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Quality Control Assessment On Comparative Study Of Different Marketed Brands Of Azithromycin Tablet

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ABSTRACT

Background

Azithromycin, a widely used antibiotic, is available in various marketed brands, raising concerns about their quality consistency and efficacy.

Aim

This study aims to conduct a comprehensive quality control assessment of different brands of Azithromycin tablets available in the market.

Methodology

The research methodology involves the collection of samples from pharmacy, followed by physicochemical analysis, including uniformity of weight, hardness, friability, disintegration time, dissolution profile.

Result

The two different marketed brands of Azithromycin tablet shows almost same result about thickness, hardness, friability, disintegration time, dissolution,etc. the slight change in the shape and colour of the selected tablets and thickness of Azithromycin tablet was determined to be 5.98±0.2828 (A) and 5.01±0.1283 (B). And the hardness of tablet was determined to be between 4.63kg ±0.3716to 4.77 kg±0.3606.The percentage friability of azithromycin tablets ranged from 0.5835% (A) to 0.5555% (B), and the weight variation, disintegration time, dissolution time met the requirements according to IP. All test are passed and showing the nearly same result.

Conclusion

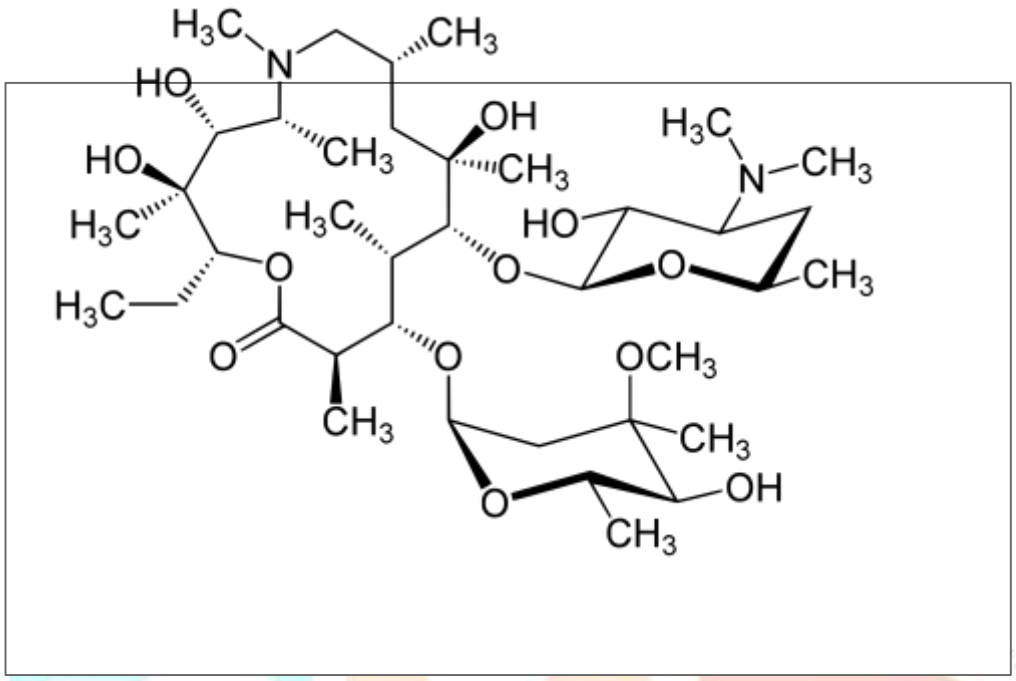
The findings of this study will provide valuable insights into the quality and consistency of different marketed brands of Azithromycin tablets, aiding healthcare professionals and regulatory authorities in making informed decisions regarding their prescription and regulation. Furthermore, it will contribute to enhancing patient safety and optimizing therapeutic outcomes.

Keywords: Azithromycin, friability, hardness, dissolution, disintegration

INTRODUCTION

Azithromycin is a macrolide antibiotic, a semi-synthetic product derived from erythromycin.It is a 15-membered lactone-macrolide ring compound derived from erythromycin by addinga methylated nitrogen to the lactone ring. [1]

Chemical Structure



Chemical Formula: $C_{38}H_{72}N_2O_{12}$ [2]

IUPAC Name : Azithromycin is (2R,3S,4R,5R,8R,10R,11R,12S,13R,14R)-13-[2,6-dideoxy-3-C-methyl-3-O-methyl-α-L-ribo-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy- 3,5,6,8,10,12,14 heptamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)-β-D-xylo- hexapyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one monohydrate or dihydrate. [2]

