ASSESSMENT OF THE QUALITY CONTROL CRITERIA FOR FIVE BRANDS OF CIPROFLOXACIN (500 MG) TABLETS AVAILABLE IN BANGLADESH

By

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

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BRAC University
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Declaration

It is hereby declared that

1. The thesis submitted is my 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.

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Approval

The thesis titled “Assessment of the quality control criteria for five brands of Ciprofloxacin (500 mg) tablets available in Bangladesh” submitted by
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Ethics Statement

This study doesn’t involve any animal or human trial.

Abstract

Five brands of 500 mg Ciprofloxacin tablets sold in Bangladesh were assessed for quality control characteristics in this study. This is to evaluate their adherence to USP guidelines. Tests were conducted on randomly chosen samples from each brand to measure weight variation, hardness, friability, disintegration, and dissolution. Every brand showed outstanding friability performance (<1% weight loss) and complied with weight variation standards (±5% deviation). In the disintegration test, all five brands of Ciprofloxacin tablets tested broke in the medium in 3 minutes 5 seconds to 9 minutes 3 seconds. This means they all met the medicine standards. Moreover, in the dissolution test, a drug release profile of less than 31% means patients would not get enough therapeutic effect as it doesn't fulfill the USP/BP guidelines of drug dissolution testing.

Keywords: Ciprofloxacin, adherence, characteristics, therapeutic effect, dissolution, disintegration.

Dedication

I dedicate this work to my beloved father and mother who dedicated their lives for my upbringing, my respected faculty members whose guidance was immense and my fellow classmates who always encouraged me throughout this undergraduate journey.

Acknowledgement

My deepest gratitude and regards to my project supervisor Dr. Mohd. Raeed Jamiruddin (Associate Professor, School of Pharmacy, BRAC University) for his constant guidance and continuous encouragement to make this work successful.

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List of Acronyms

USP United States Pharmacopeia

BP British Pharmacopeia

GSF Gastric Simulated Fluid

CIPRO Ciprofloxacin

Chapter 1

Introduction

1.1 General

Due to the increase in generic pharmaceuticals from different suppliers, prescribers and consumers now have to select from a wide range of products that seem to be pharmaceutically identical, which put pressure on regulatory bodies and led to an increase in poor quality and unauthorized goods (Waffo Tchounga et al., 2023). To overcome this problem, the quality control criteria should be strictly measured. The purpose of this study was to assess the quality control standards of five different brands of ciprofloxacin hydrochloride tablets sold by pharmacies in Bangladesh. The factors determined are hardness, friability, weight uniformity disintegration and dissolution. These interchangeability and bioequivalency can be determined by measuring quality-control characteristics (Uddin, M.S. et al., 2017). It gives medical professionals confidence that using innovative brands rather than generic ones won't have a detrimental impact on patient care. Additionally, pharmaceutical businesses are encouraged to adhere to Good Manufacturing Practices (GMP) and ensure consistency in their output through regular quality assessment (Dash, A. K. 2024).

1.2 Various Bacterial Infections

Gonorrhea, urethral problem, and gonococcal urethritis can all be treated with oral ciprofloxacin tablet. Urinary tract infections (UTIs), acute uncomplicated cystitis in females, persistent bacterial prostatitis, lower respiratory tract infections, acute exacerbations of persistent bronchitis, and complex intra-abdominal infections caused by sensitive organisms are among the bacterial infections for which ciprofloxacin is advised (Sanders C. C. 1988).

1.3 Chemistry of Ciprofloxacin

Ciprofloxacin is a second-generation fluorinated quinolone antibacterial drug with a wide range of activity, ciprofloxacin can be given intravenously or topically. (1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinolinecarboxylic acid) is the chemical name for ciprofloxacin. C17H18FN3O3 is its empirical formula, and its molecular weight is 331.4 g/mol. It is a light yellow to slightly yellowish crystalline substance. Ciprofloxacin hydrochloride (USP) is the monohydrochloride monohydrate salt of ciprofloxacin (Sanders C. C. 1988).

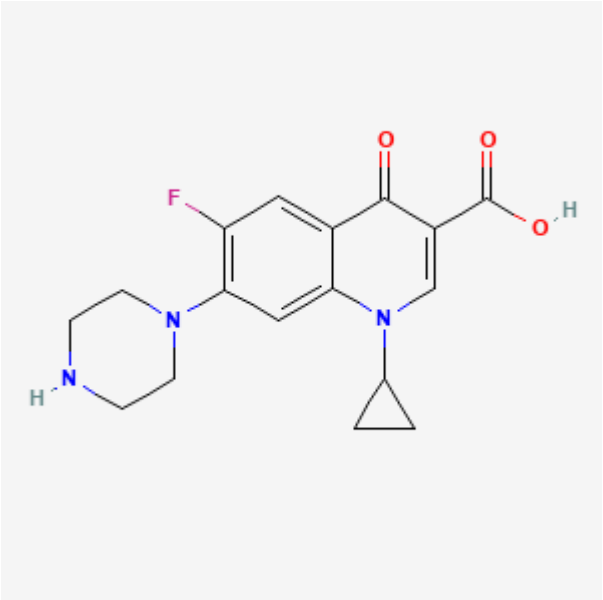

Figure 1: Structure of Ciprofloxacin (PubChem, n.d.)

Table 1: Characteristics of Ciprofloxacin (PubChem, n.d.)

Molecular Formula	$C_{17}H_{18}FN_3O_3$
Chemical Name	1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinolinecarboxylic acid
Solubility	<1mg/mL, Soluble in dilute 0.1 N HCL, practically insoluble in Ethanol.
Molecular mass	331.34 g/mol
Melting point	255-257 °C
Boiling point	581.8±50.0° C
Appearance	white to light yellow crystalline powder

1.3.1 Mechanism of Action

Ciprofloxacin hydrochloride stops bacterial cell division by blocking topoisomerase IV and DNA gyrase, a type II topoisomerase (Sanders C. C. 1988). Like other fluoroquinolones, ciprofloxacin reduces absorption and bioavailability by forming a chelate complex with antacids and metallic cations. Certain gram-positive bacteria can also be effectively treated with ciprofloxacin. The most effective quinolone against Pseudomonas aeruginosa is ciprofloxacin. Ciprofloxacin should not be used as the first line of treatment if penicillin-susceptible Streptococcus pneumonia is the predominant pathogen. For patients who have gram-negative bacterial predisposing factors or mixed infections, ciprofloxacin is a suitable treatment option. It can be used either alone or in combination with other antibacterial drugs to

treat diseases such urinary tract infections and stomach infections where the bacterial pathogen has not been identified (Sanders C. C. 1988).

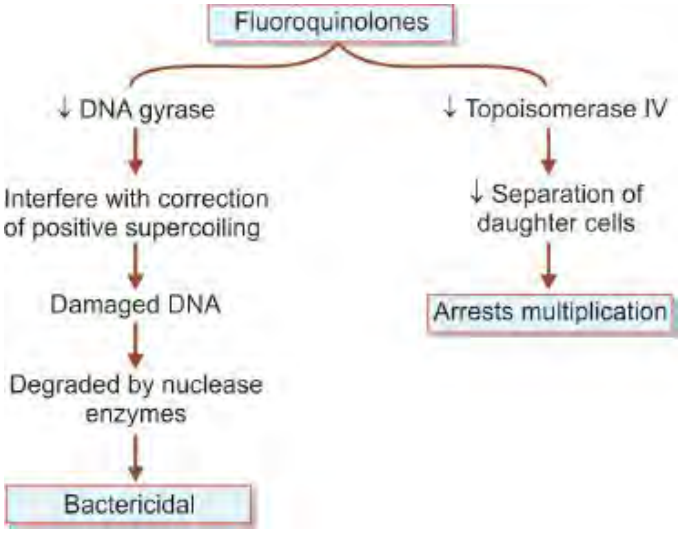

Figure 2: Mechanism of action of Ciprofloxacin

1.4 Side Effects

Some common side effects of ciprofloxacin includes nausea, diarrhoea, redness in the eye, bad taste in the mouth. Moreover, some serious side effects may occur such as heat rhythm issues, liver or kidney issues, allergic reactions, severe tiredness, muscle weakness, pain in abdomen, and swollen ankles (Tsai, W. C., & Yang, Y. M. 2011).

1.4.1 Contraindication

Patients having a history of hypersensitivity to ciprofloxacin or its ingredients are contraindicated for the medication. The literature has shown anaphylactoid responses and anaphylaxis after the initial ciprofloxacin dose. Another contraindication is the concomitant use of tizanidine to treat muscle spasms. Tizanidine's pharmacokinetics are changed by CYP1A2 inhibition (ciprofloxacin), which raises tizanidine levels and lowers blood pressure, heart rate, and psychomotor activity. Patients with myasthenia gravis should stay away from

ciprofloxacin and its fluoroquinolone class since they may worsen muscle weakening (Tsai, W. C., & Yang, Y. M. 2011).

1.5 In-Process Quality Control

In the pharmaceutical industry, the in-process quality control (IPQC) process is a crucial component of manufacturing procedures that ensures products meet predetermined safety, efficacy, and quality standards at every stage of production. Tablet weight variation, hardness, friability, disintegration tests, pH checks, viscosity tests, and environmental control in the manufacturing area are common IPQC criteria. By detecting and resolving issues in real time, IPQC contributes to increased operational efficiency and reduces the possibility of creating defective goods for the market.

1.5.1 Quality Control Parameters of Solid Dosage Forms

For pharmaceutical goods to be safe, effective, and tent, solid dosage form quality control is essential. Before pills or capsules are put on the market, these criteria are used to make sure that their quality meets the requirements. Weight change and the organoleptic test are the two main quality control procedures that are performed to ensure that the drug content in each unit is equal. Tests for friability and hardness assess mechanical strength to endure handling and packaging. Dissolution testing is used to ascertain the rate and degree of drug release, which directly impacts bioavailability, and disintegration time is used to ascertain how quickly a dosage form disintegrates under physiological conditions ((Uddin, M.S. et al., 2017).

1.5.2 Weight Variation

A weight variation test is one of the key quality control measures for solid dosage forms (tablets and capsules) to guarantee dose consistency and product uniformity. A specified number of units are chosen and weighed for this test. After determining the mean weight, the weight of each unit is next compared to the average weight. Depending on the average weight of the

tablet, the variance must be within the pharmacopeial (USP, BP) limits. Insignificant variations could be a sign of improper powder flow, inadequate die filling, or compression problems (Ganesh et al., 2022). Every unit is guaranteed to offer the right dosage thanks to the test and guarantees that the product is effective, safe, and compliant with legal requirements (Ganesh et al., 2022).

Table 2: Weight variation tolerance for tablets according USP guidelines (Tawde et al., 2024)

Average weight of the tablet	Percentage of difference
130 mg or less	±10%
From 130 mg through 324 mg	±7.5%
More than 324 mg	±5%

1.5.3 Hardness Test

To ensure that solid dosage forms have the specific mechanical strength to be handled, packaged, and shipped without breaking or crumbling. A tablet is subjected to a regulated force during the test until it fractures. According to Narlawar et al. (2024), breaking force is commonly measured in kg or newtons. Thickness, diameter, and hardness can all be measured simultaneously using contemporary hardness testers (Narlawar et al., 2024). A regulated force is applied to a tablet until it breaks during the test. According to USP, the majority of formulations in practice adhere to widely recognized ranges. While film-coated tablets usually require a hardness of 6–10 kgf, uncoated tablets typically require 4–8 kgf (Table 3).

Table 3: USP Acceptance Criteria of Hardness test (Navya Sri & Reddy, 2023)

Tablet Type	Tablet Hardness
Uncoated Tablets	4-8 kg (40-80 N)
Flim-coated Tablets	6-10 kg (60-80 N)

1.5.4 Friability Test

Friability test is done to assess how well solid dosage form withstand mechanical pressure during production, packaging, and transportation. This test is an essential quality control procedure (Daria et al., 2022). A predetermined number of pre-weighed tablets are placed in a spinner for this test, and the tablets are repeatedly rolled and dropped—typically 100 revolutions at 25 rpm (Daria et al., 2022). To calculate the percentage of weight loss, tablets are dedusted and weighed again after the test. The outcome shows how much chipping, crumbling, or breaking has occurred. Pharmacopeial standards like the USP and BP state that a maximum weight loss of 1% is typically regarded as acceptable (Daria et al., 2022). In order to guarantee that tablets retain their integrity over the course of their shelf life and provide the desired therapeutic effect, the test is essential (Daria et al., 2022).

1.5.6 Disintegration Test

For solid pharmaceutical dosage forms, such tablets and capsules, another essential quality control method is the disintegration test. Finding the amount of time needed for a dosage form to disintegrate into smaller pieces under standardized settings is the main purpose. This procedure guarantees that the active pharmaceutical ingredient becomes accessible for the body's subsequent absorption and breakdown (Silva et al., 2018). Tablets are periodically submerged in a liquid medium at 37 ± 0.5°C during the test, which is usually conducted using a basket-rack assembly (Silva et al., 2018). The basket rises and falls at a controlled rate

throughout the test. As a result, the medium can pass through the tablets and break them down (Silva et al., 2018). According to Silva et al. (2018), the endpoint is attained when all fragments pass through the mesh screen and there is no longer a palpable core. According to Silva et al. (2018), this test guarantees product performance and batch-to-batch consistency. Additionally, the disintegration time is 15 minutes for uncoated tablets, 30 minutes for coated ones, 30 minutes for film-coated tablets, and 60 minutes or an hour for enteric-coated tablets (Silva et al., 2018).

1.5.7 Dissolution Test

A crucial quality control procedure for determining the rate and degree of active pharmaceutical ingredient (API) release from solid dosage forms is the dissolution test. UV-Vis spectrophotometry is used to measure the amount of medication released into the medium at predetermined intervals (Barsagade et al., 2021; Zaborenko et al., 2019). This test is essential for predicting in vivo drug performance because it simulates the release of medicines in the gastrointestinal tract. Dissolution testing is mandated by regulatory bodies for bioequivalency research, quality assurance, and product development (Zaborenko et al., 2019). According to Table 4, USP uses a three-stage acceptance system for dissolution tests (Stages S1, S2, and S3). All six tested units must release at least Q + 5% during Stage S1. Testing moves on to S2 if this condition is not fulfilled. The average value of 12 tablets in S2 must be at least Q, with no unit dropping below Q −15%. Stage S3 is carried out if the situation is continuing noncompliance.

Table 4: BP, USP, PhEur, JP and PhInt acceptance criteria for dissolution test of tablet (Navya Sri & Reddy, 2023)

Level	Sample tested	Acceptance criteria
S1	6	Each value is not less than Q + 5%
S2	6	Average value of the 12 dosage units (S1 + S2) is equal to or greater than Q

		and no unit is less than Q-15%
S3	12	Average value of 24 dosage units (S1 + S2 + S3) is equal to or greater than Q; not more than 2 units are less than Q - 15%; no unit is less than Q - 25%.

1.6 Aims of this Study

This study's main aim is to assess and contrast the quality control measures of various brands of ciprofloxacin tablets that are sold in Bangladesh. The goal is to assess the quality to which various marketed brands of Ciprofloxacin tablets in Bangladesh can adhere to pharmacopeial standards by critically comparing their quality control criteria. To make sure that every tablet stays uniform and healthy, basic mechanical and physical characteristics including weight fluctuations, thickness, hardness, and friability are tested. In order to make sure that each brand is suitable for releasing medications, it also looks into how quickly each brand disintegrates. In order to compare drug release profiles and confirm that each formulation satisfies the necessary bioavailability standards, dissolution tests will also be carried out. Additionally, it will examine each brand's disintegration time to make sure it can be used to release medications. Moreover, comparing these characteristics across different companies to find any variations in quality and determine which goods exhibit the best levels of dependability, safety, and therapeutic effectiveness ((Uddin, M.S. et al., 2017).

Chapter 2

Methodology

2.1 Samples

For the test, the selected tablet is Ciprofloxacin 500mg. In Bangladesh, many brands of Ciprofloxacin can be found. Of these, 5 brands were chosen and gathered from various pharmacies in Dhaka. To uphold a clear perspective a code name has been used for each brand.

Table 5: Different brands along with their manufacturer names:

Tablet	Code name
Ciprofloxacin 500mg	Cipro-1
Ciprofloxacin 500mg	Cipro-2
Ciprofloxacin 500mg	Cipro-3
Ciprofloxacin 500mg	Cipro-4
Ciprofloxacin 500mg	Cipro-5

2.2 Reagents & solvents

Simulated gastric fluid is used in dissolution media. To prepare this medium, 8.3 ml HCL is added in 1000 ml water through stirring.

