardness and friability of tablets. The result of the hardness test of different brands of Ebastin 10 mg tablets was found to be 66.6kg and the results of the Friability test was found to be 0.29 % (Rahman, 2019). The result of the hardness test of different brands of Linagliptin tablets was found to be 0.8 kg and the results of the Friability test was found to be 0% (Agarwala, 2024). The results of the Friability test of different brands of Atrovastin 20 mg tablets was found to be 0.740% and the result of the hardness test was found to be 6.20 kg (Shimu, 2024). The results of

the Friability test of different brands of Amlodipine Besylate tablets was found to be 0% and the results of the hardness test was found to be 3.02 kg (Mahfuja & Miti, 2024). The results of the hardness test of different brands of Perdnisolone 5 mg tablet was found to be 2.68 kg and the results of the Friability test was found to be 0% (Morshed, 2015).

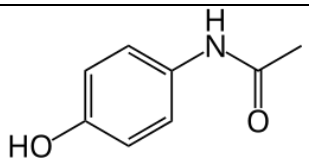
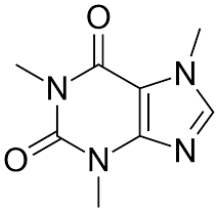
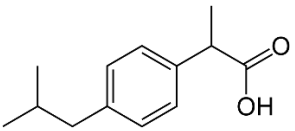
1.2 Rationale of the study

Paracetamol is sometimes formulated in combination with caffeine to enhance its analgesic and antipyretic effects. Caffeine is known to improve paracetamol absorption and increase cerebral blood flow, leading to faster onset of action and improved pain relief. In Bangladesh, paracetamol–caffeine combinations such as *Napa Extra* (Beximco Pharmaceuticals Ltd.) and *Ace Plus* (Square Pharmaceuticals) are widely used. These products typically contain 500 mg of paracetamol and 65 mg of caffeine per tablet and are available as over-the-counter medicines. They are commonly used to treat headaches, fever, migraines, muscle pain, sore throat, and flu-related discomforts due to their affordability and effectiveness. Although numerous pharmaceutical companies in Bangladesh manufacture paracetamol tablets, variations in formulation composition, excipient selection, compression force, and production techniques can lead to differences in physical quality attributes such as hardness and friability. These variations may influence a tablet's mechanical integrity, stability, and disintegration behavior, potentially affecting its therapeutic performance.

Paracetamol, also known as acetaminophen, is one of the most frequently used over-the-counter (OTC) medicines for relieving pain and reducing fever. In Bangladesh, it is manufactured by numerous pharmaceutical companies and marketed in a wide range of strengths and dosage forms. Because paracetamol is classified as an essential medicine, its quality has a direct impact on therapeutic effectiveness, patient safety, and public confidence in pharmaceutical products. Paracetamol is commercially available in many doses and dosage forms. (Table) in Bangladesh including tablets, peadiahic crops, oral suspsyrup,

suppository and IV infusion. Paracetamol is also available in various combinations in Bangladesh. Some combinations are summarized below:

Table 1 Drug combinations of paracetamol tablet available in Bangladesh

			
	Paracetamol	Caffeine	Ibuprofen
Generic name with dose	Paracetamol 500 mg	Paracetamol 500 mg Caffeine 65 mg	Paracetamol 500 mg Ibuprofen 200 mg
Pharmacological effect	Analgesic and antipyretic; inhibits central prostaglandin synthesis	Enhanced analgesic and antipyretic action; faster onset of pain relief.	Combined analgesic, antipyretic, and anti-inflammatory effects; synergistic pain relief.

Although there have been many studies reporting hardness and friability of tablets having the same drug, few studies have evaluated the effect of drug combination or the dose. In our study the effect of the dose of paracetamol on the hardness and friability of paracetamol tablets have been evaluated. In addition the effect of combination of other drugs with paracetamol on the hardness and friability has also been studied. Hardness test and friability test were performed on multiple products. Results from the hardness test and friability test were compared by statistical analysis using SPSS.

