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Quality control assessment on comparative study of different marketed brands of Clopidogrel tablet

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ABSTRACT

This study aims to assess the quality parameters of Clopidogrel tablets from different manufacturers available in the Bangladeshi market. Clopidogrel is a potent antiplatelet and antithrombotic drug.This study aims to conduct a comprehensive quality control assessment of different brands of Clopidogrel tablets available in the market.Clopidogrel is a potent

anti-platelets and antithrombotic drug. It is film coated and 75 mg tablet. The objective of our study was to evaluate the quality parameters of some marketed clopidrogel tablet and to compare the parameters among them.To assess the quality, nine different marketed clopidogrel 75 mg tablet were selected and in-vitro dissolution test, potency, disintegration time were carried out.[2] Other general quality parameters of these tablets like weight variation, hardness, friability were also determined according to established protocols. All the brands comply the requirements of ‘‘Indian Pharmacopoeia’’ as they showed acceptable weight variation range.Friability of all brands was less than 1%. No significant differences were founding disintegration time as they disintegrated within 15 minutes. In case of dissolution profile all brands showed better dissolution time as they released more than 75% of drug in 45 minute. The hardness of one brand was within the range 40-60N. The limitation of the potency must be within 95-105%.

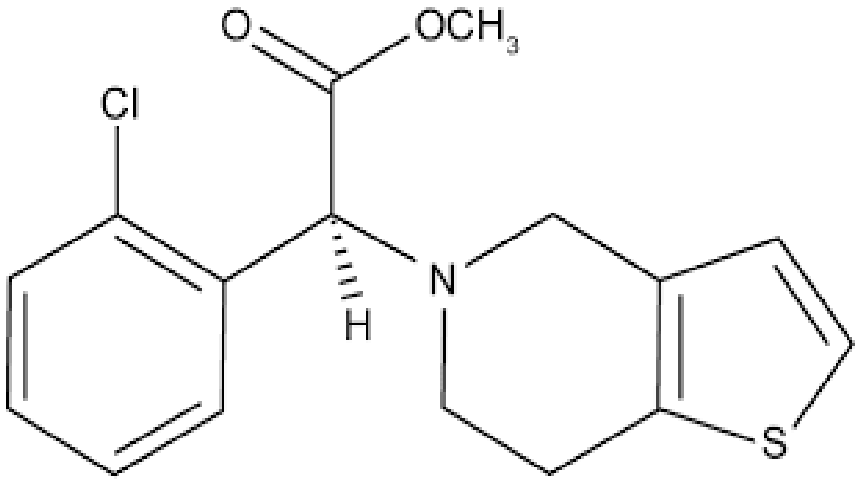
KEYWORDS : Clopidogrel, friability ,hardness, dissolution, disintegration.

INTRODUCTION

Drug profile

Clopidogrel, an antiplatelet drug with structural and pharmacological similarities to ticlopidine, is used to prevent blood clots in a range of illnesses including peripheral vascular disease, coronary artery disease, and cerebrovascular disease. Clopidogrel inhibits ADP-induced platelet aggregation by directly inhibiting the binding of Adenosine Diphosphate (ADP) to its receptor and the consequent ADP-mediated activation of the glycoprotein GPIIb/IIIa complex.

Chemical structure :



Chemical formula : C16H16ClNO2S

IUPAC name : Clopidogrel is Methyl

(2S)-2-(2-chlorophenyl)-2-(6,7-dihydro-4H-thieno[3,2-c]pyridin-5-yl)acetate[2]

Molecular weight : 321.82 g/mol[2]

Category : anti-platelets and antithrombotic**[**2]

Solubility : Freely soluble in methanol, sparingly soluble in methylene chloride, and nearly insoluble in ethyl ether and water at neutral pH**..**[3]

Clopidogrel bisulfate was first registered in the US Pharmacopeia in 2007. The chemical name is (+)-α-(2-chlorophenyl)-6,7-dihydrothieno[3,2- c]Pyridine-5(4H)-acetic acid methyl ester sulfate. This compound prevents platelet aggregation caused by adenosine diphosphate (ADP) by inhibiting its binding to the receptor and activating the glycoprotein GPIIb/IIIa complex. It effectively reduces the risk of ischemic strokes, heart attacks, and claudication caused by vascular illnesses including atherosclerosis. A literature survey found several methods for detecting clopidogrel in pharmaceutical dosage forms, such as chemometry, spectrophotometry, and thin-layer chromatography.