2.3 List of Apparatus/ Glassware's

Table 6: List of Apparatus/ Glassware's used throughout this project

Container	Pipettes
Beaker	Glass rod
Volumetric flasks	Filter paper
Dropper	Stop watch
Measuring Cylinders	

2.4 Weight Variation

2.4.1 Method

Using analytical balance, ten tablets weighed separately. The mean weight of the tablets was determined along with the percentage. The variation of each tablet from the average weight was measured.

2.4.2 Instrument

Analytical Balance, Model-FH 200

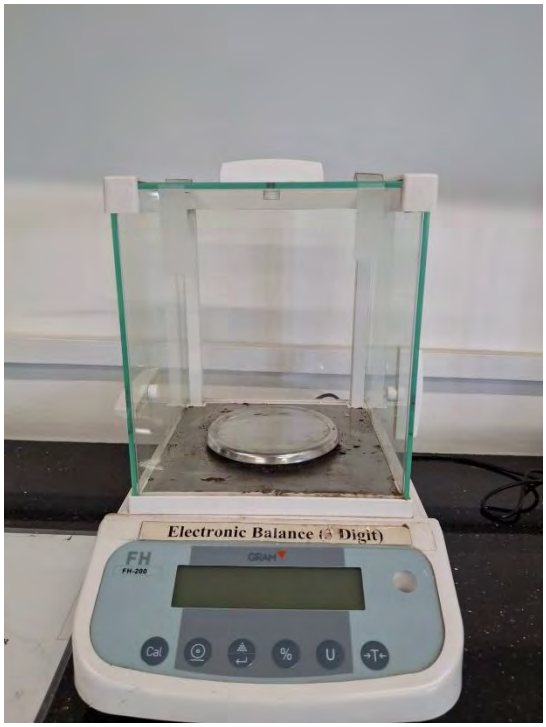

Figure 3: Precision scale FH-200

2.4.3 Calculation

Weight variation = (Tablet weight−Average weight/Average weight)× 100

2.5 Hardness Test

2.3.1 Method

The tablets were picked, and each tablet was positioned directly opposite between the instrument's gripping ends. A continuously growing force was exerted until the tablet broke, and breaking force was shown automatically in Newtons. The process was carried out for all tablets, and determined the mean hardness**.**

2.3.2 Instrument

Model: Wincom YD-1

Figure 4: Tablet hardness tester

2.4 Disintegration Test

2.4.1 Method

The disintegration test was conducted at 37 ± 0.5°C, which is similar to the body's normal temperature. Each tube in the basket rack was filled with six tablets separately. The usual frequency of 29–32 cycles per minute was used to allow the basket to move up and down. Every tablet was monitored during the run, and the endpoint was noted when there was only insoluble coating fragments left on the screen. To verify adherence to USP acceptance requirements, the total disintegration time for each of the six units was recorded.

2.4.2 Instrument

Model: BJ-2

Figure 5: Tablet disintegration tester

2.5 Dissolution Test

2.5.1 Method

The test is conducted at a regulated temperature of 37 ± 0.5°C, and the instrument's average agitation speed was 75 rpm. 900 milliliters of a designated dissolving medium (GSF) are utilized. Samples are taken out at specified intervals, filtered, and UV-Vis at 276 nm is used for analysis.

2.5.2 Instrument

Model: Logan UDT-804

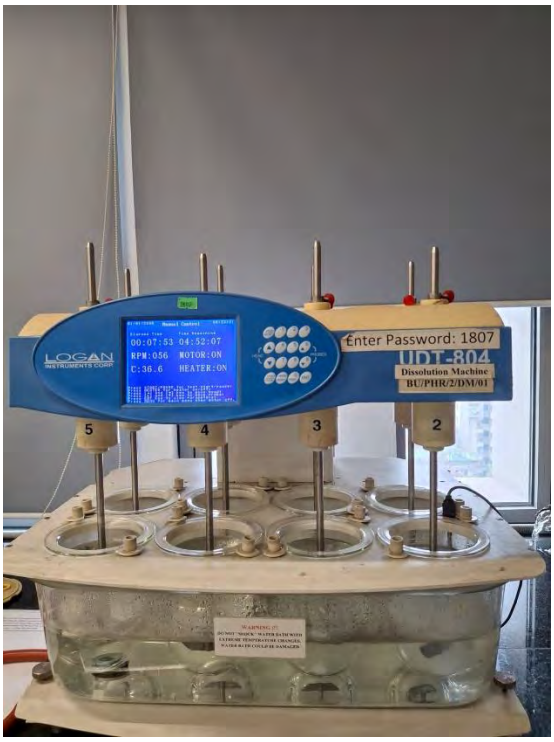

Figure 6: Tablet dissolution tester

2.5.3 Calculation

% of drug release = (Absorbance× Dilution factor× 900/)1000

Dilution factor = 50

2.6 Friability

2.6.1 Method

A friability tester (Electro lab EF-2) was used to weigh and place a randomly selected tablet from each brand in its drum. The drum was set up to rotate at 25 rpm for approximately 4 minutes, totaling 100 revolutions, for this test. The tablet then required to be taken out of the drum, cleaned, and weighed. Each brand's average weight reduction % was recorded.

2.6.2 Instrument

Model: Electro lab EF-2

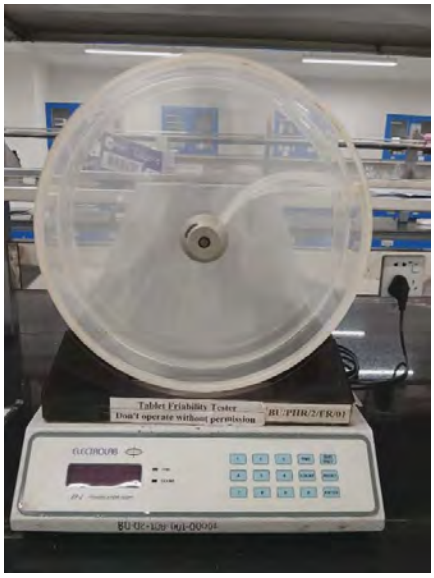

Figure 7: Tablet friability tester

Chapter 3

Result

3.1 Weight Variation

The percentage of variation of five different brands of Ciprofloxacin (500 mg) are given below.

3.1.1 Cipro-1 500 mg Tablet

Table 7: Weight Variation of Cipro-1 500 mg Tablet

Number of Tablets	Weight of Individual Tablets (g)	Average Weight (g)	Individual Weight Variation (%)	Highest Weight Variation (%)	Lowest Weight Variation (%)
1	0.776	0.7682	1.02%	1.54%	-0.29%
2	0.766		-0.29%		
3	0.780		1.54%		
4	0.759		-1.2%		
5	0.757		-1.46%		
6	0.772		0.5%		
7	0.753		-1.97%		
8	0.770		0.23%		
9	0.775		0.88%		
10	0.774		0.75%		

The standard deviation of individual weights is 0.0091.

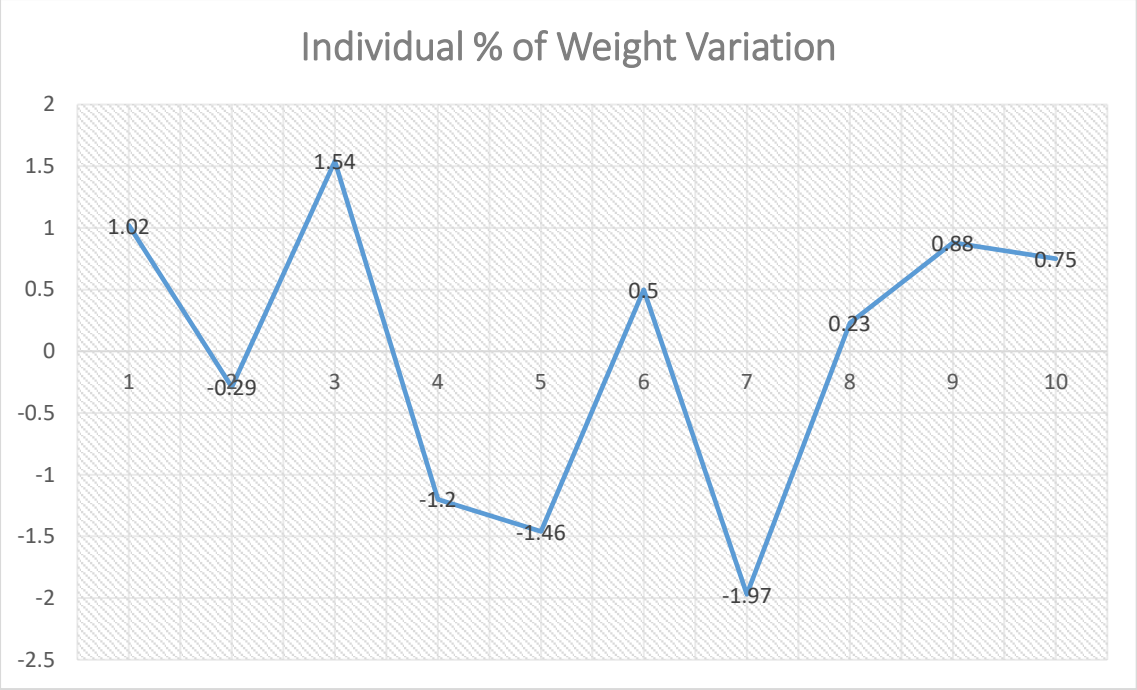

Figure 8: Individual weight variation percentage of (Cipro-1 500 mg).

The x-axis indicates the number of the tablets used for test and the y-axis indicate the percentage of weight variation detected for each marketed tablet.

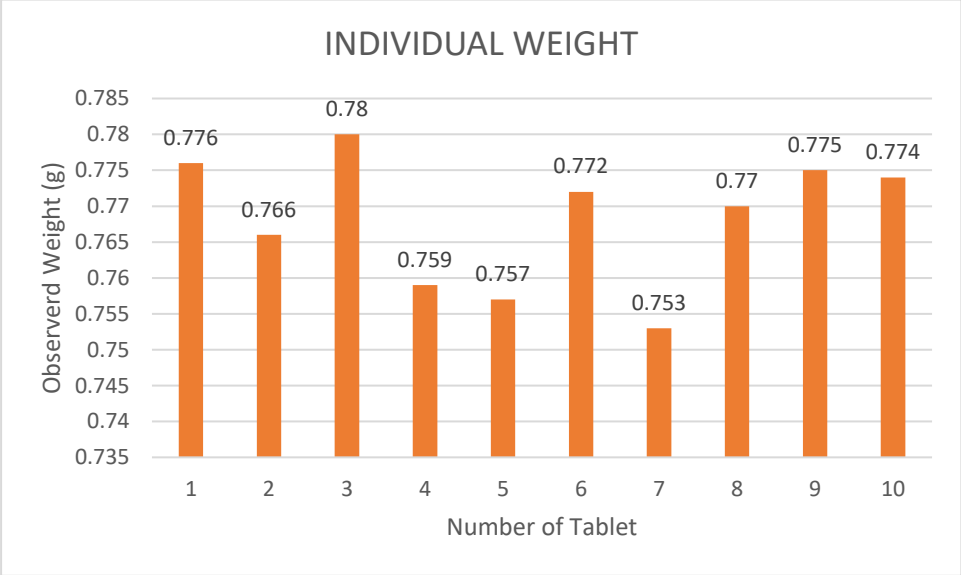

Figure 9: Weight of individual tablet (Cipro-1 500mg).

The X-axis indicate the numbers of tablet used for test and the Y- axis indicate weight variation of individual tablet.

3.1.2 Cipro-2 500 mg Tablet

Table 8: Weight variation of Cipro-2 500 mg tablets

Number of Tablets	Weight of Individual Tablets (g)	Average Weight (g)	Individual Weight Variation (%)	Highest Weight Variation (%)	Lowest Weight Variation (%)
1	0.881	0.8818	-0.09%	1.83%	-1.79%
2	0.889		0.82%		
3	0.882		0.02%		
4	0.88		-0.20%		
5	0.898		1.83%		
6	0.866		-1.79%		
7	0.89		0.92%		
8	0.876		-0.65%		
9	0.888		0.70%		
10	0.868		-1.50%		

The standard deviation of individual weights is 0.00947.

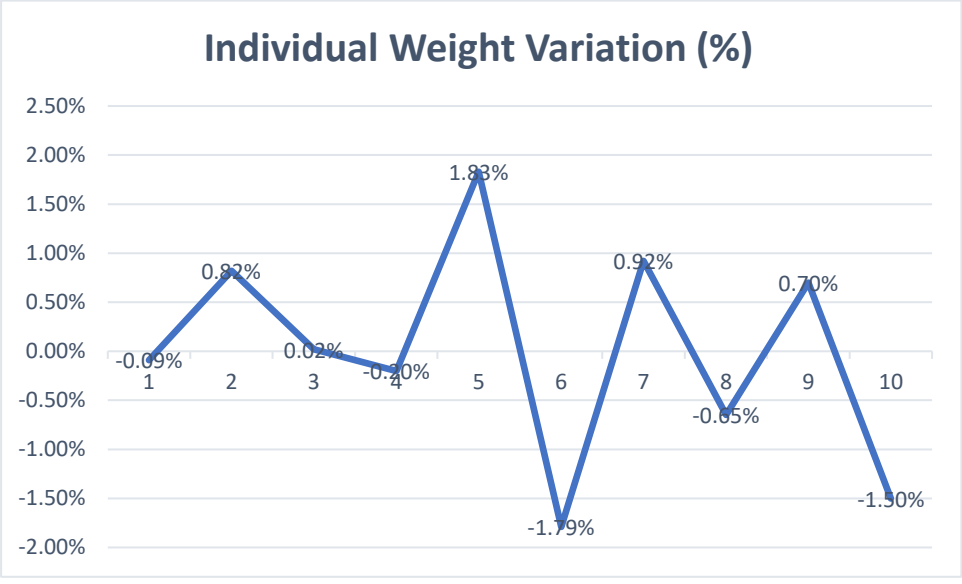

Figure 10: Individual weight variation percentage of (Cipro-2 500 mg).

The x-axis indicates the number of the tablets used for test and the y-axis indicate the percentage of weight variation detected for each marketed tablet.

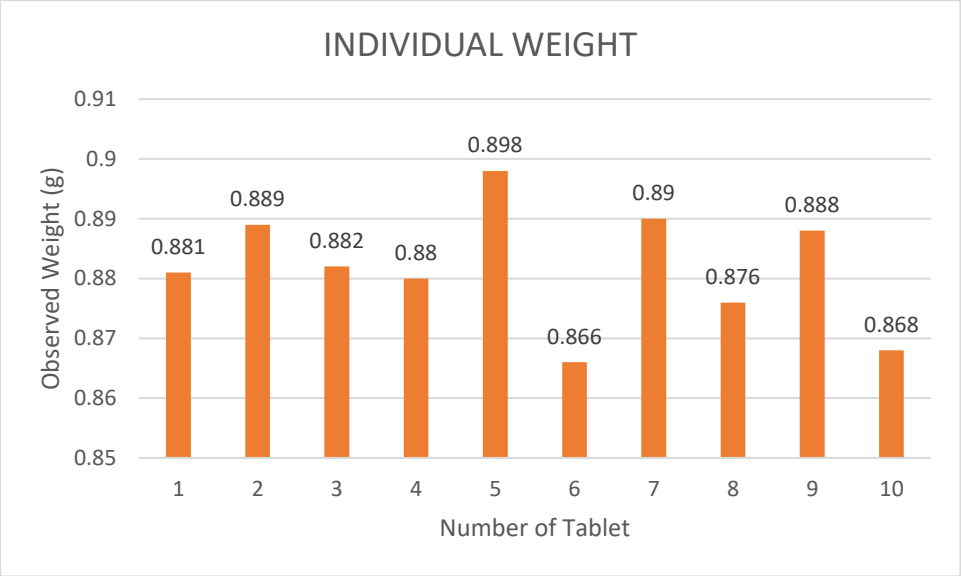

Figure 11: Weight of individual tablet (Cipro-2 500mg)

The X-axis indicate the numbers of tablet used for test and the Y- axis indicate weight variation of individual tablet.