1.3 Aims and objectives of the study

The objectives of this study were:

- To measure the hardness of selected oral paracetamol tablet brands available in Bangladesh.
- To determine the friability of the same brands using standard pharmacopeia methods.
- To compare hardness and friability results between different doses and combination formulations.
- To compare hardness and friability results between different combinations
- To assess compliance with pharmacopeia specifications.
- To analyze the influence of formulation differences on tablet mechanical strength.

This study aims to answer the following research questions, “Does the dose of the drug affect hardness and friability of tablets?” and “Does drug combinations affect the hardness and the friability of the tablets?”

Chapter 02 Materials and methods

2.1 Study Design

This study was an in vitro experimental analysis conducted to evaluate the hardness and friability of selected commercially available oral paracetamol tablet brands in Bangladesh.

To study the effect of dose on tablet friability and hardness the tests were performed on three brands of paracetamol 500 mg tablets, three brands of paracetamol 665mg tablets and three brands of paracetamol 1000mg tablets. To study the effect of drug combination on tablet friability and hardness the tests were further performed of paracetamol 500mg with caffeine 65mg tablets and paracetamol 500mg with ibuprofen 200mg tablets.

2.2 Collection of the sample

Fifteen different brands of paracetamol tablets were purchased from retail pharmacies in Dhaka, Bangladesh. The selected products included:

Table 2 Details of tablets used in study

Sl.	Brand name (Generic name with dose)	Manufacturer	Batch no.	Exp. date
1.	Ace (Paracetamol 500mg)	Square Pharmaceuticals Ltd.	5J01807	9/27
2.	Reset (Paracetamol 500mg)	Incepta Pharmaceuticals Ltd.	25024	07/28
3.	Napa (Paracetamol 500mg)	Beximco Pharmaceuticals Ltd.	11600461	12/28
4.	Ace XR (Paracetamol 665mg)	Square Pharmaceuticals	5K03758	09/27

		Ltd.		
5.	Reset ER (Paracetamol 665mg)	Incepta Pharmaceuticals Ltd.	25063	06/27
6.	Napa extend (Paracetamol 665mg)	Beximco Pharmaceuticals Ltd.	49541301	11/27
7.	Ace Power (Paracetamol 1000mg)	Square Pharmaceuticals Ltd.	5L02313	10/27
8.	Feva one (Paracetamol 1000 mg)	Ad-din Pharmaceuticals LTD	B021	12/27
9.	NapaOne (Paracetamol 1000mg)	Beximco Pharmaceuticals Ltd.	49543271	11/27
10.	Ace Plus (Paracetamol 500mg Caffeine 65mg)	Square Pharmaceuticals Ltd.	5D00897	03/28
11.	Reset Plus (Paracetamol 500mg Caffeine 65mg)	Incepta Pharmaceuticals Ltd.	24007	05/28
12.	Napa Extra (Paracetamol 500mg Caffeine 65mg)	Beximco Pharmaceuticals Ltd.	49542871	11/28
13.	Ace Duo (Paracetamol 500mg Ibuprofen 200mg)	Square Pharmaceuticals Ltd.	5K01196	09/27
14.	Flamex Duo (Paracetamol 500mg Ibuprofen 200mg)	Aci Limited	A0278	10/27
15.	Nmax (Paracetamol 500mg Ibuprofen 200mg)	Beximco Pharmaceuticals Ltd.	49539981	10/27

2.3 Instruments and Equipment

The following equipment was used in this study:

Table 3 Details of instruments used in study

Instrument	Model No.	Company name	Country
Friability tester	EF2 USP	Electrolab	India
Hardness tester	YD-1	Wincom	Chaina

2.4 Statistical Analysis

The obtained hardness and friability data were analyzed using SPSS software. One-way ANOVA was used to determine statistically significant differences among brands and formulations. A p-value of less than 0.05 was considered statistically significant.