The purpose of this study is to compare quality attributes such as physicochemical parameters such as weight variation, hardness, friability, disintegration time, and dissolution profile of different marketed brands of clopidogrel tablets using different tests following approved protocols as per established procedures.

The variety of clopidogrel brands available in our pharmaceutical market makes it difficult for doctors and pharmacists to find the right one. Many of these medications are significantly less expensive than the original drug brand, causing physicians and pharmacists to overlook their quality, safety, and effectiveness. A product's quality is determined by its conformity to predetermined criteria, which are critical for assuring efficacy and safety.

Ensuring chemical and pharmaceutical equivalency of medications is critical. They should be equivalent in terms of strength, quality, purity, active ingredient release profile, and dosage form for the same mode of

administration. Although clinical trials and scientific literature give some information, post-marketing surveillance is critical for product development, standardization, and regulation. As a result, post-marketing surveillance of licensed medicines is critical in determining their quality, therapeutic efficacy, and safety for public use.

METHOD AND MATERIAL

Study design:

Quality parameter testing on two distinct brands of clopidogrel were performed in the laboratory using various apparatus and reagents.

Area of study

The study was conducted in the department of pharmacy in the nandkumar shinde college of pharmacy, vaijapur, Chatrapati Sambhaji nagar,from March 2024 to April 2024

Materials

An in vitro analysis was performed to evaluate the physicochemical quality control parameters of two distinct brands of clopidogrel tablets. These are known as A.All of the drugs were chosen based on demand in the local market, were labeled with 75 mg clopidogrel per tablet, and were bought from a retail pharmacy in Lasur Station, Maharashtra, India. Quality is evaluated using a variety of tests, including general appearance, weight fluctuation, content homogeneity, thickness, hardness, friability, disintegration, and dissolution test.

Equipment

- Analytical balance
- Vernier caliper
- Hardness tester
- Friability
- Disintegration apparatus
- Dissolution apparatus

Chemical and reagents

- 0.1 M Phosphate buffer
- clopidogrel
- Water

0.1 M phosphate buffer preparation

11.8 grams of KH2PO4 and 2.3 grams of K2HPO4 were dissolved in 100 ml of water. The pH was then adjusted to 6. This method was used to prepare various volumes of the phosphate buffer as needed for the experiment.

Methodology

Physical characteristic

Visual assessment for physical properties such as size, shape, and personally checked taste and odor of the selected tablet.

Thickness

Ten tablet of each brand were selected at random and their thickness and diameter were measured with a Vernier caliper. Means and standard deviations were calculated.[15]

Hardness

The tablet hardness test is performed using a tablet hardness tester from Monsanto, Pfizer, or Schleuniger. The Monsanto hardness tester features a barrel with a compressible spring between two plungers. The bottom plunger makes contact with the tablet, while the higher plunger presses on it until it breaks, compressing the spring and measuring the force in kilograms. Ten tablets are typically tested, with an acceptable range of 4 - 6 kg (40 - 60 N), unless otherwise specified.[13]

Friability

A Roche friabilator is used in a laboratory to examine the friability of tablets. Ten pills are first weighed, placed in the friabilator, and rotated at 25 rpm for four minutes. Following the operation, the tablets are dedusted and reweighed. Friability is calculated as a percentage based on the difference between initial and final weights, using the following
formula:

Friability =[(Initial weight - Final weight) / Initial weight] × 100%.

Traditional compressed tablets that lose less than 0.5% to 1% of their weight after 100 rotations are commonly accepted.[14]

Weight variation

According to IP, the test was performed on 10 tablets, each weighing independently and calculating the average weight. According to IP, the tablet passes the test if no more than two separate weights deviate from the average weight by the specified percentage deviation, as outlined in Table 1, and none of them deviate by more than double that percentage.