3.1.3 Cipro-3 500mg Tablet

Table 9: Weight variation of Cipro-3 500 mg tablets

Number of Tablets	Weight of Individual Tablets (g)	Average Weight (g)	Individual Weight Variation (%)	Highest Weight Variation (%)	Lowest Weight Variation (%)
1	0.787	0.791	-0.50%	1.13%	-1.13%
2	0.782		-1.13%		
3	0.786		-0.63%		
4	0.792		0.12%		
5	0.784		-0.89%		
6	0.798		0.88%		
7	0.8		1.13%		
8	0.793		0.25		
9	0.8		1.13%		
10	0.788		-0.37%		

The standard deviation of individual weights is 0.006633.

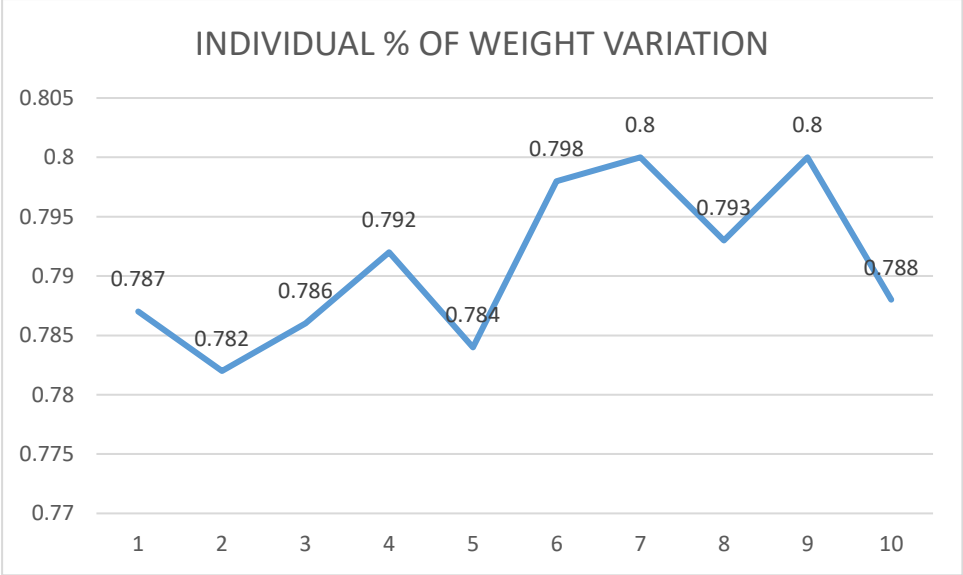

Figure 12: Individual weight variation percentage of (Cipro-3 500 mg).

The x-axis indicates the number of the tablets used for test and the y-axis indicate the percentage of weight variation detected for each marketed tablet.

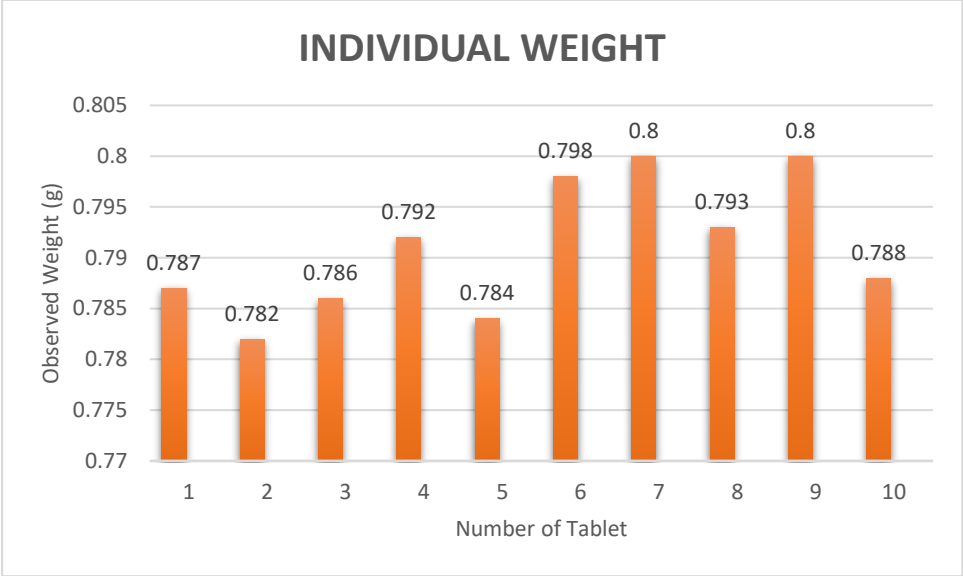

Figure 13: Weight of individual tablet (Cipro-3 500mg).

The X-axis indicate the numbers of tablet used for test and the Y- axis indicate weight variation of individual tablet.

3.1.4 Cipro-4 500mg Tablet

Table 10: Weight variation of Cipro-4 500 mg tablets

Number of Tablets	Weight of Individual Tablets (g)	Average Weight (g)	Individual Weight Variation (%)	Highest Weight Variation (%)	Lowest Weight Variation (%)
1	0.838	0.8262	1.4%	1.9%	-1.48%
2	0.816		-1.2%		
3	0.842		1.9%		
4	0.823		-0.39%		
5	0.814		-1.48%		
6	0.821		-0.6%		
7	0.826		-0.02%		
8	0.831		0.5%		
9	0.823		-0.39%		
10	0.828		0.21%		

The standard deviation of individual weights is 0.0081917.

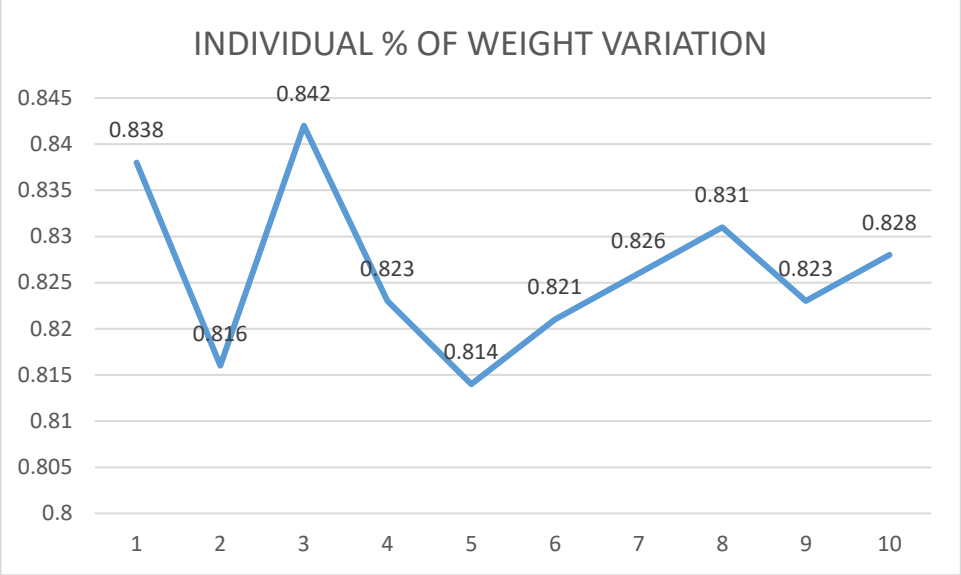

Figure 14: Individual weight variation percentage of (Cipro-4 500 mg).

The x-axis indicates the number of the tablets used for test and the y-axis indicate the percentage of weight variation detected for each marketed tablet.

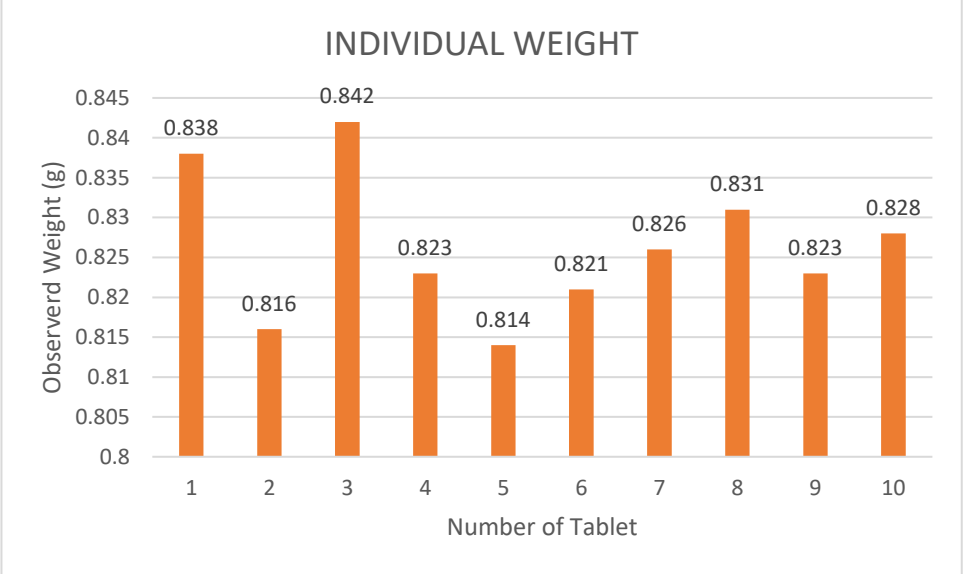

Figure 15: Weight of individual tablet (Cipro-4 500mg).

The X-axis indicate the numbers of tablet used for test and the Y- axis indicate weight variation of individual tablet.

3.1.5 Cipro-5 500mg Tablet

Table 11: Weight variation of Cipro-5 500 mg tablets

Number of Tablets	Weight of Individual Tablets (g)	Average Weight (g)	Individual Weight Variation (%)	Highest Weight Variation (%)	Lowest Weight Variation (%)
1	0.771	0.74	4.19%	4.19%	-2.97%
2	0.733		-1%		
3	0.718		-2.97%		
4	0.768		3.78%		
5	0.744		0.55%		
6	0.734		-0.81%		
7	0.736		-0.55%		
8	0.731		-1.2%		
9	0.719		-2.83%		
10	0.746		0.81%		

The standard deviation of individual weights is 0.017963.

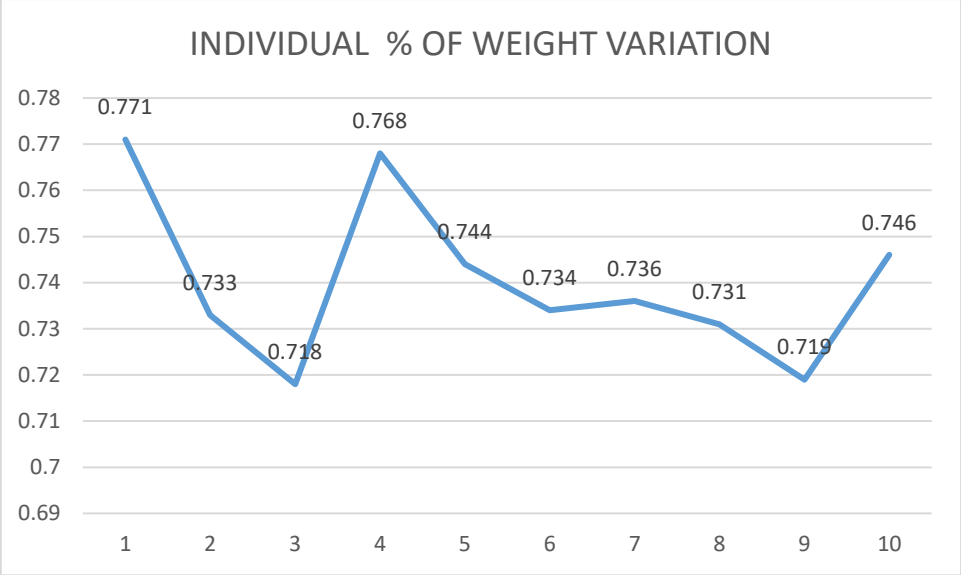

Figure 16: Individual weight variation percentage of (Cipro-5 500 mg)

The x-axis indicates the number of the tablets used for test and the y-axis indicate the percentage of weight variation detected for each marketed tablet.

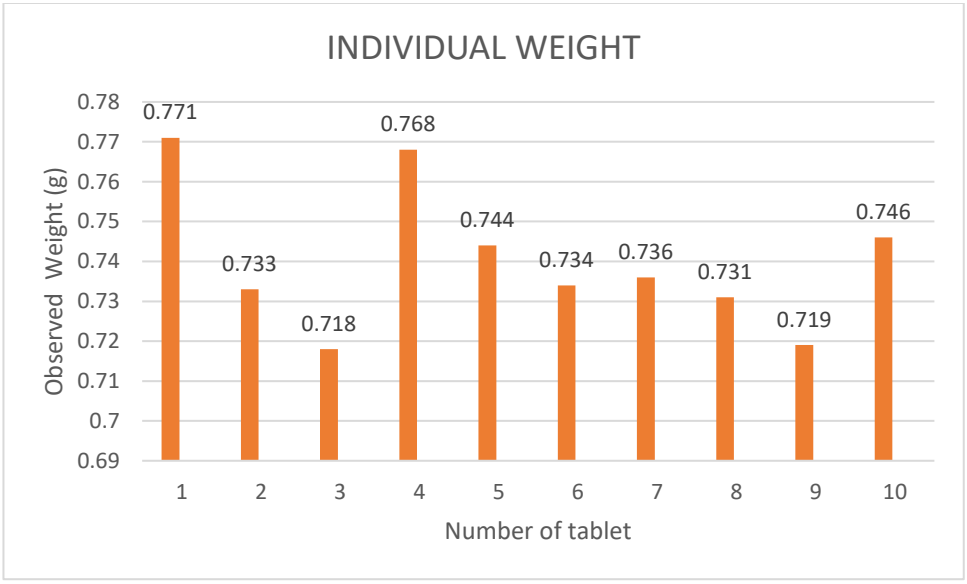

Figure 17: Weight of individual tablet (Cipro-5 500mg)

The X-axis indicate the numbers of tablet used for test and the Y- axis indicate weight variation of individual tablet.

3.1.6 Standard deviation of weight variation

Table 12: Standard deviation of weight variation.

Tablet	Standard Deviation of Weight Variation
Cipro-1	0.0091
Cipro-2	0.0094
Cipro-3	0.0066
Cipro-4	0.0081
Cipro-5	0.0179

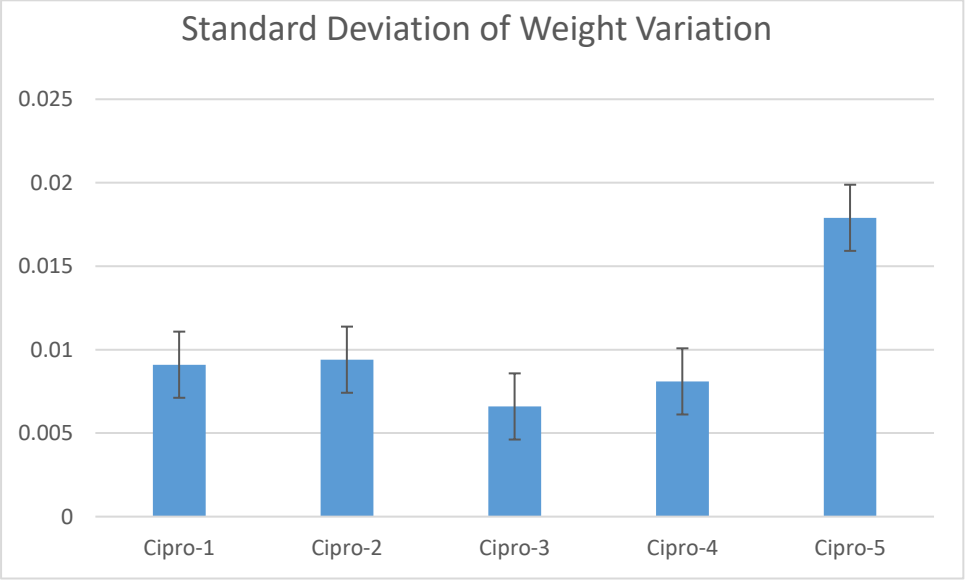

Figure 18: Standard deviation of weight variation

3.2 Hardness Test

3.2.1 Cipro-1 500 mg Tablet

Table 13: Hardness test of Cipro-1 500 mg.

Number of tablets	Hardness (g)	Average (g)
1	16.18	16.365
2	17.86	
3	17.53	
4	17.76	
5	19.12	
6	15.72	
7	17.30	
8	13.04	
9	15.79	
10	13.35	

The standard deviation of tablet's hardness value is 1.97.