2.5 Procedure for Hardness test

To perform the hardness test was performed on the tablet was kept on the cleaned leveled tablet surface of the instrument. The tester was switched on by pressing the "ON/ZERO" key and allowed to be tare. The unit kg was selected by pressing the *UNITS key. Then, the Guard cover was slid towards the 'knob end" to open. A tablet was placed on the tablet platform. The safety guard cover was slid back to the initial position to close. It was ensured that the tablet touched the load cell end jaw and was close to the axial center of the breaking point. Then, the knob was made to turn. The process was continued till the tablet was fractured.

2.6 Procedure for Friability test

To perform the friability test on five tablets were weighed using a weighing balance, and this was considered as the initial weight. The tablets were placed in the section 1 of the drum of the friability tester and rotated 100 times. The tablets were re-weighed; this was

considered as the final weight. The percent weight loss was calculated. The percentage weight loss was calculated using the formula:

$$\%Friability = \frac{(Initial\ weight\ - Final\ weight)}{Initial\ weight} \times 100$$

Figure 1 Hardness tester

Figure 2 Friability tester

Chapter 03 Results

3.1 Results for Friability test

The results of the friability test are listed on the table below.

Table 4 Results of Friability test

Sl.	Brand	Generic name with dose	Initial weight (g)	Final weight (g)	% weight loss
1.	A	Paracetamol 500 mg	2.767	2.747	0.7228
2.	B	Paracetamol 500 mg	3.12	3.106	0.0045
3.	C	Paracetamol 500 mg	2.829	2.822	0.0025
4.	D	Paracetamol 665 mg	3.86	3.858	0.0005
5.	E	Paracetamol 665 mg	3.828	3.821	0.0018
6.	F	Paracetamol 665 mg	3.593	3.59	0.0008
7.	G	Paracetamol 1000 mg	5.727	5.719	0.0014
8.	H	Paracetamol 1000 mg	5.408	5.4	0.0015
9.	I	Paracetamol 1000 mg	5.733	5.726	0.0012
10.	J	Paracetamol 500 mg Caffeine 65 mg	3.436	3.261	0.0509
11.	K	Paracetamol 500 mg Caffeine 65 mg	3.261	3.909	-0.1987
12.	L	Paracetamol 500 mg Caffeine 65 mg	3.909	3.436	0.1210
13.	M	Paracetamol 500 mg Ibuprofen 200 mg	4.359	4.35	0.0021
14.	N	Paracetamol 500 mg Ibuprofen 200 mg	4.798	4.8	-0.0004

15.	O	Paracetamol 500 mg Ibuprofen 200 mg	4.994	4.399	0.1191

3.2 Statistical analysis for friability tests comparing effect of dose of drug

The ANOVA table obtained using SPSS comparing friability between tablets containing different doses of paracetamol is given below.

ANOVA

% weight loss

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.117	2	.059	1.019	.416
Within Groups	.345	6	.057		
Total	.462	8			

The Tukey's post hoc table obtained using SPSS comparing friability between tablets containing different doses of paracetamol is given below.

Multiple Comparisons

Dependent Variable: % weight loss

Tukey HSD

(I) 1= Paracetamol 500 mg, 2= Paracetamol 665 mg, 3= Paracetamol 1000 mg	(J) 1= Paracetamol 500 mg, 2= Paracetamol 665 mg, 3= Paracetamol 1000 mg	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
1	2	.2422333	.1957695	.476	-.358441	.842908
	3	.2419000	.1957695	.477	-.358775	.842575
2	1	-.2422333	.1957695	.476	-.842908	.358441
	3	-.0003333	.1957695	1.000	-.601008	.600341
3	1	-.2419000	.1957695	.477	-.842575	.358775
	2	.0003333	.1957695	1.000	-.600341	.601008

3.3 Statistical analysis for friability tests comparing effect of drug combination

The ANOVA table obtained using SPSS comparing friability between tablets containing different combinations of drugs with paracetamol is given below.