Molecular Weight: 749.0 (anhydrous) [2]

Category: Antibacterial [2]

Description: A white or almost white powder [2]

Solubility: it is freely soluble in anhydrous ethanol and in dichloromethane and practicallyinsoluble in water [2]

Dose: [2]

- 500 mg once daily, for 3 days or
- 500 mg once on day 1 followed by 250 mg once daily for 4 days

Azithromycin is one of the best-selling antibiotics in the world [3].The drug was originally used against infections caused by respiratory pathogens. It is also used to treat bacterial infections such as sexually transmitted diseases, as well as ear, sinus, skin, throat and genital infections[4],most commonly those that cause otitis, tonsillitis, Throat infection, laryngitis, bronchitis, pneumonia, Typhoid and sinusitis[3]It has bacteriostatic antibacterial activity by binding to the 50s ribosomal subunit and inhibiting RNA-dependent protein production. It works well against gram-positive and gram-negative infections. It has more effect against gram-negative organisms, especially genitourinary pathogens (e.g., C. Trachomatis, U. Urealyticum, N. Gonorrhoeae, and T. Pallidum). [5.] Azithromycin is a poorly soluble, highly permeable antibiotic classified as Class II in the Biopharmaceutical Classification System (BSC). The number of drug candidates that are poorly soluble in water has recently increased strongly in drug development [6]. Because the dissolution rate is not sufficient to completely dissolve the drug in the gastrointestinal tract. Its limited

solubility results in poor and variable oral absorption. As a result, dissolution is the rate-limiting step in drug absorption. Thus, in vitro in vivo correlation (IVIVC) can be expected [7].

The various different brands of azithromycin in our pharmaceutical Market makes it challenging for doctors and pharmacists to find the right brand. Many of these medications are available at significantly lower prices compared to the original drug brand, leading physicians and pharmacists to overlook their quality, safety, and effectiveness. The quality of a product is determined by its adherence to predefined standards, which are crucial for ensuring its efficacy and safety. [8]. Ensuring the chemical and pharmaceutical equivalence of medicines is crucial. They should match in terms of potency, quality, purity, and active ingredient release profile and dosage form for the same route of administration [9-12]. Although clinical trials and scientific literature provide some information, post-marketing surveillance is essential for product improvement, standard setting and regulation. Therefore, post-marketing surveillance of approved medicines is crucial to assess their quality, therapeutic efficacy and safety for public use.

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 Azithromycin tablet.

METHOD AND MATERIAL

Area of Study

The study was conducted in the department of pharmacy in the Nandkumar Shinde College of Pharmacy, Vaijapur, Chhatrapati Sambhajinagar, from March 2024 to April 2024

Materials

An in vitro analysis was conducted to assess the physicochemical quality control parametersof Azithromycin tablets of two different brands. These are named as A (ZATHRIN manufactured and marketed by FDC Limited.) and B (AZILUP, manufactured by Scott-Edil Pharmacia Ltd. And marketed by LUPIN LTD.).All the drug are selected on demand in localmarket were labelled contain 250 mg Azithromycin per tablet and obtained from retail pharmacy of Lasur station, Maharashtra, India. The various test are performed to evaluate quality like general appearance, weight variation test, content uniformity, thickness, hardness, friability test, disintegration test, dissolution test.

Equipment

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

Chemical and Reagents

- 0.1 M Phosphate buffer
- Azithromycin
- 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. ThepH was then adjusted to 6. This method was used to prepare various volumes of the phosphate buffer as needed for the experiment.

METHODOLOGY

Physical Characteristics

The visual inspection for the physical characteristics like size, shape, and manually testedtaste and odour of the selected tablet

Thickness

Ten tablets of each brand were randomly taken and their thickness were determined using aVernier caliper. Mean and standard deviation were calculated. [15]

Hardness

The tablet hardness test involves using a tablet hardness tester such as Monsanto, Pfizer, or Schleuniger. In the Monsanto hardness tester, there's a barrel with a compressible spring between two plungers. The lower plunger touches the tablet, and the upper one is pressed against the tablet until it breaks, compressing the spring and recording the force in kilograms.Typically, ten tablets are tested, with an acceptable range of 4 – 6 kg (40 – 60 N), unless stated otherwise. [13]

Friability

The friability test for tablets is conducted using a Roche friabilator in a laboratory. Twenty tablets are initially weighed, placed in the friabilator, and operated at 25 rpm for 4 minutes. After the operation, the tablets are dedusted and reweighed. The difference between the initialand final weights is used to calculate the friability expressed as a percentage using the Formula:

Friability = ((Initial weight – Final weight) / Initial weight) x 100%.