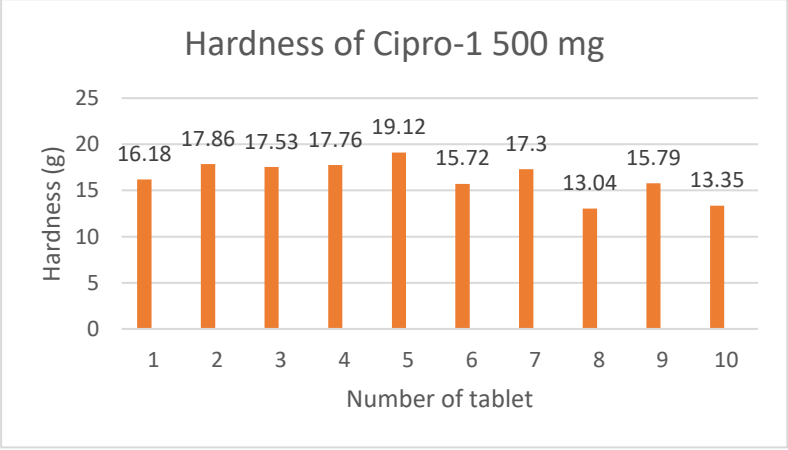

Figure 19: Hardness of Cipro-1 500 mg.

3.2.2 Cipro-2 500 mg Tablet

Table 14: Hardness test of Cipro-2 500 mg

Number of tablets	Hardness (g)	Average (g)
1	7.58	9.153
2	9.35	
3	10.64	
4	7.73	
5	8.28	
6	8.23	
7	11.31	
8	8.52	
9	9.89	
10	10	

The standard deviation of tablet's hardness value is 1.277g.

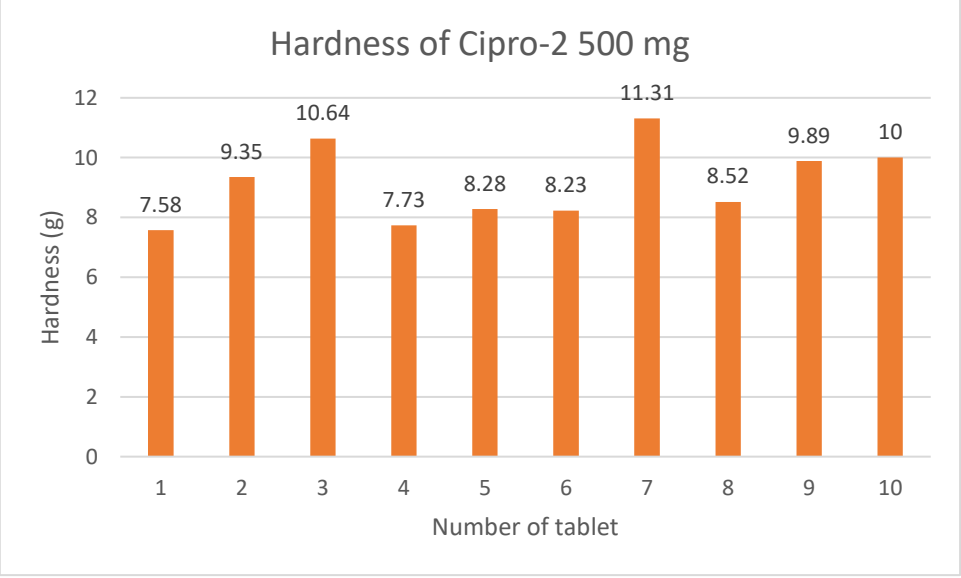

Figure 20: Hardness of Cipro-2 500 mg

The X-axis represent numbers of tablet used in experiment. Y- axis shows the hardness value of the tablets.

3.2.3 Cipro-3 500 mg Tablet

Table 15: Hardness test of Cipro-3 500 mg

Number of tablets	Hardness (g)	Average (g)
1	17.46	17.023
2	18.34	
3	17.18	
4	17.31	
5	17.44	
6	18.10	
7	15.31	
8	15.44	
9	17.35	
10	16.30	

The standard deviation of tablet's hardness value is 1.024g.

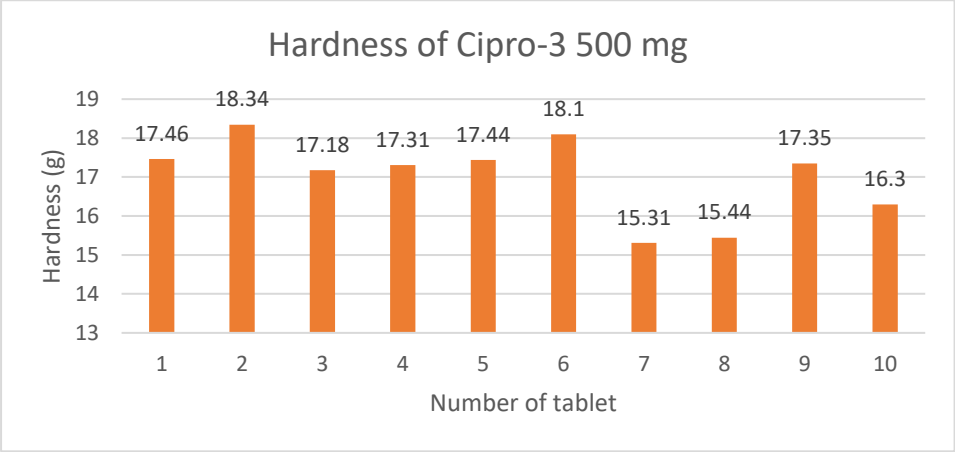

Figure 21: Hardness of Cipro-3 500 mg.

3.2.4 Cipro-4 500 mg Tablet

Table 16: Hardness test of Cipro-4 500 mg

Number of tablets	Hardness (g)	Average (g)
1	13.65	14.086
2	14.11	
3	14.72	
4	13.30	
5	13.48	
6	13.49	
7	14.67	
8	15.52	
9	13.53	
10	14.39	

The standard deviation of tablet's hardness value is 0.725g.

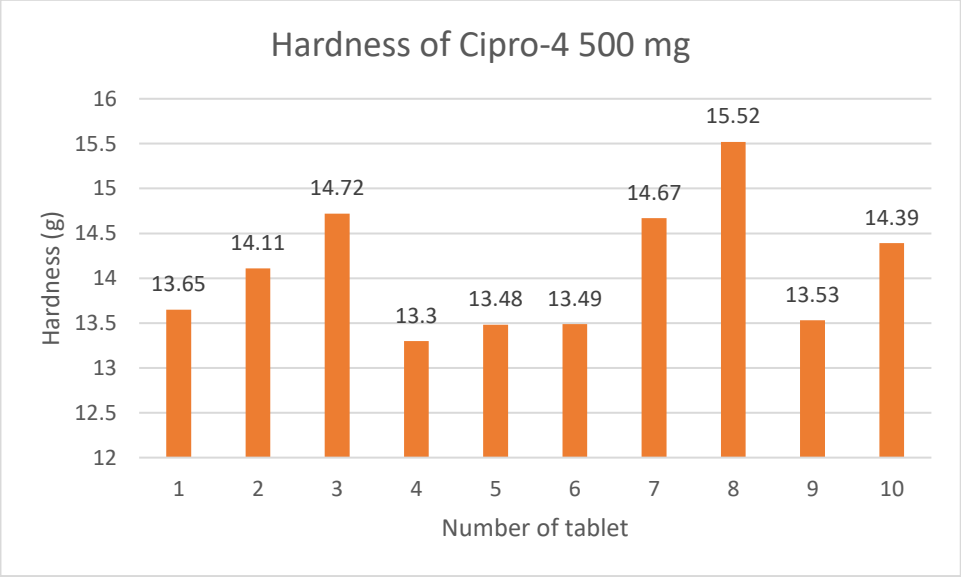

Figure 22: Hardness of Cipro-4 500 mg.

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3.2.5 Cipro-5 500 mg Tablet

Table 17: Hardness test of Cipro-5 500 mg

Number of tablets	Hardness (g)	Average (g)
1	14.64	15.365
2	15.04	
3	19.08	
4	12.05	
5	17.98	
6	14.01	
7	19.08	
8	14.95	
9	11.74	
10	15.08	

The standard deviation of tablet's hardness value is 2.610g.

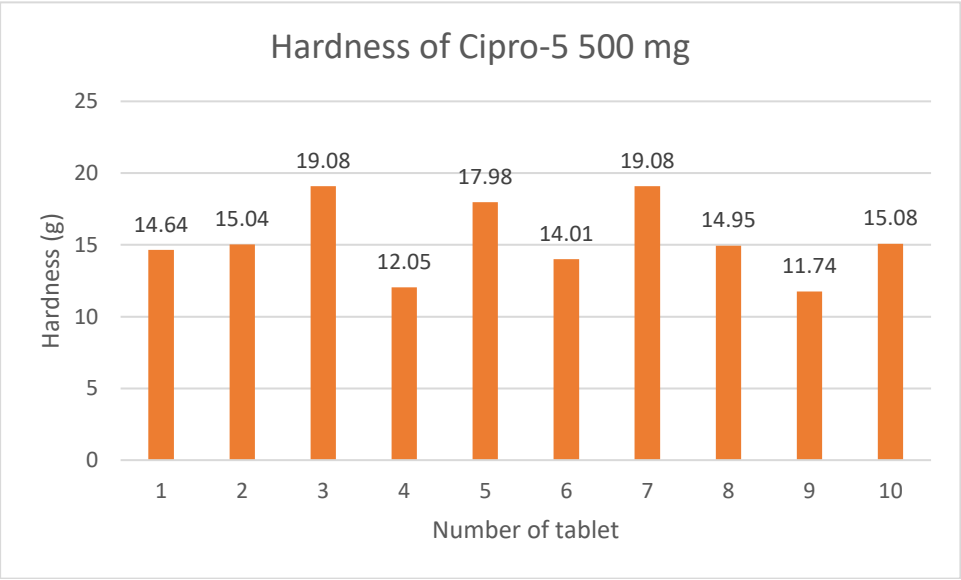

Figure 23: Hardness of Cipro-5 500 mg.

3.2.6 Average Hardness in Kg

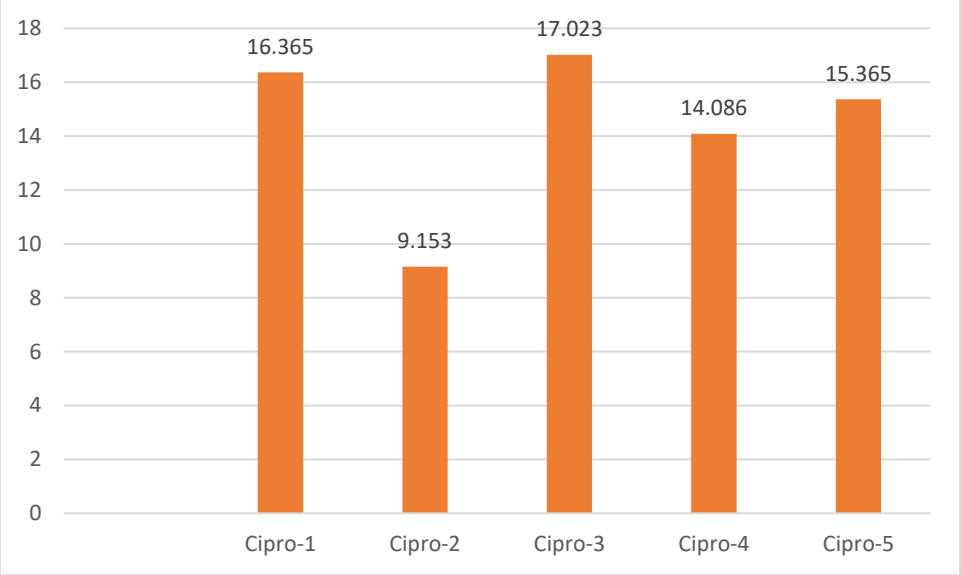

Figure 24: Average hardness of different brand tablets

3.2.7 Standard deviation of Hardness

Table 18: Standard deviation of Hardness

Tablet	Standard Deviation of Hardness
Cipro-1	1.97
Cipro-2	1.277
Cipro-3	1.024
Cipro-4	0.725
Cipro-5	2.610

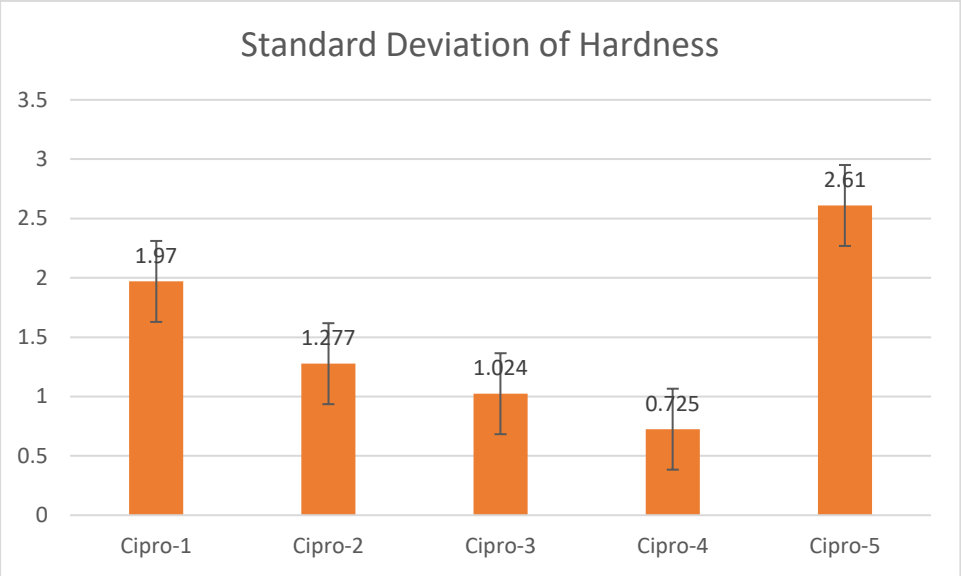

Figure 25: Standard deviation of Hardness

3.3 Friability Test

Table 19: Friability test result

Brand Name	Before Test	After Test
Cipro-1	7.706g	7.108g
Cipro-2	8.825g	8.290g
Cipro-3	7.901g	7.901g
Cipro-4	8.258g	8.257g
Cipro-5	7.404g	7.402g

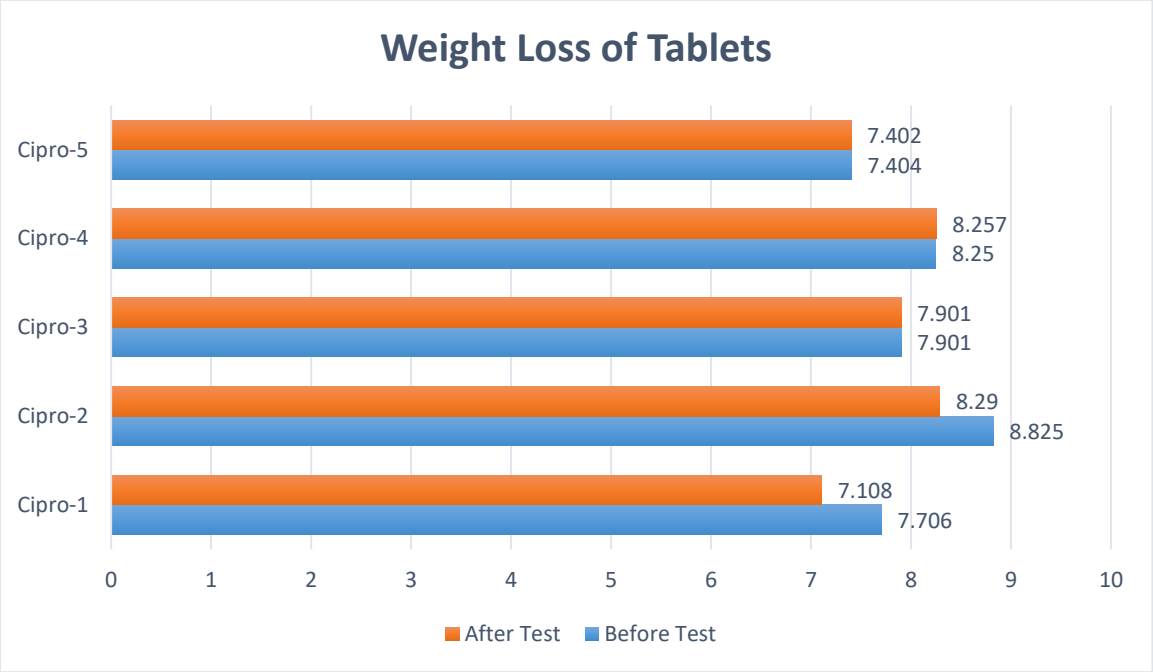

Figure 26: Weight loss tablets of different brands (Ciprofloxacin)

The graph shows weight loss of different brand of montelukast by comparing the initial weight and the final weight after test.