ANOVA

% weight loss

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	29.459	2	14.729	.943	.440
Within Groups	93.715	6	15.619		
Total	123.174	8			

The Tukey's post hoc table obtained using SPSS comparing friability between tablets containing different combinations of drugs with paracetamol is given below.

Multiple Comparisons

Dependent Variable: % weight loss

Tukey HSD

(I) 1= Paracetamol 500 mg, 4= Paracetamol 500 mg Caffeine 65 mg, 5= Paracetamol 500 mg Ibuprofen 200 mg	(J) 1= Paracetamol 500 mg, 4= Paracetamol 500 mg Caffeine 65 mg, 5= Paracetamol 500 mg Ibuprofen 200 mg	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
1	4	.1073333	3.2268847	.999	-9.793635	10.008302
	5	-3.7831000	3.2268847	.510	-13.684068	6.117868
4	1	-.1073333	3.2268847	.999	-10.008302	9.793635
	5	-3.8904333	3.2268847	.493	-13.791402	6.010535
5	1	3.7831000	3.2268847	.510	-6.117868	13.684068
	4	3.8904333	3.2268847	.493	-6.010535	13.791402

3.4 Results for Hardness test

The results of the hardness test are listed on the table below.

Table 5 Results of hardness tests

Sl.	Brand	Generic name with dose	Replicate 1 (kg)	Replicate 2 (kg)	Replicate 3 (kg)	Average
1.	A	Paracetamol 500 mg	19.2	19.7	18.9	19.27
2.	B	Paracetamol 500 mg	17.4	18.2	17.2	17.60
3.	C	Paracetamol 500 mg	12.7	11.1	12.17	11.99
4.	D	Paracetamol 665 mg	17.12	17.5	18.17	17.60
5.	E	Paracetamol 665 mg	18.74	19.8	18.2	18.91
6.	F	Paracetamol 665 mg	17.23	17.83	17.12	17.39
7.	G	Paracetamol 1000 mg	18.2	18.74	19.01	18.65
8.	H	Paracetamol 1000 mg	16.49	15.44	16.3	16.08
9.	I	Paracetamol 1000 mg	10.1	10.4	12.2	10.90
10.	J	Paracetamol 500 mg Caffeine 65 mg	13.56	14.37	15.08	14.34
11.	K	Paracetamol 500 mg Caffeine 65 mg	20	20	20	20.00
12.	L	Paracetamol 500 mg Caffeine 65 mg	15.2	17.6	19.38	17.39
13.	M	Paracetamol 500 mg Ibuprofen 200 mg	10.58	12.2	12.25	11.68
14.	N	Paracetamol 500 mg Ibuprofen 200 mg	19.1	19.6	19.2	19.30
15.	O	Paracetamol 500 mg	9.2	10.4	10.3	9.97

		Ibuprofen 200 mg				

3.5 Statistical analysis for hardness tests comparing effect of dose of drug

The ANOVA table obtained using SPSS comparing hardness between tablets containing different doses of paracetamol is given below.

ANOVA

kg

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	34.802	2	17.401	2.167	.136
Within Groups	192.711	24	8.030		
Total	227.513	26			

Tukey's post hoc table obtained using SPSS comparing hardness between tablets containing different doses of paracetamol is given below.

Multiple Comparisons

Dependent Variable: kg

Tukey HSD

(I) 1= Paracetamol 500 mg, 2= Paracetamol 665 mg, 3= Paracetamol 1000 mg,	(J) 1= Paracetamol 500 mg, 2= Paracetamol 665 mg, 3= Paracetamol 1000 mg,	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
1	2	-1.6822222	1.3358014	.431	-5.018102	1.653657
	3	1.0766667	1.3358014	.703	-2.259213	4.412546
2	1	1.6822222	1.3358014	.431	-1.653657	5.018102
	3	2.7588889	1.3358014	.119	-.576991	6.094769
3	1	-1.0766667	1.3358014	.703	-4.412546	2.259213
	2	-2.7588889	1.3358014	.119	-6.094769	.576991

3.6 Statistical analysis for hardness tests comparing effect of drug combination

The ANOVA table obtained using SPSS comparing hardness between tablets containing different combinations of drugs with paracetamol is given below.