Average weight (mg)	Percentage deviation (%)
80 mg or less	10
More than 80 mg but less than 250 mg	7.5
250 mg or more	5

Table .1: weight variation limits for film coated tablet according to IP[2]

Formula for weight variation test

Weight Variation = (Iw - Aw)/Aw X 100% Where, Iw = Individual weight of tablet

Aw = Average weight of tablet.

Disintegration test

The disintegration apparatus consists of 6 glass tubes with a 10 number mesh at the bottom, each measuring 3 inches long. The arrangement of six tubes is arranged in a medium. simulated in the disintegration environment. A thermostat mechanism for heating the liquid and preserving the Temperature at 37°±2°.This system is designed to move up down via a distance of 5 to 6 cm at a frequency of 28 to 32 Cycles per minute. This test requires three clopidogrel tablets. from each brand were used in phosphate buffer, pH 7.4.

The media was tested at 37°C using a Tablet Disintegration Tester.The disintegration time was defined as the moment when no particle remain on the basket of the system.

Dissolution test

The tablets were tested for dissolution using a IP dissolution equipment I (paddle) in 900 ml of pH 7.4 phosphate buffer at 50 rpm and 37±0.5ºC.temperature. Just as the temperature reached 37ºC, The tablet was dropped in the vessel, and the paddle was allowed to rotate. Test sample (10ml) was withdrawn at a specific time intervals and replaced with new.Dissolution medium of equal volume and kept at the same temperature. The collected samples were filtered and examined.UV Spectrophotometer at 222 nm against a blank. Release rate were computed as the percentage of medication release using the Calibration curve.

AIM AND OBJECTIVE

Aim

The aim of study is to compare quality attributes such as physicochemical parameters like weight variation, hardness,friability, disintegration time, dissolution profile by different tests following approved protocols as per established procedures of different two marketed brands of clopidogrel tablet.

Objective

- Evaluate quality control measures of multiple brands of clopidogrel tablets.
- Compare quality attributes across brands.
- Assess adherence to regulatory standards.
- Provide insights for healthcare professionals and consumers.

PLAN OF WORK

Research and Selection:

- Gather information on clopidogrel tablets available in the market.
- Identify several brands for comparison based on availability and relevance.

Literature review

-Examine previous studies on clopidogrel tablets quality control, regulatory standards, manufacturing processes, and brand comparisons. Identify gaps, consider methodologies, and understand clinical relevance to inform your study design.

Quality Control Parameters:

- Determine key quality attributes to assess (e.g., physical characteristics, chemical composition, dissolution rate).
- Establish criteria for evaluating adherence to regulatory standards (e.g., pharmacopoeial requirements).

Sample Collection:

- Procure samples of clopidogrel tablets from selected brands.
- Ensure samples are representative and adequately labeled.

Experimental Setup:

- Set up equipment and instruments for quality control assessments (e.g., balance, dissolution apparatus).
- Follow standard protocols for testing each quality parameter.

Quality Assessment:

- Perform tests on each sample according to predetermined parameters.
- Record observations and measurements accurately.

Data Analysis:

- Analyze collected data to compare quality attributes across brands.
- Identify any variations or discrepancies in quality control measures.

Interpretation:

- Interpret findings in the context of regulatory standards and guidelines.
- Discuss implications for product quality and consistency.

Report :

- Compile results into a research paper or report format.