3.4 Disintegration Test

Table 20: Disintegration test result of different brands of Ciprofloxacin.

Brand Name	Disintegration Time (minutes)
Cipro-1	4 min 47 sec
Cipro-2	5 min
Cipro-3	3 min 5 sec
Cipro-4	9 min 3 sec
Cipro-5	5 min 33 sec

3.5 Dissolution Test

3.5.1 Cipro-1 500 mg Tablet (GSF Solution)

Table 21: Cipro-1 500 mg GSF solution dissolution test absorbance data.

For Tablet-1,

Time	Absorbance	% Drug Release
15	0.498	22.41%
30	0.591	26.595%
45	0.639	28.755%
60	0.682	30.69%

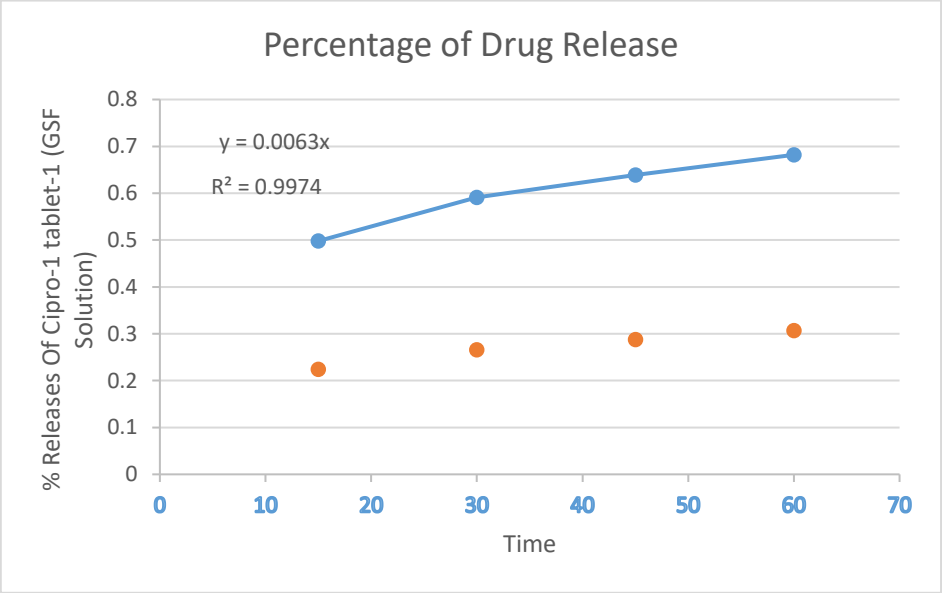

Figure 27: Drug release percentage Cipro-1(tablet-1) 500 mg tablet in GSF solution

The X- axis shows the time interval and the Y- axis shows the absorbance.

Table 22: Cipro-1 500 mg GSF solution dissolution test absorbance data.

For Tablet-2,

Time	Absorbance	Drug Release
15	0.412	18.54%
30	0.653	29.385%
45	0.709	31.905%
60	0.045	2.025%

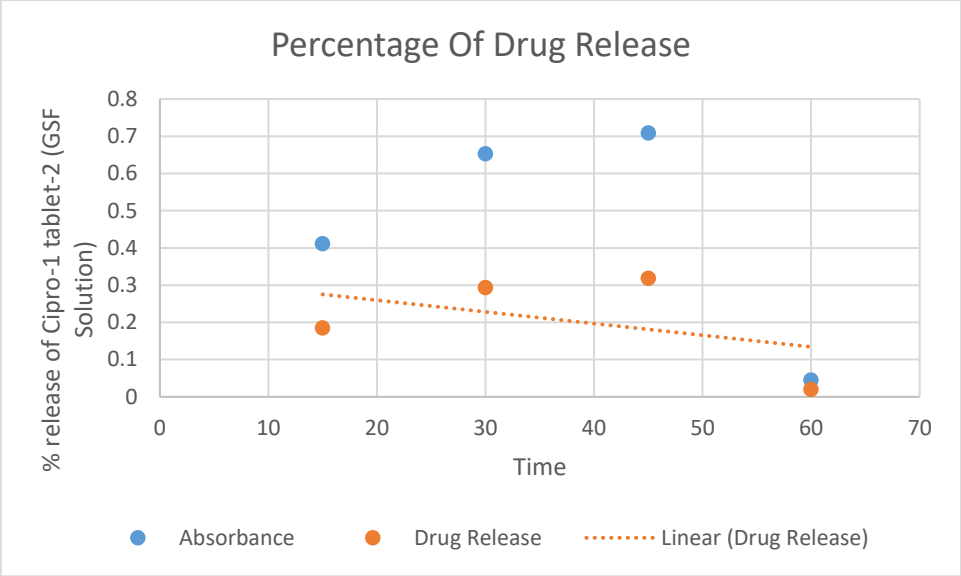

Figure 28: Drug release percentage of Cipro-1 (tablet-2) 500 mg tablet in GSF solution

Table 23: Cipro-1 500 mg GSF solution dissolution test absorbance data

For Tablet-3,

Time	Absorbance	Drug Release
15	0.526	23.67%
30	0.528	23.76%
45	0.699	31.455
60	0.713	32.085

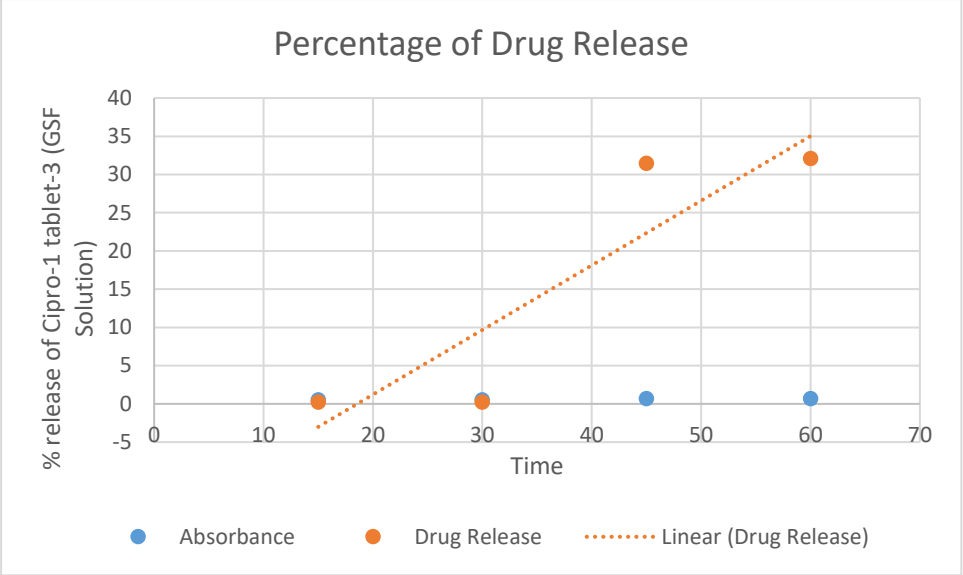

Figure 29: Drug release percentage of Cipro-1 (tablet-3) 500 mg tablet in GSF solution.

Table 24: Cipro-1 500 mg GSF solution dissolution test absorbance data

For Tablet-4,

Time	Absorbance	Drug Release
15	0.607	27.31%
30	0.721	32.45%
45	0.684	30.75%
60	0.677	30.47%

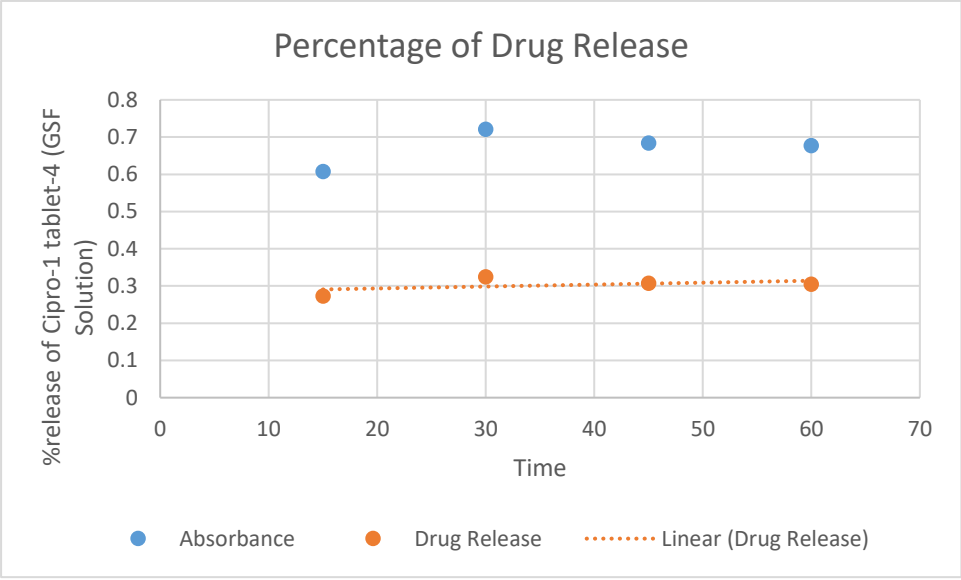

Figure 30: Drug release percentage of Cipro-1 (tablet-4) 500 mg tablet in GSF solution

Table 25: Cipro-1 500 mg GSF solution dissolution test absorbance data

For Tablet-5,

Time	Absorbance	Drug Release
15	0.647	29.12%
30	0.672	30.24%
45	0.704	31.86%
60	0.625	28.12%

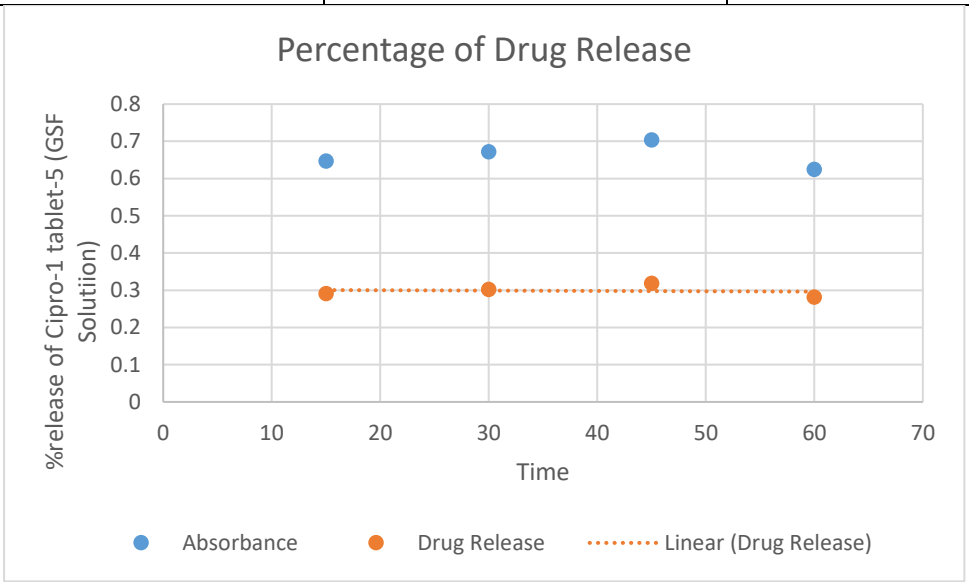

Figure 31: Drug release percentage of Cipro-1 (tablet-5) 500 mg tablet in GSF solution.

Table 26: Cipro-1 500 mg GSF solution dissolution test absorbance data

For Tablet-6,

Time	Absorbance	Drug Release
15	0.632	28.44%
30	0.689	31.05%
45	0.741	33.34%
60	0.693	31.18%

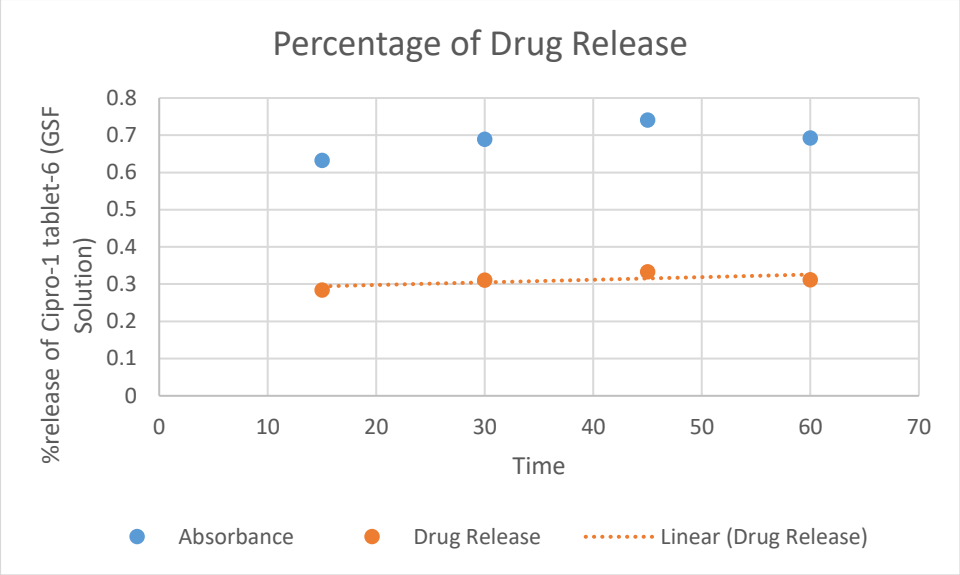

Figure 32: Drug release percentage of Cipro-1 (tablet-6) 500 mg tablet in GSF solution.

3.5.2 Cipro-2 500 mg Tablet (GSF Solution)

Table 27: Cipro-2 500 mg GSF solution dissolution test absorbance data.

For Tablet-1,

Time	Absorbance	% Drug Release
15	0.615	27.67%
30	0.328	14.76%
45	0.735	33.07%
60	0.555	24.97%

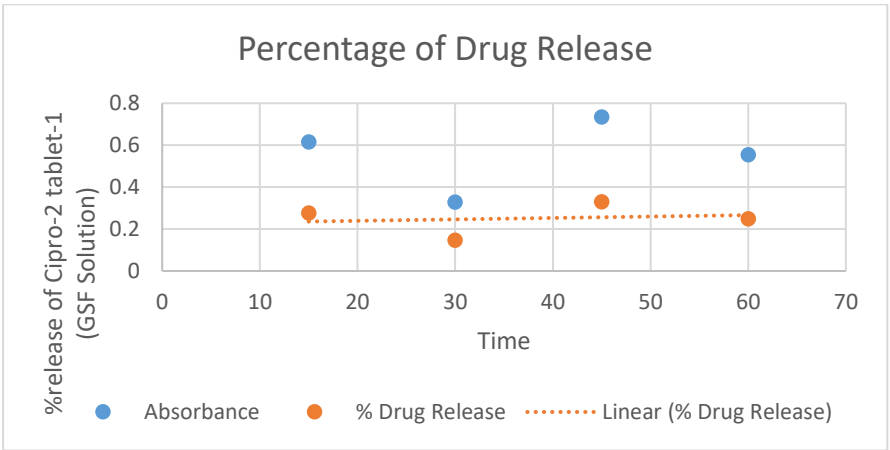

Figure 33: Drug release percentage of Cipro-2 (tablet-1) 500 mg tablet in GSF solution.

X- axis shows the time interval and the Y- axis shows the absorbance

Table 28: Cipro-2 500 mg GSF solution dissolution test absorbance data.