Conventional compressed tablets that lose less than 0.5% to 1% of their weight after 100revolutions are generally considered acceptable. [14]

Weight Variation

According to IP, the test performed on 20 tablet weigh individually and calculate average weight. As per IP, The tablet passes the test if no more than two of the individual weight differ 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.

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

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

Weight variation test is expressed in percentage.

Formula for weight variation test

Weight Variation = (Iwi – Aw)/Aw X 100%

Where, Iw = Individual weight of tablet

Aw = Average weight of tablet.

Disintegration

A 1000 ml beaker was filled with about 700 ml of distilled water, and the beaker was then putwithin the apparatus. Each basket rack tube held one azithromycin tablet, a plastic disc covered each tablet, and the basket rack was precisely positioned inside the beaker. The temperature maintained to 37°C +2°C .The time in minutes calculated that the tablets needed todisintegrate and get through the mesh was recorded. [15]

Dissolution

Dissolution test for Film coated tablet according to IP by Apparatus no.1.

For Azithromycin tablet, A 1000 ml beaker of the dissolution device was filled with around 900 ml of 0.1M phosphate buffer. In each beaker, one tablet of azithromycin was added. An auto heater was used to heat the dissolving medium to 37±5 degrees Celsius, and the speed was regulated to 100 r.p.m.5 ml of the solution were taken out of beaker every ten minutes, which was then replenished with five millilitres of distilled water. Filter paper was then used to filter the extracted solution. The sample's withdrawn solution was appropriately diluted, and a UV-visible spectrophotometer was used to detect absorbance at 298 nm. Ultimately, theazithromycin tablet's % release was ascertained. [16]

RESULT AND DISCUSSION

The physicochemical properties of two distinct brands of azithromycin tablets are nearlyidentical in their outcomes, indicating no apparent difference between them.

1. Physical Characteristics

Azithromycin tablets from two different manufacturers that are advertised havesomewhat altered in size and shape

Table 2. Physical Characteristics

Sr.No	Tablet	Size	Shape	Taste	Odour
1	A	14 mm × 9 mm	Oval	Slightly bitter	No Odour
2	B	9 mm × 9 mm	Convex	Slightly bitter	No Odour

2. Thickness

Azithromycin tablet thickness was determined to be 5.98±0.2828 (A) and 5.01±0.1283 (B) as shown in table no 3.All azithromycin tablet brands met the thickness limits, based on this result. Consistency in tablet thickness is essential for both customer needs and tablet packaging. The tablet's thickness changes in relation to tablet weight, compressive load, and die fill variations. Monitoring the can help you control this variance. Raw material's physical characteristics, ongoing the uniformity of punch lengths on the upper and lower. The drug's granulation characteristics, such as particle size and density and dispersion of particles. [17] As per Indian Tablet thickness is regulated by pharmacopoeia. To within five percent of a benchmark. Howthickness of the tablets of Azithromycin between the two brands showed that they were within the allowed range (±5%).