ANOVA

kg

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	62.410	2	31.205	2.508	.103
Within Groups	298.566	24	12.440		
Total	360.975	26			

Tukey's post hoc table obtained using SPSS comparing friability between tablets containing different combinations of drugs with paracetamol is given below.

Multiple Comparisons

Dependent Variable: kg

Tukey HSD

(I) 1= Paracetamol 500 mg, 4= Paracetamol 500 mg Caffeine 65 mg, 5= Paracetamol 500 mg Ibuprofen 200 mg	(J) 1= Paracetamol 500 mg, 4= Paracetamol 500 mg Caffeine 65 mg, 5= Paracetamol 500 mg Ibuprofen 200 mg	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
1	4	-.9577778	1.6626779	.834	-5.109962	3.194406
	5	2.6377778	1.6626779	.271	-1.514406	6.789962
4	1	.9577778	1.6626779	.834	-3.194406	5.109962
	5	3.5955556	1.6626779	.098	-.556629	7.747740
5	1	-2.6377778	1.6626779	.271	-6.789962	1.514406
	4	-3.5955556	1.6626779	.098	-7.747740	.556629

Chapter 04 Discussion

All tested brands showed friability values less than 1% acceptable mechanical resistance. The results are summarized in the following figure.

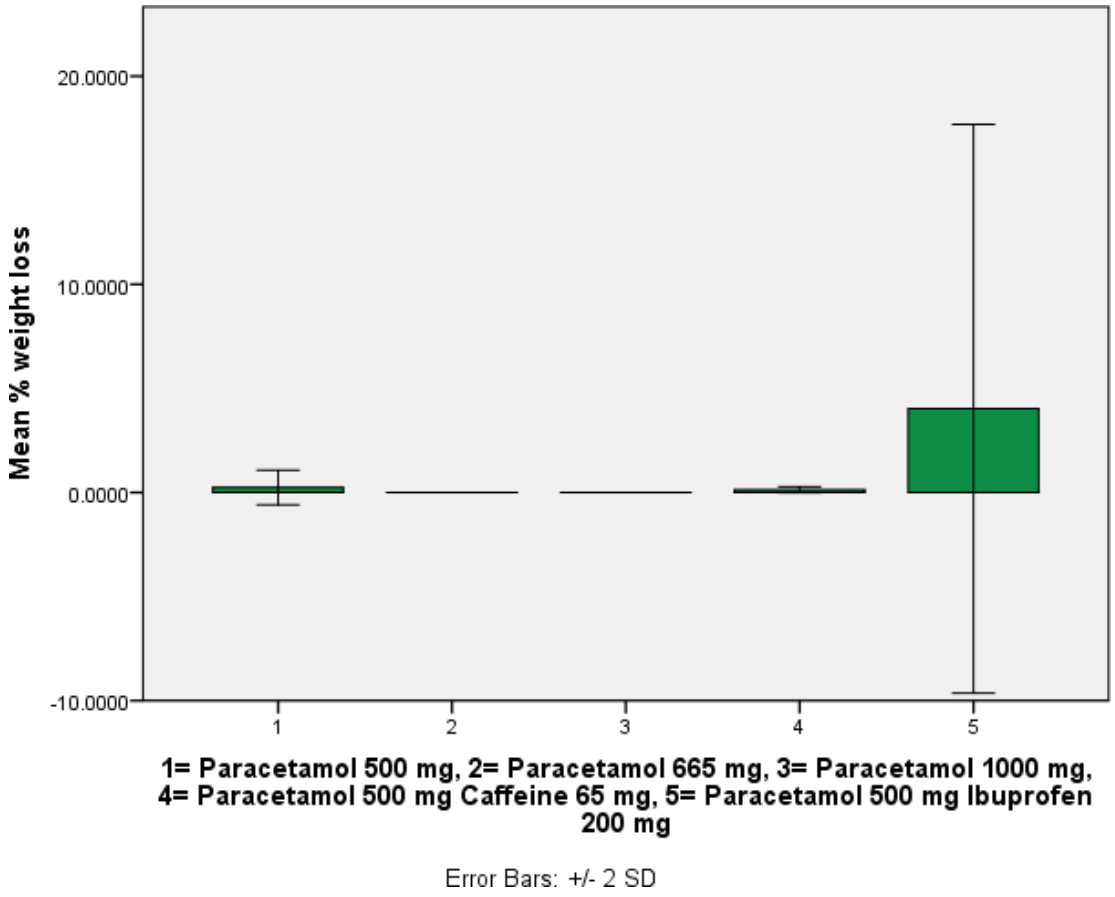


Figure 3 Summary of friability tests

ANOVA was performed to compare the friability of tablets containing different doses of paracetamol (paracetamol 500mg, paracetamol 665mg, and paracetamol 1000mg). The null hypothesis was, “There was no significant difference in friability between tablets containing the different doses of paracetamol”. The obtained P value was 0.416 which is greater than

0.05. So, we cannot reject the null hypothesis. Therefore, we conclude that there is no significant difference in friability between tablets containing the different doses of paracetamol Tukey’s post hoc test also showed similar results between groups as all.

We again performed ANOVA to compare the friability of tablets containing different drug combinations with paracetamol. The null hypothesis was “There is no significant difference in friability between tablets containing different drug combinations with paracetamol”.

The obtained P value was 0.440 which is greater than 0.05. So, the null hypothesis cannot be rejected. Therefore, to conclude, we can say that there is no significant difference in friability between tablets containing different drug combinations with paracetamol. Tukey’s post hoc test also showed similar results between groups as all.

The result of the following test is in agreement with published works stating that tablets friability is dependent on formulation. (Allen & McPherson, 2023).

All tested brands showed hardness values greater than the minimum acceptable limit of 4 kg demonstrating acceptable mechanical resistance. The results are summarized in the following figure.