For Tablet-2,

Time	Absorbance	% Drug Release
15	0.713	32.08%
30	0.763	34.33%
45	0.832	37.44%
60	0.693	31.18%

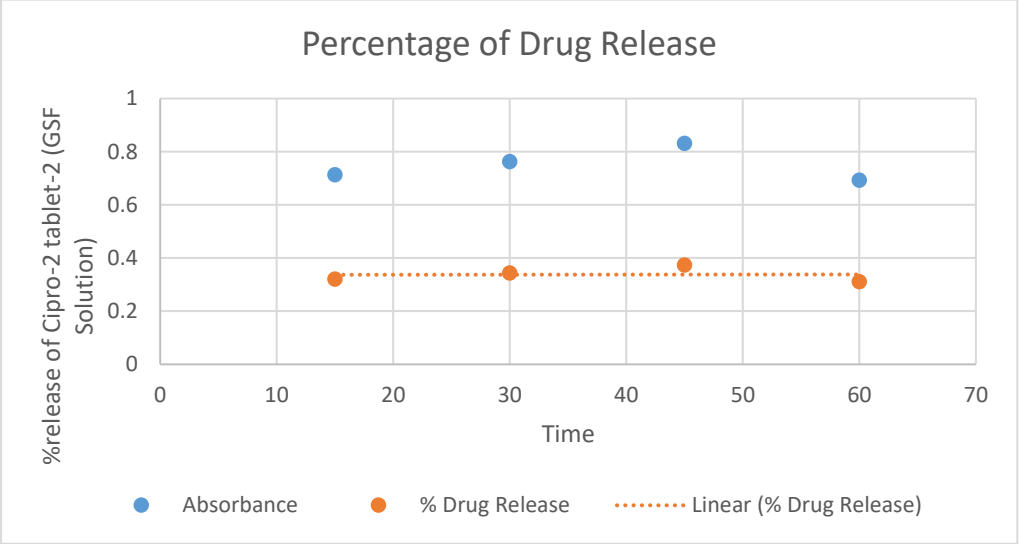

Figure 34: Drug release percentage of Cipro-2 (tablet-2) 500 mg tablet in GSF solution.

X- axis shows the time interval and the Y- axis shows the absorbance

Table 29: Cipro-2 500 mg GSF solution dissolution test absorbance data.

For Tablet-3,

Time	Absorbance	% Drug Release
15	0.736	33.12%
30	0.696	31.32%
45	0.705	31.72%
60	0.710	31.95%

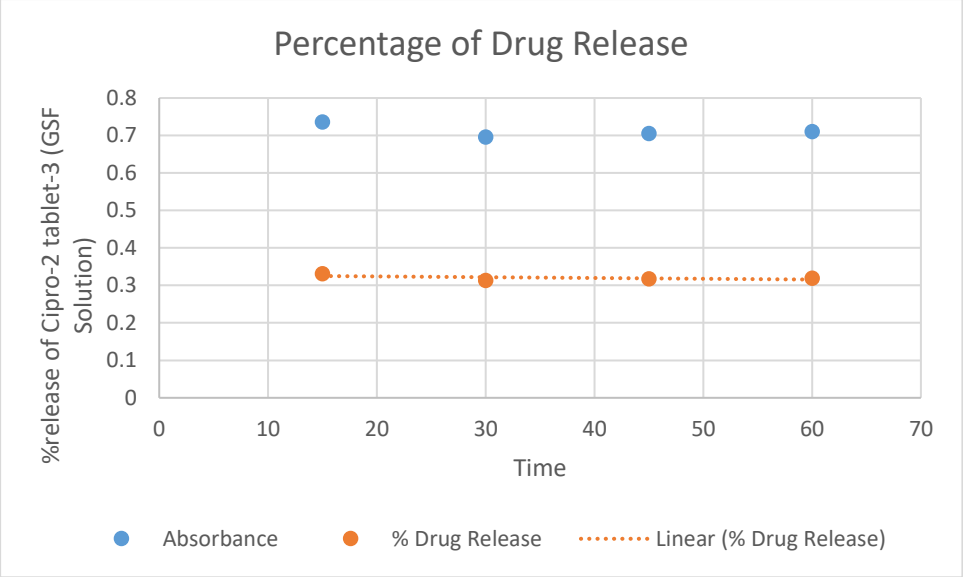

Figure 35: Drug release percentage of Cipro-2 (tablet-3) 500 mg tablet in GSF solution.

X- axis shows the time interval and the Y- axis shows the absorbance.

Table 30: Cipro-2 500 mg GSF solution dissolution test absorbance data.

For Tablet-4,

Time	Absorbance	% Drug Release
15	0.598	26.91%
30	0.648	29.16%
45	0.606	27.27%
60	0.674	30.33%

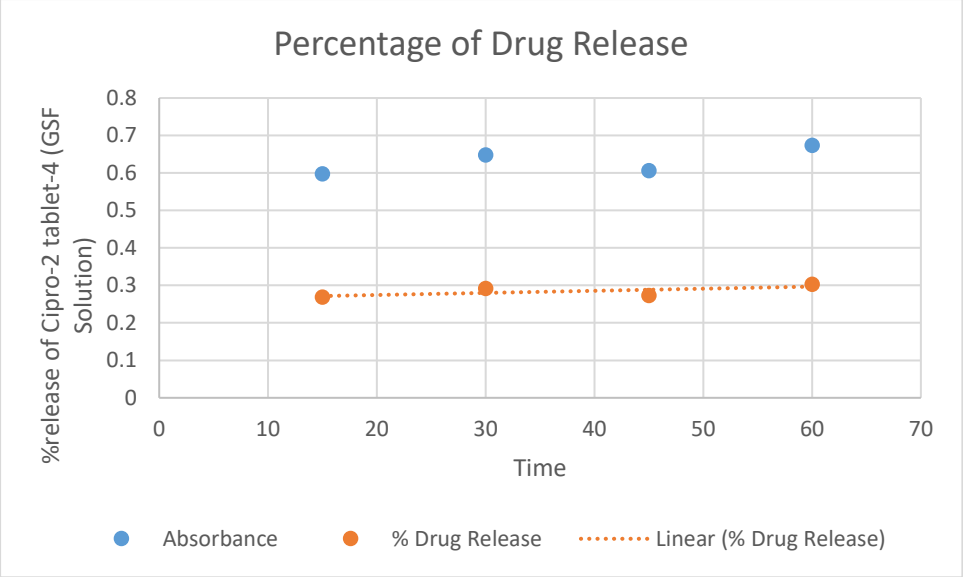

Figure 36: Drug release percentage of Cipro-2 (tablet-4) 500 mg tablet in GSF solution.

X- axis shows the time interval and the Y- axis shows the absorbance

Table 31: Cipro-2 500 mg GSF solution dissolution test absorbance data.

For Tablet-5,

Time	Absorbance	% Drug Release
15	0.645	29.02%
30	0.642	28.89%
45	0.671	30.19%
60	0.667	30.01%

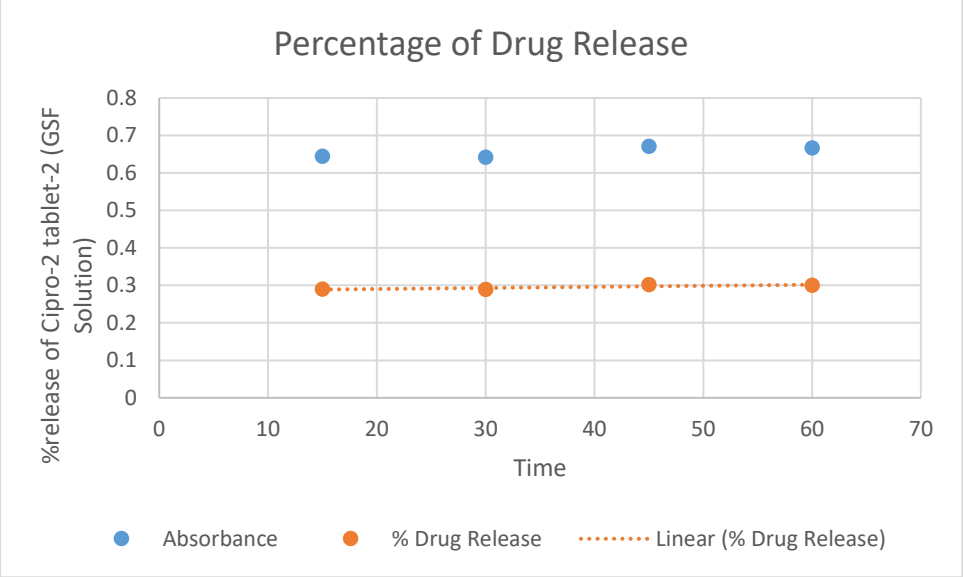

Figure 37: Drug release percentage of Cipro-2 (tablet-5) 500 mg tablet in GSF solution.

X- axis shows the time interval and the Y- axis shows the absorbance.

Table 32: Cipro-2 500 mg GSF solution dissolution test absorbance data.

For Tablet-6,

Time	Absorbance	% Drug Release
15	0.575	28.87%
30	0.597	26.86%
45	0.651	29.29%
60	0.736	33.12%

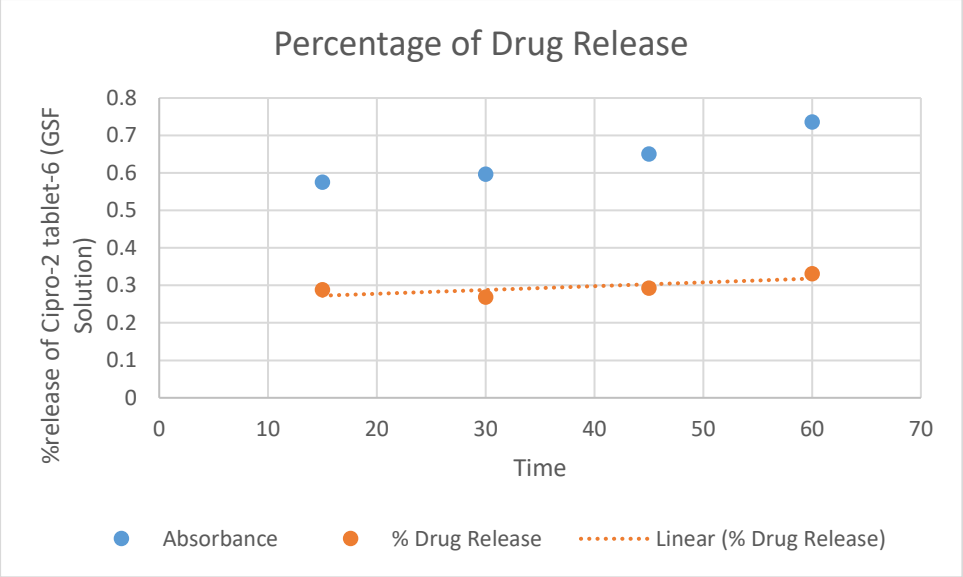

Figure 38: Drug release percentage of Cipro-2 (tablet-6) 500 mg tablet in GSF solution.

X- axis shows the time interval and the Y- axis shows the absorbance

3.5.3 Cipro-3 500 mg Tablet (GSF Solution)

Table 33: Cipro-3 500 mg GSF solution dissolution test absorbance data.

For Tablet-1,

Time	Absorbance	% Drug Release
15	0.651	29.29%
30	0.023	1.03%
45	0.813	36.58%
60	0.704	31.68%

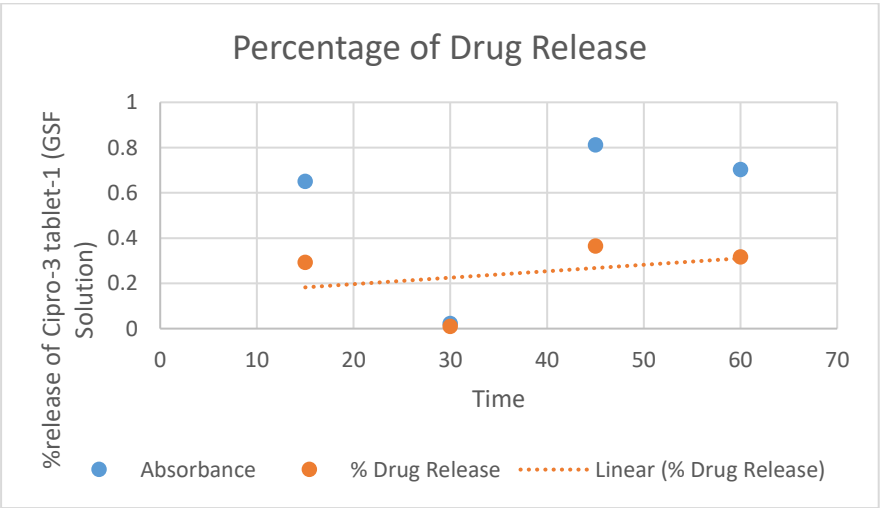

Figure 39: Drug release percentage of Cipro-3 (tablet-1) 500 mg tablet in GSF solution.

X- axis shows the time interval and the Y- axis shows the absorbance

Table 34: Cipro-3 500 mg GSF solution dissolution test absorbance data.

For Tablet-2,

Time	Absorbance	% Drug Release
15	0.670	30.15%
30	0.726	32.67%
45	0.788	35.46%
60	0.707	31.81%

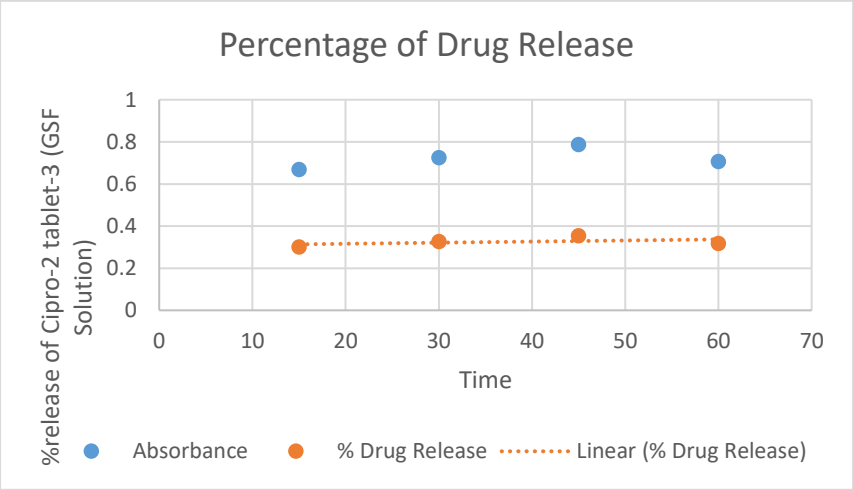

Figure 40: Drug release percentage of Cipro-3 (tablet-2) 500 mg tablet in GSF solution

X- axis shows the time interval and the Y- axis shows the absorbance

Table 35: Cipro-3 500 mg GSF solution dissolution test absorbance data.

For Tablet-3,

Time	Absorbance	% Drug Release
15	0.681	30.64%
30	0.672	30.24%
45	0.058	2.61%
60	0.692	31.14%

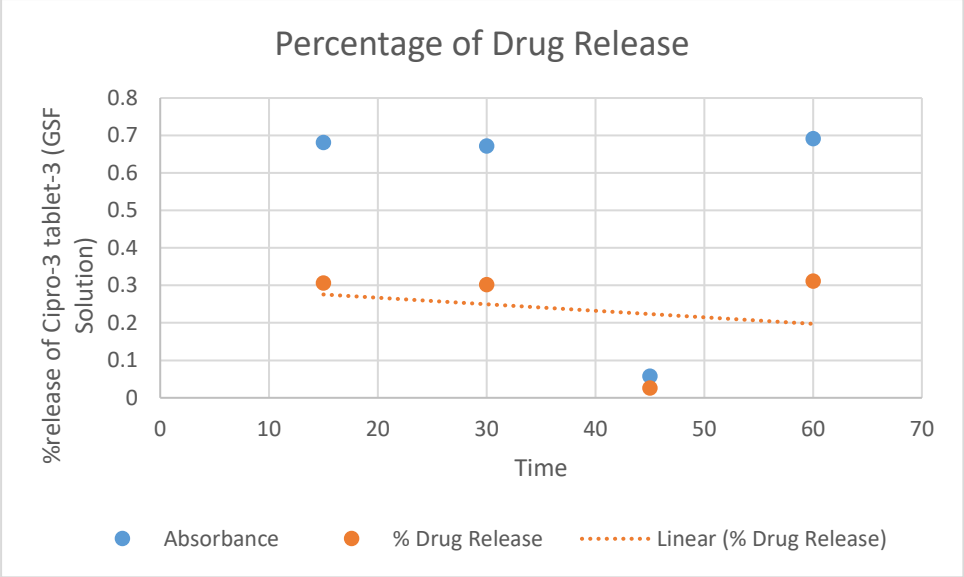

Figure 41: Drug release percentage of Cipro-3 (tablet-3) 500 mg tablet in GSF solution

X- axis shows the time interval and the Y- axis shows the absorbance

Table 36: Cipro-3 500 mg GSF solution dissolution test absorbance data.