RESULT AND DISCUSSION

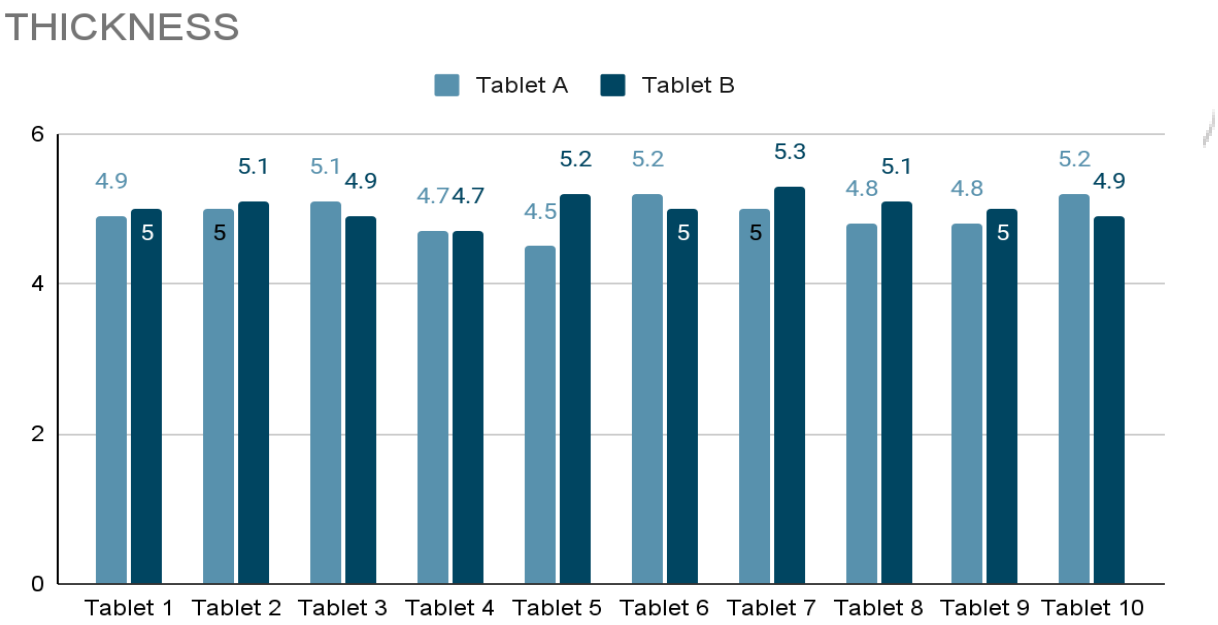
Physical characteristic

Sr. no.	Tablet	Size	Shape	Taste	Odour
1	A	9mm × 9mm	Round, Biconvex	Bitter	No odour
2	B	9mm × 9mm	Heart shape	Loss of taste	No odour