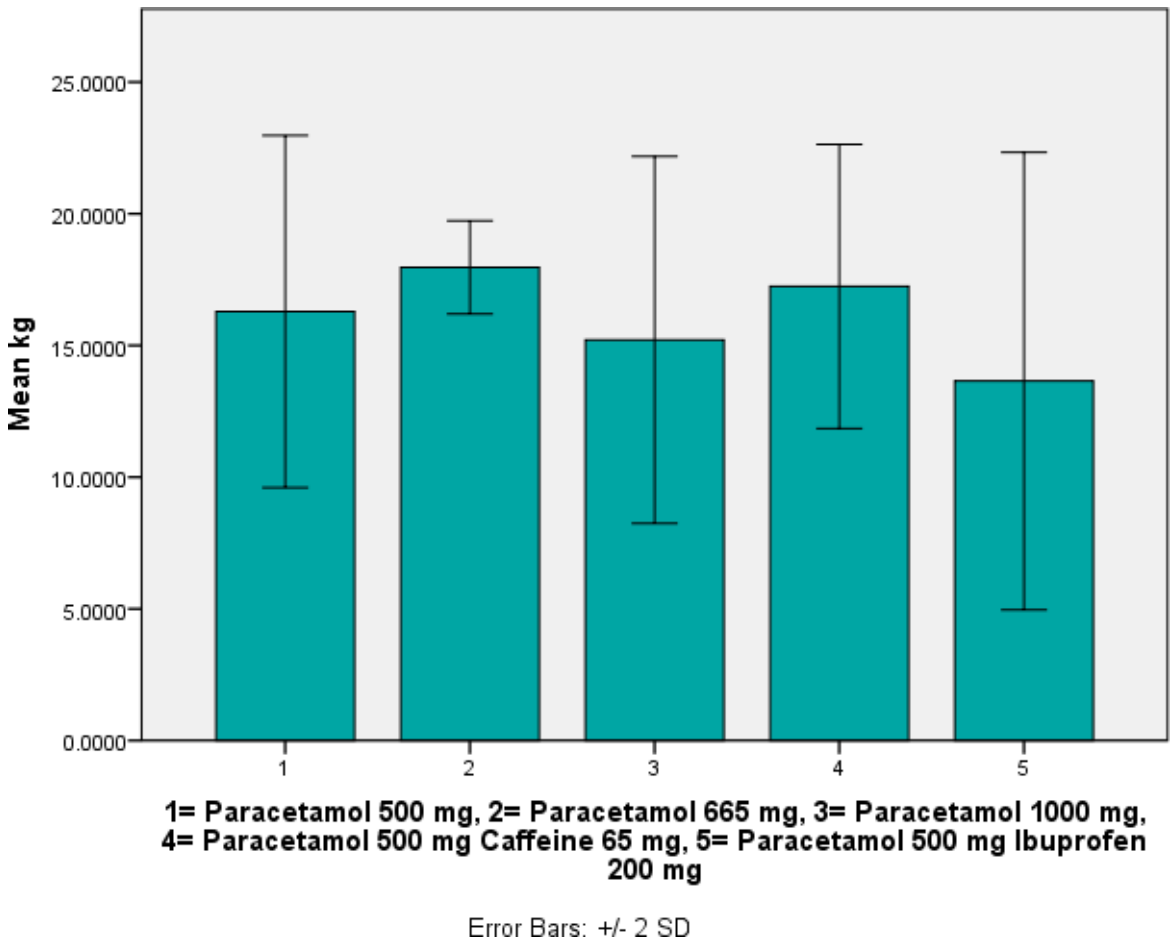


Figure 4 Summary of hardness tests

ANOVA was further performed to compare the hardness of tablets containing different doses of paracetamol. The null hypothesis was "There is no significant difference in hardness between tablets containing different doses of paracetamol". The obtained P value was 0.136 which is greater than 0.05. So, we cannot reject the null hypothesis. Therefore, to conclusion, we can say no significant difference in hardness between tablets containing different doses of paracetamol. Tukey's post hoc test also showed similar results between groups as all.

We again performed ANOVA to compare the hardness of tablets containing different drug combinations with paracetamol. The null hypothesis was "There is no significant difference in hardness between tablets containing different drug combinations with paracetamol". The obtained P value was 0.103 which is greater than 0.05. So, we cannot reject the null

hypothesis. Therefore, finally, it can be said that there is no significant difference in hardness between tablets containing different combinations with paracetamol.

The results of the hardness test are in agreement with published work stating that the desert hardness is dependent on applied pressure during tableting granulation characteristics and type of tablet. (Allen & McPherson, 2023).

Chapter 05 Conclusion

This study provides a comparative in vitro evaluation of hardness and friability among selected oral paracetamol tablet brands marketed in Bangladesh, including different dose strengths and combination formulations with caffeine and ibuprofen. The findings demonstrate that all tested brands met pharmacopeia specifications for friability and exhibited acceptable hardness values, indicating adequate mechanical strength and resistance to physical stress during handling, packaging, and transportation.

Statistical analysis using one-way ANOVA revealed no significant differences in friability or hardness between tablets containing different doses of paracetamol and those formulated in combination with caffeine or ibuprofen ($p > 0.05$). These results suggest that variations in dose and combination formulations did not significantly influence the mechanical quality of the tested products.

Errors were made in measuring the friability of Brands K and N. The experiments could be repeated for these brands.

Overall, the evaluated paracetamol tablet brands showed satisfactory quality performance in terms of mechanical integrity. However, continuous post-marketing quality assessment and regulatory surveillance are recommended to maintain consistency, ensure patient safety, and uphold public confidence in locally manufactured pharmaceutical products. Future studies should incorporate additional quality parameters such as disintegration time, dissolution profile, and assay to provide a more comprehensive evaluation of tablet quality.

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