For Tablet-4,

Time	Absorbance	% Drug Release
15	0.436	19.62%
30	0.599	26.95%
45	0.721	32.45%
60	0.758	34.11%

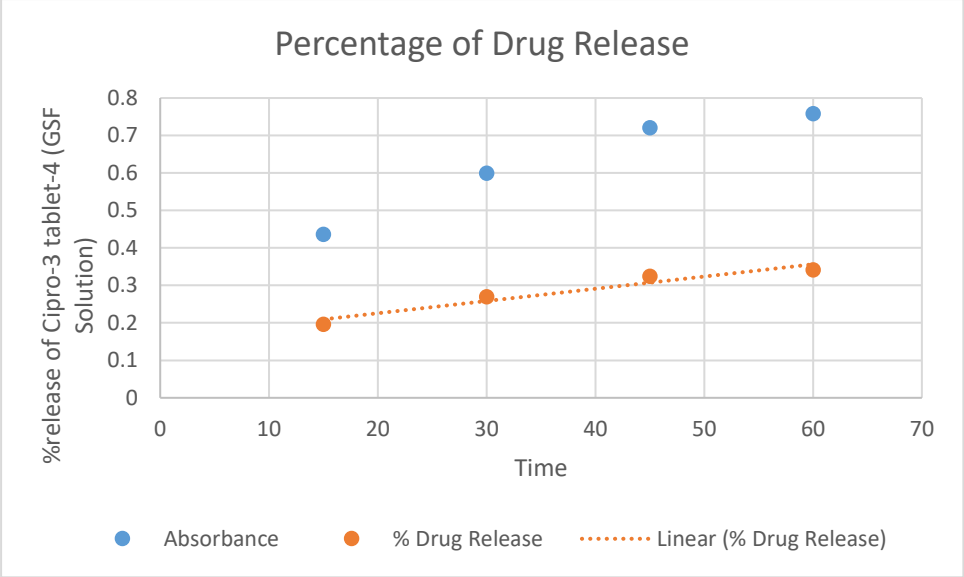

Figure 42: Drug release percentage of Cipro-3 (tablet-4) 500 mg tablet in GSF solution

X- axis shows the time interval and the Y- axis shows the absorbance

Table 37: Cipro-3 500 mg GSF solution dissolution test absorbance data.

For Tablet-5,

Time	Absorbance	% Drug Release
15	0.516	23.22%
30	0.657	29.56%
45	0.659	29.65%
60	0.652	29.34%

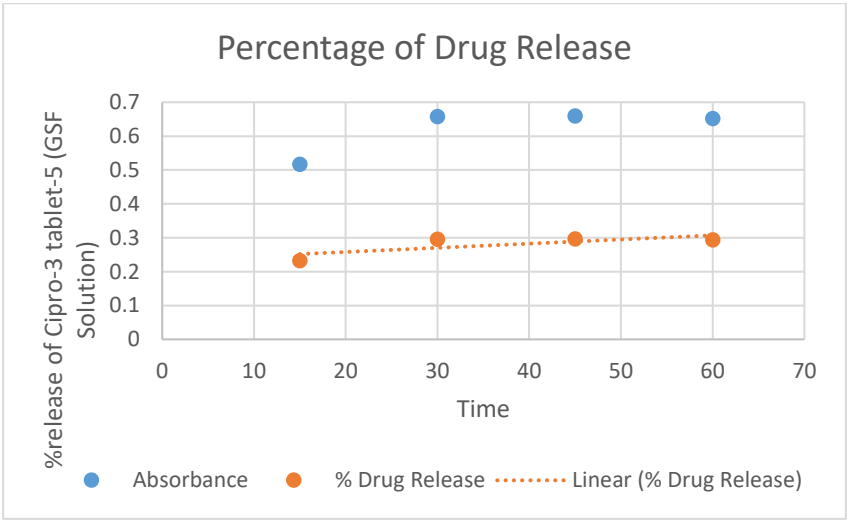

Figure 43: Drug release percentage of Cipro-3 (tablet-5) 500 mg tablet in GSF solution.

X- axis shows the time interval and the Y- axis shows the absorbance.

Table 38: Cipro-3 500 mg GSF solution dissolution test absorbance data.

For Tablet-6,

Time	Absorbance	% Drug Release
15	0.604	27.18%
30	0.709	31.90%
45	0.522	23.49%
60	0.602	27.09%

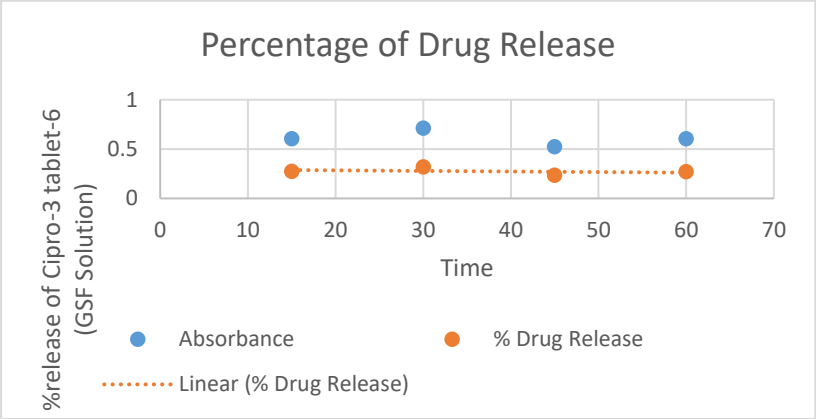

Figure 44: Drug release percentage of Cipro-3 (tablet-6) 500 mg tablet in GSF solution

X- axis shows the time interval and the Y- axis shows the absorbance.

3.5.4 Cipro-4 500 mg Tablet (GSF Solution)

Table 39: Cipro-4 500 mg GSF solution dissolution test absorbance data.

For Tablet-1,

Time	Absorbance	% Drug Release
15	0.158	7.11%
30	0.524	23.58%
45	0.631	28.39%
60	0.638	28.71%

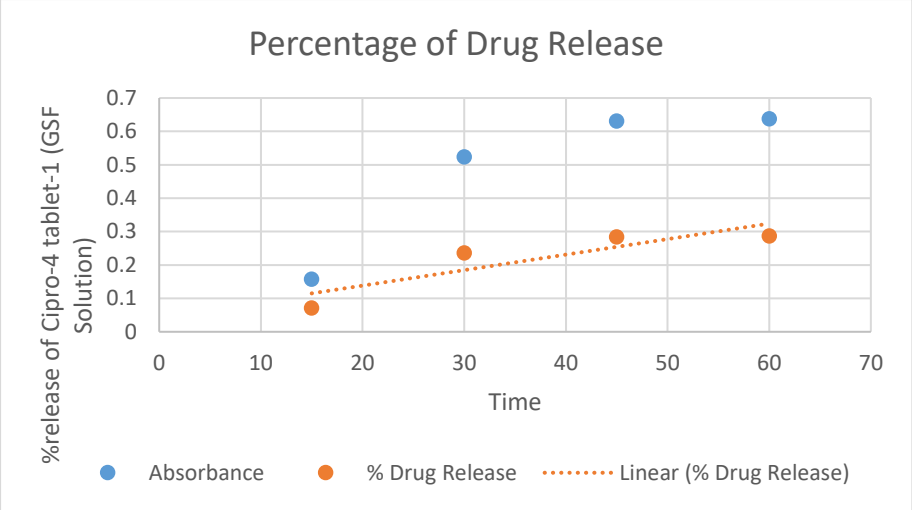

Figure 45: Drug release percentage of Cipro-4 (tablet-1) 500 mg tablet in GSF solution.

X- axis shows the time interval and the Y- axis shows the absorbance

Table 40: Cipro-4 500 mg GSF solution dissolution test absorbance data.

For Tablet-2,

Time	Absorbance	% Drug Release
15	0.263	11.83%
30	0.567	25.51%
45	0.666	29.97%
60	0.662	29.79%

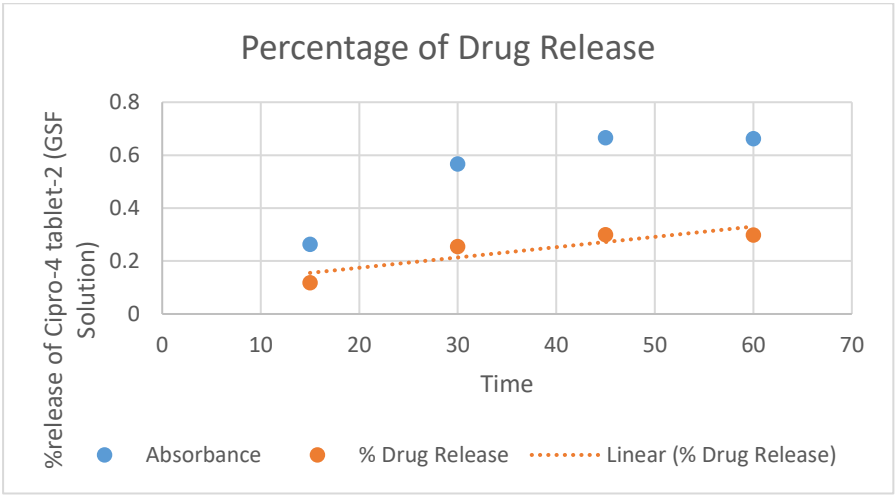

Figure 46: Drug release percentage of Cipro-4 (tablet-2) 500 mg tablet in GSF solution.

X- axis shows the time interval and the Y- axis shows the absorbance

Table 41: Cipro-4 500 mg GSF solution dissolution test absorbance data.

For Tablet-3,

Time	Absorbance	% Drug Release
15	0.221	9.94%
30	0.267	12.01%
45	0.474	21.33%
60	0.692	31.14%

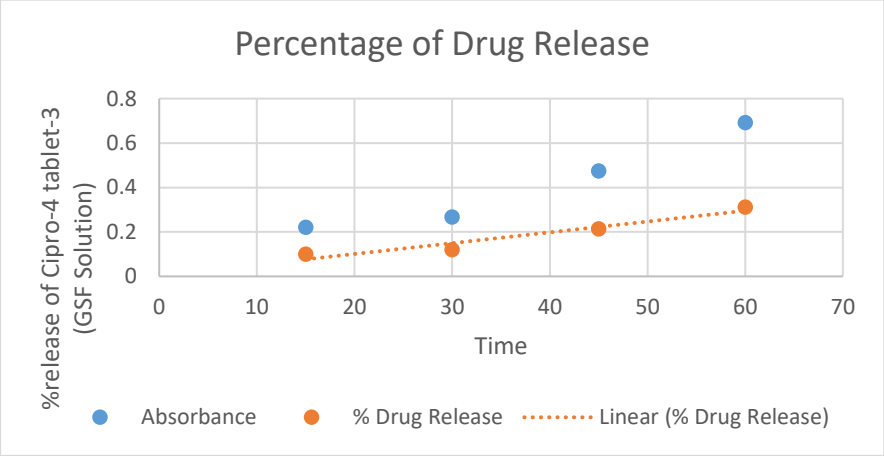

Figure 47: Drug release percentage of Cipro-4 (tablet-3) 500 mg tablet in GSF solution.

X- axis shows the time interval and the Y- axis shows the absorbance

Table 42: Cipro-4 500 mg GSF solution dissolution test absorbance data.

For Tablet-4,

Time	Absorbance	% Drug Release
15	0.273	12.28%
30	0.399	17.95%
45	0.675	30.37%
60	0.662	29.79%

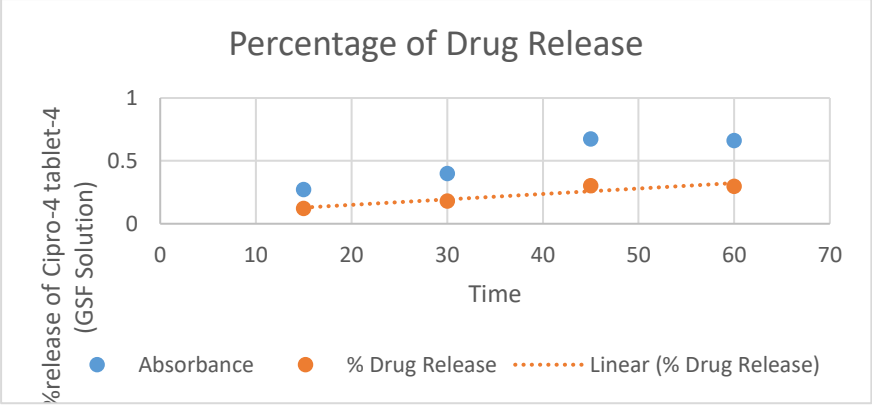

Figure 48: Drug release percentage of Cipro-4 (tablet-4) 500 mg tablet in GSF solution

X- axis shows the time interval and the Y- axis shows the absorbance

Table 43: Cipro-4 500 mg GSF solution dissolution test absorbance data.

For Tablet-5,

Time	Absorbance	% Drug Release
15	0.329	14.80%
30	0.566	25.47%
45	0.574	25.83%
60	0.608	27.36%

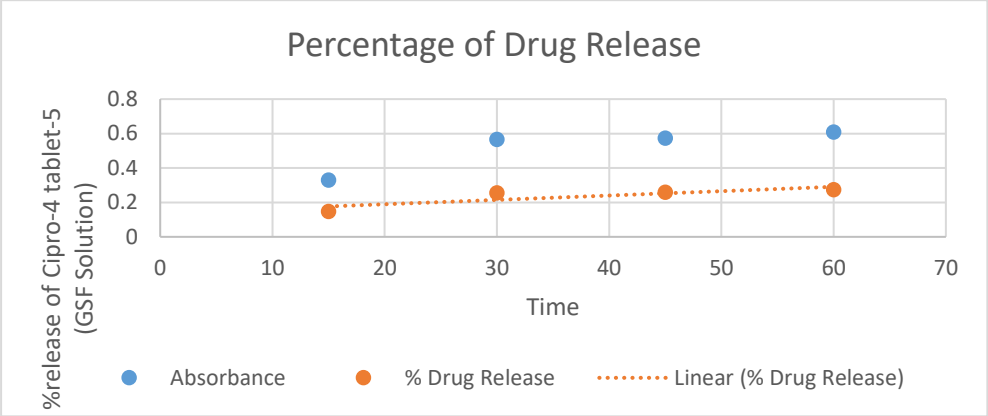

Figure 49: Drug release percentage of Cipro-4 (tablet-5) 500 mg tablet in GSF solution

X- axis shows the time interval and the Y- axis shows the absorbance.

Table 44: Cipro-4 500 mg GSF solution dissolution test absorbance data.

For Tablet-6,

Time	Absorbance	% Drug Release
15	0.378	17.01%
30	0.641	28.845%
45	0.700	31.5%
60	0.698	31.41%

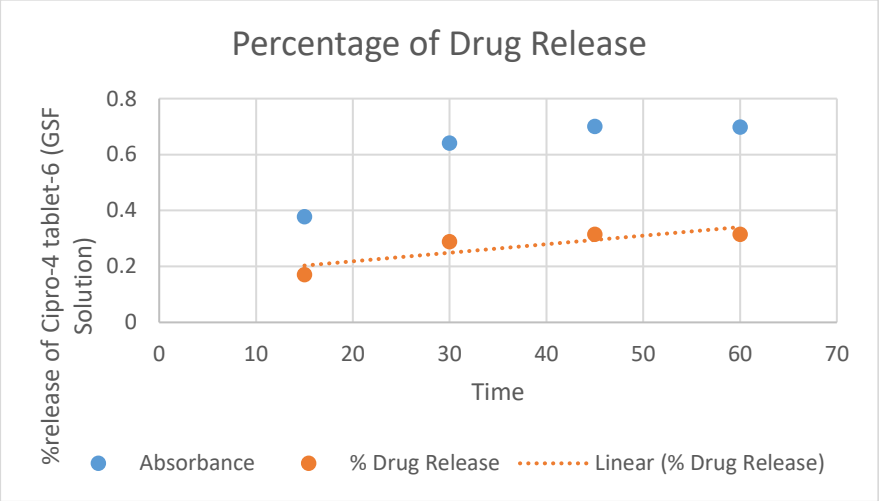

Figure 50: Drug release percentage of Cipro-4 (tablet-6) 500 mg tablet in GSF solution

X- axis shows the time interval and the Y- axis shows the absorbance

3.5.5 Cipro-5 500 mg Tablet (GSF Solution)

Table 45: Cipro-5 500 mg GSF solution dissolution test absorbance data.