Table no. Physical Characteristics

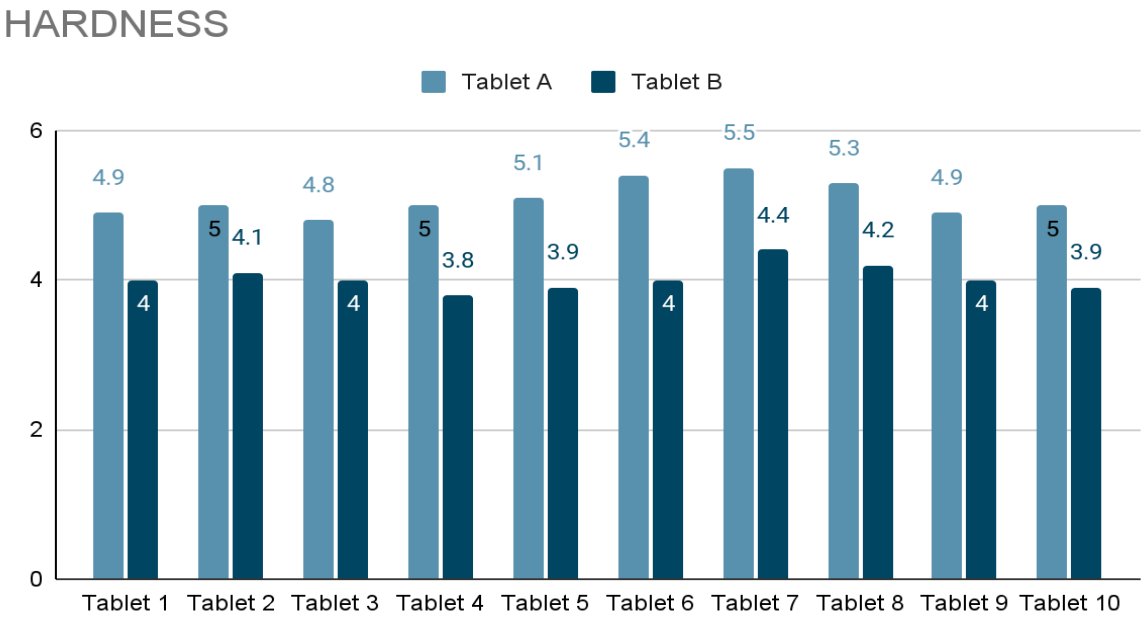
Thickness

Sr.no	Tablet	Thickness (mm) (Mean ± SD),N = 10
±1	A	4.92±0.2135
2	B	5.02±0.16074



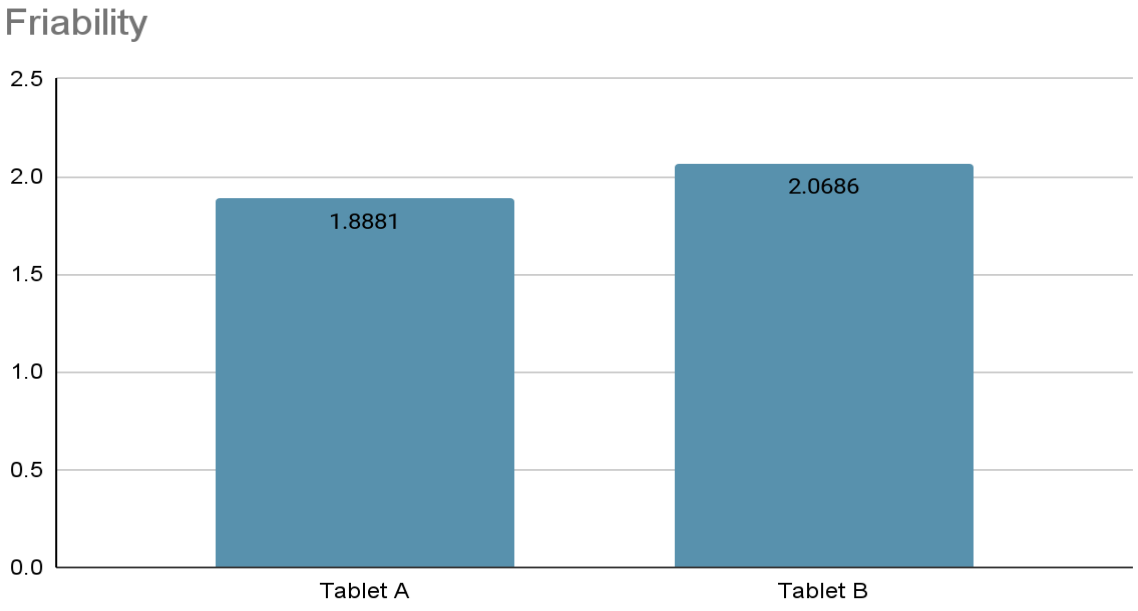
Hardness

Sr.no	Tablet	Hardness (kg/f) (Mean ± SD),N = 10
1	A	5.09±0.2255
2	B	4.03±0.16649



Friability

Sr.no	Tablet	Friability (%) (Mean),N = 10
1	A	1.8881%
2	B	2.0686%

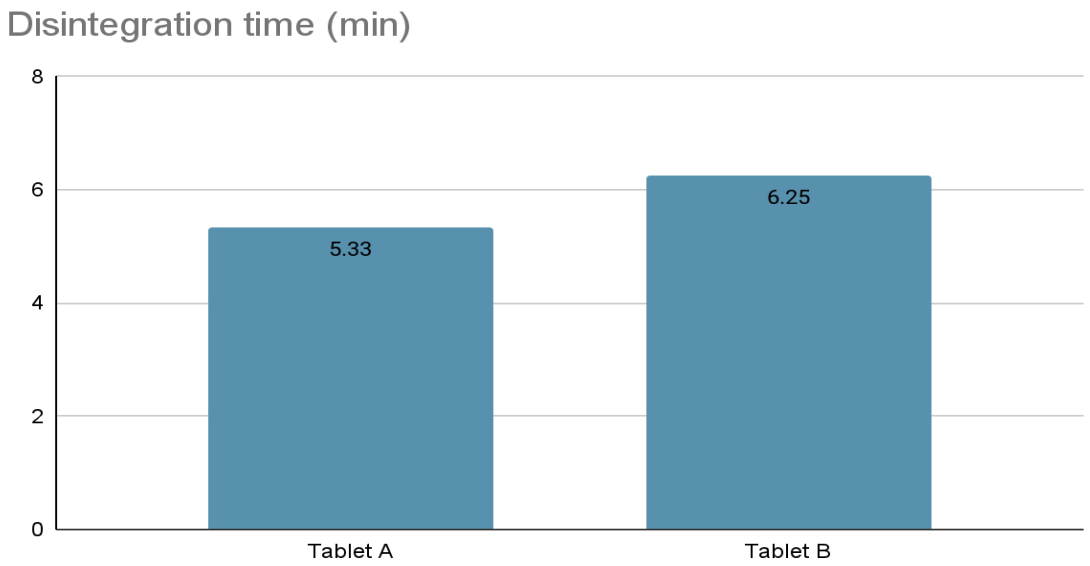


Weight variation

Sr.no	Tablet	Weight Variation (mg) (Mean ± SD),N = 10
1	A	270.1±2.8441
2	B	227.2±4.4

Disintegration test

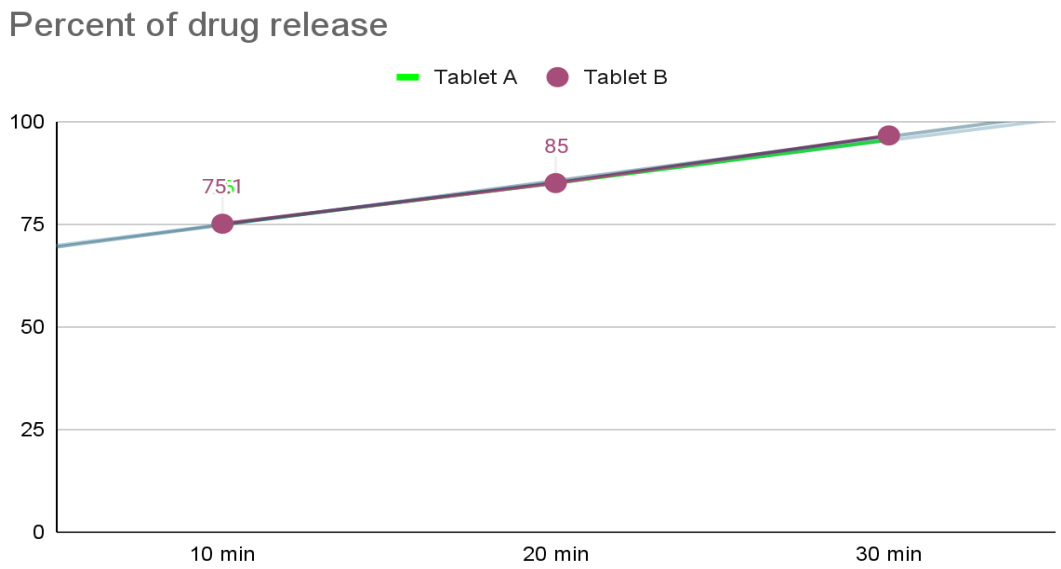
Sr.no	Tablet	Disntegration time (min) (Mean)(N=6)
1	A	5.33
2	B	6.25



Dissolution test

Time in min	Absorbance		Percent of drug release	
	Tablet A	Tablet B	Tablet A	Tablet B
10	0.102	0.103	75	75.1
20	0.150	0.160	85	85
30	0.201	0.210	95.5	96.6

Table no. Dissolution test



CONCLUSION:

Based on the comparative study of different marketed brands of clopidogrel tablets, the research concludes that there are significant variations in quality control parameters among the different brands. These variations may impact the efficacy and safety of the medication, highlighting the importance of rigorous quality control assessments in pharmaceutical manufacturing. Further research and regulatory efforts are needed to ensure consistent quality and standardization acrossall brands of clopidogreltablets to safeguard public health.

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