For Tablet-1,

Time	Absorbance	% Drug Release
15	0.545	24.52%
30	0.636	28.62%
45	0.668	30.06%
60	0.624	28.08%

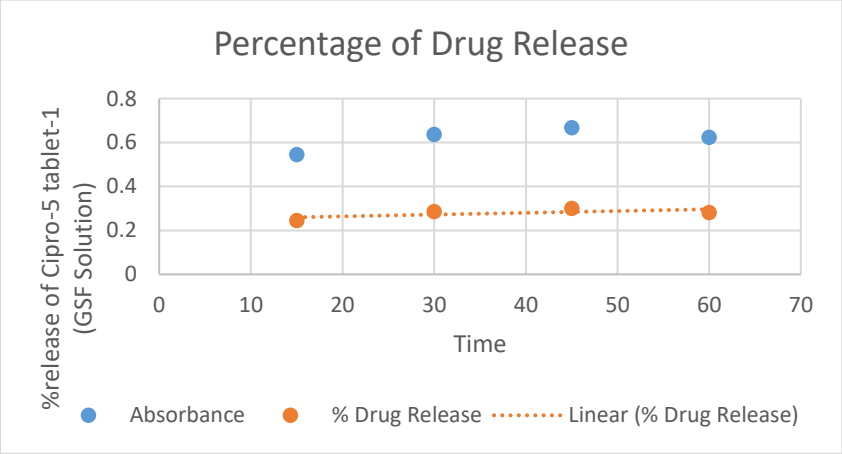

Figure 51: Drug release percentage of Cipro-5 (tablet-1) 500 mg tablet in GSF solution

X- axis shows the time interval and the Y- axis shows the absorbance

Table 46: Cipro-5 500 mg GSF solution dissolution test absorbance data.

For Tablet-2,

Time	Absorbance	% Drug Release
15	0.562	25.29%
30	0.713	32.08%
45	0.638	28.71%
60	0.658	29.61%

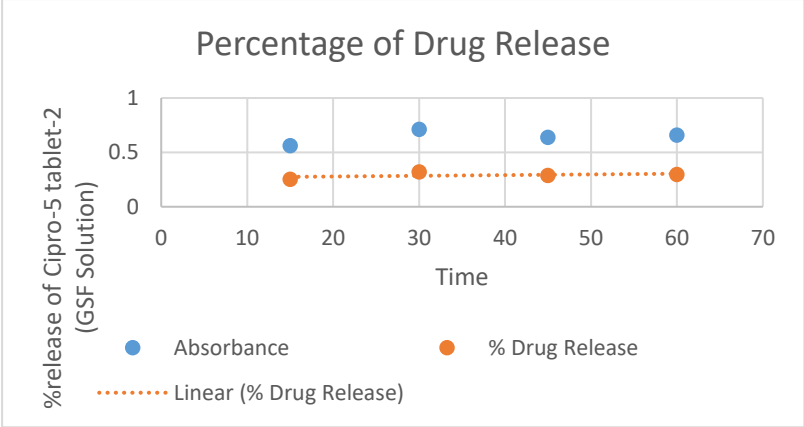

Figure 52: Drug release percentage of Cipro-5 (tablet-2) 500 mg tablet in GSF solution.

X- axis shows the time interval and the Y- axis shows the absorbance

Table 47: Cipro-5 500 mg GSF solution dissolution test absorbance data.

For Tablet-3,

Time	Absorbance	% Drug Release
15	0.366	16.47%
30	0.605	27.22%
45	0.635	28.57%
60	0.603	27.13%

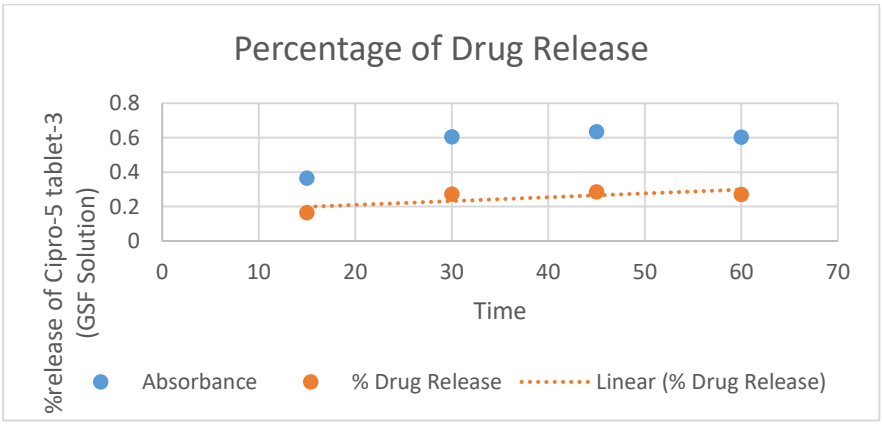

Figure 53: Drug release percentage of Cipro-5 (tablet-3) 500 mg tablet in GSF solution.

X- axis shows the time interval and the Y- axis shows the absorbance

Table 48: Cipro-5 500 mg GSF solution dissolution test absorbance data.

For Tablet-4,

Time	Absorbance	% Drug Release
15	0.424	19.08%
30	0.584	26.28%
45	0.570	25.65%
60	0.661	29.74%

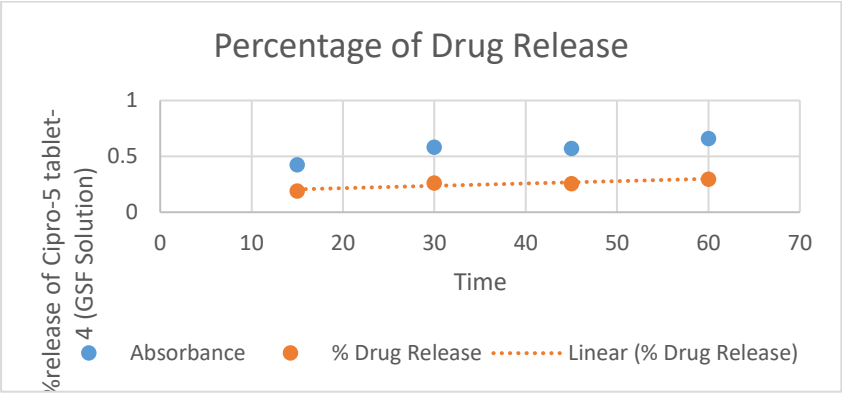

Figure 54: Drug release percentage of Cipro-5 (tablet-4) 500 mg tablet in GSF solution

X- axis shows the time interval and the Y- axis shows the absorbance

Table 49: Cipro-5 500 mg GSF solution dissolution test absorbance data.

For Tablet-5,

Time	Absorbance	% Drug Release
15	0.657	29.56%
30	0.670	30.15%
45	0.689	31.00%
60	0.748	33.66%

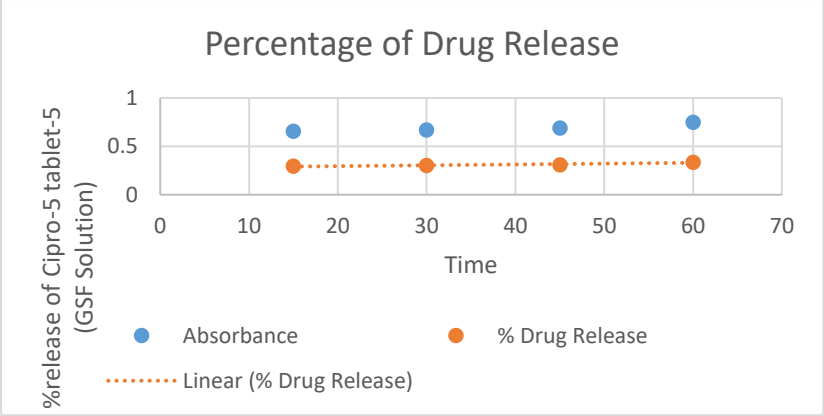

Figure 55: Drug release percentage of Cipro-5 (tablet-5) 500 mg tablet in GSF solution.

X- axis shows the time interval and the Y- axis shows the absorbance

Table 50: Cipro-5 500 mg GSF solution dissolution test absorbance data.

For Tablet-6,

Time	Absorbance	% Drug Release
15	0.830	37.35%
30	0.577	25.96%
45	0.733	32.98%
60	0.687	30.91%

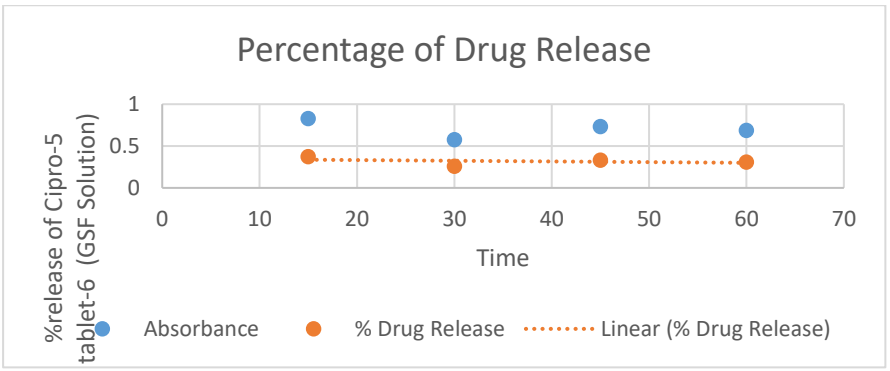

Figure 56: Drug release percentage of Cipro-5 (tablet-6) 500 mg tablet in GSF solution.

X- axis shows the time interval and the Y- axis shows the absorbance.

3.5.6 Different Brands % of Drug Release GSF Solution

Table 51: Different Brands % of Drug Release GSF Solution

By calculating all the arithmetic mean at specific time interval for 15 min, 30min, 45 min and 60 min,

Time	Cipro-1	Cipro-2	Cipro-3	Cipro-4	Cipro-5
15	24.915%	29.612%	26.683%	12.162%	25.378%
30	28.913%	27.553%	25.392%	22.228%	28.385%
45	31.344%	31.497%	26.707%	27.898%	29.495%
60	25.762%	30.260%	30.862%	29.700%	29.855%

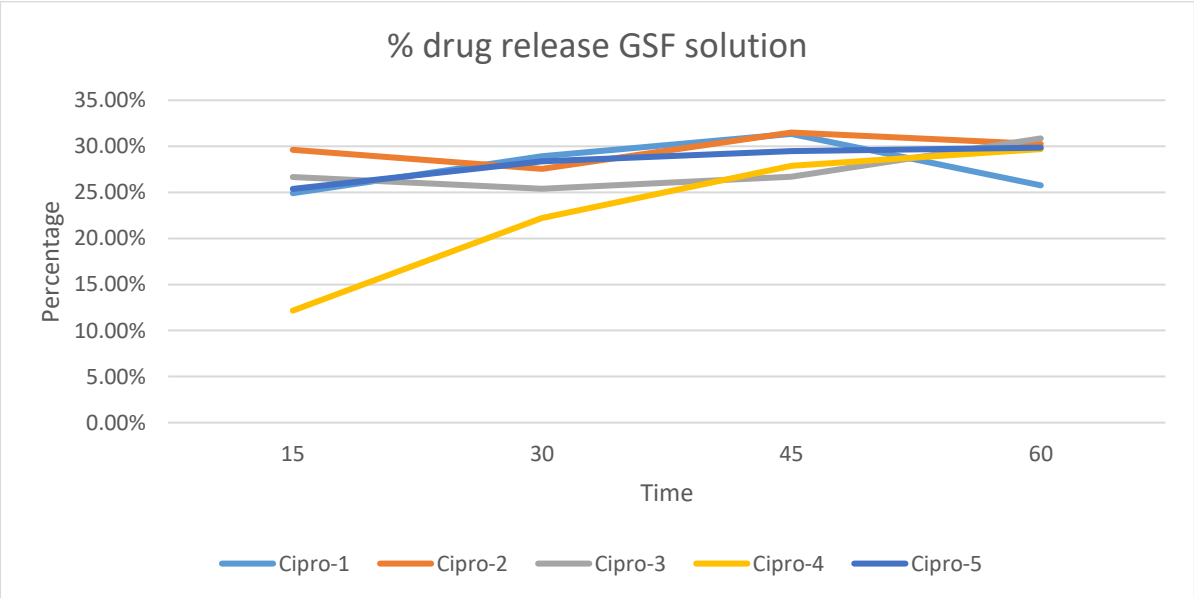

Figure 57: Different Brands % of Drug Release GSF Solution

Chapter 4

Discussion

4.1 Weight Variation Test

In order to guarantee therapeutic consistency and dose uniformity across all tablet units, the weight variation test is an essential quality control measure. USP regulations state that tablets weighing more than 324 mg shouldn't differ from the average weight by more than ±5%. Additionally, pills weighing between 130 and 324 mg are permitted to deviate by ±7.5% (Navya Sri & Reddy, 2023). According to the British Pharmacopoeia (2014), tablets with a strength greater than 250 mg must pass the first uniformity of weight test with a deviation of ± 5% from the average (uncoated or hard coated tablets). The BP standard, which stipulates that no tablet shall depart from the average by more than 10% and no more than two tablets should deviate by ± 5%, was satisfied by the tablets. According to pharmacopoeia requirements, the results demonstrate that the five brands of ciprofloxacin tablets under investigation have suitable weight consistency.

4.2 Hardness Test

The hardness test, often called the crushing strength test, assesses how well a tablet can withstand handling without chipping or breaking. Dissolution, disintegration, and friability could also be impacted. The harder the pill is, the less friable it is and the longer it takes to disintegrate. The hardness of the five ciprofloxacin brands varied a lot. Cipro-4 had the uniform batches with a standard deviation of 0.725. This was much lower compared to brands. The standard deviation of Cipro-3 was 1.024. That of Cipro-2 was 1.277. The standard deviation of hardness ranged from 0.725 to 2.610 among the brands. Cipro-4, Cipro-3 and Cipro-2 showed variation in hardness. The hardness of ciprofloxacin brands showed a lot of variation. Cipro-3 and Cipro-2 also had low standard deviation of hardness. The variation in hardness was lowest for Cipro-4, among all the five ciprofloxacin brands. The Cipro-1 tablets had a deviation of 1.970. The Cipro-5 tablets had a deviation of 2.610. This is a problem because the Cipro-1 and Cipro-5 tablets were not consistent. The Cipro-5 tablets did not do well. They had a standard deviation of 2.610. The Cipro-5 tablets did not have the consistency, as the Cipro-1 tablets.

4.3 Friability Test

The Cipro-3, Cipro-4 and Cipro-5 brands held up well. They had 0.00%, 0.012% and 0.027% respectively. These brands easily met the requirements. This suggests that the particles, in these brands are sticking well. It can be said that proper amount of binder used. On the other hand, Cipro-1 lost 7.76% of its weight and Cipro-2 lost 6.06%. This is a lot more, than the allowed 1.0 percent limit. These problems show that the Cipro-1 and Cipro-2 tablets are very fragile.

4.4 Disintegration

According to USP/BP guidelines, medicine standards Ciprofloxacin tablets must break apart in water within 15 minutes. All five brands of Ciprofloxacin tablets tested broke in the medium in 3 minutes 5 seconds to 9 minutes 3 seconds. This means they all met the medicine standards. The fastest breakdown was shown by Cipro-3, which completely fell apart in 3 minutes and 5 seconds. This really shows that Cipro-3 has a formula, with very good ingredients that help it break down quickly. Cipro-4 on the hand took the longest time to break apart which was 9 minutes and 3 seconds. This long breakdown time for Cipro-4 can be compared to its properties from previous tests. Cipro-4 still meets the required standard, which's 15 minutes so its extended breakdown is not a problem.

4.5 Dissolution

In the dissolution test, Cipro-1, Cipro-2 and Cipro-5 just do not seem to be able to break down than about 31 percent. This is a problem because Cipro-1, Cipro-2 and Cipro-5 are not breaking down like they are supposed to. On the other hand, Cipro-3 was the one that broke down the fastest it took 3 minutes and 5 seconds. The thing is, Cipro-3 only released about 31 percent of the medicine in the end which is not good enough because we want to reach 80 percent to make it work properly.

Chapter 5

Conclusion

To conclude, all the five brands of 500 mg Ciprofloxacin tablets all worked well when it came to the basics like how easily they break how hard they are and how much they weigh. The problem is that they did not do what they were supposed to do when it was time to dissolve. This is a quality control failure because all the brands didn’t not follow the rules that are in place.

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