Table 3. Thickness test

Sr. no	TABLET	Thickness (mm) (Mean ±SD),N=10
1	A	5.98±0.2828
2	B	5.01±0.1283

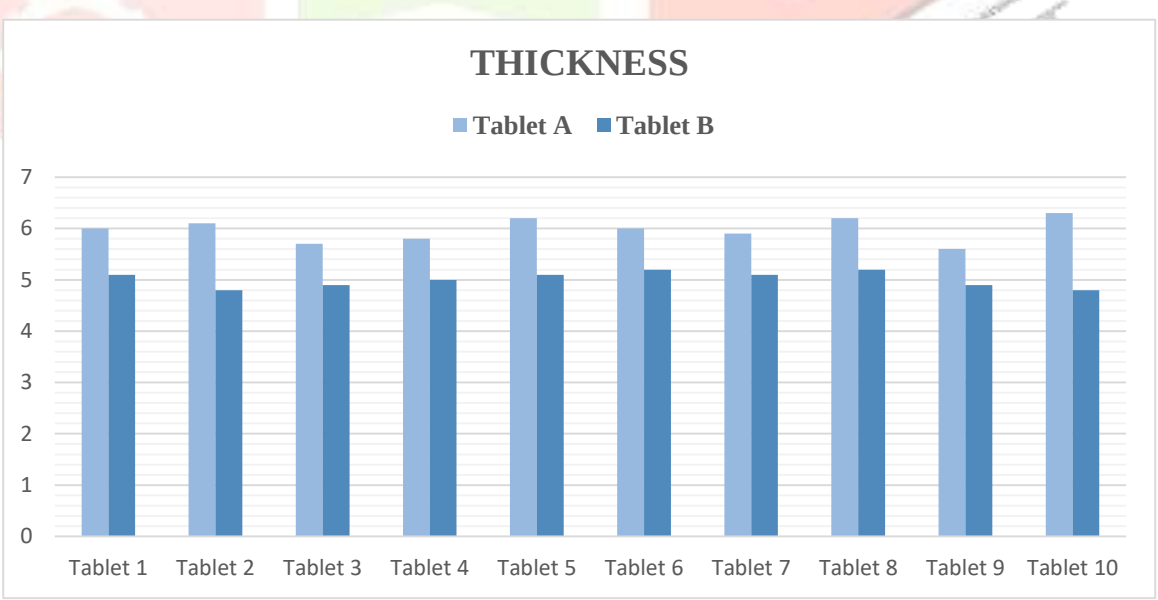


Figure 1. Thickness test

3. HARDNESS

Azithromycin tablet hardness was determined to be between 4.63kg ±0.3716to 4.77 kg±0.3606. All azithromycin tablet brands met the hardness test limits, based on this outcome. Tablet crushing strength determines their resistance to chipping, abrasion, and breaking during storage, transportation, and handling prior to storage. The weightof the material, excipients or binders employed, spacing between upper and lower punches, and compression pressure all play a role. Tablet hardness affects its density and porosity.

Tablet friability, disintegration time, medication dissolution, and releasemay all impact bioavailability. The hard tablet hinders disintegration, while the soft tablet is fragile during packing and transportation. Tablets should have a crushing strength of 4 to 7 kg (kilograms of force). [8,17,18] The average hardness for each brand was between 4 and 6 kg.

Table 4. Hardness test

Sr. No	Tablet	Hardness (Kg/f) (Mean ±SD)(N=10)
1	A	4.63±0.3716
2	B	4.77±0.3606

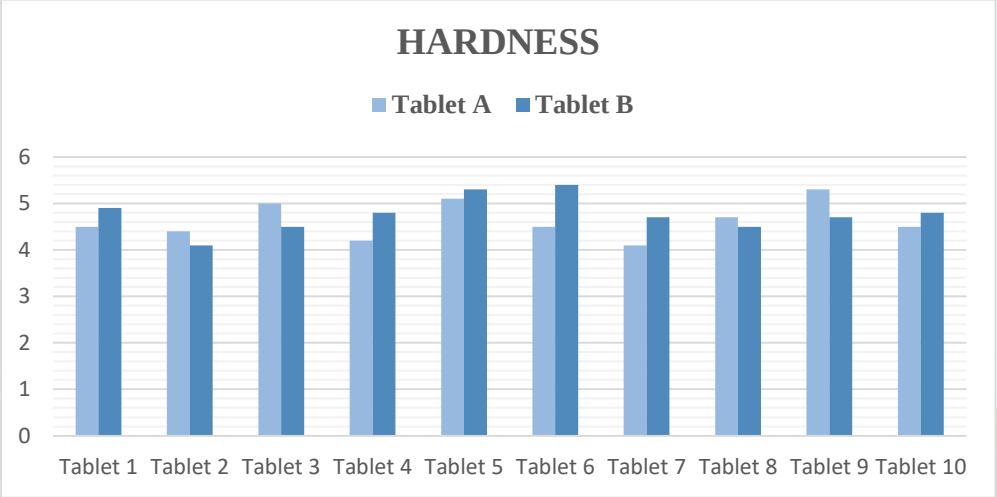


Figure 2. Hardness test

4. FRIABILITY

The percentage friability of azithromycin tablets ranged from 0.5835% (A) to 0.5555% (B), as Table no.5 illustrates. The proportion of friability should be less than 1%, under IP. All of the tested brands of azithromycin tablets met the friability standard since their percentage of friability was found to be less than 1%. As a result, the azithromycin tablets that were in circulation in Lasur station, Maharastra were strong and resilient to handling and transportation shocks. Consumer acceptability of tabletsmust have enough friability. [19]

An increased risk of mechanical erosion, which could result in the loss of the active component and reduce the drug's effectiveness, is associated with a high friability. The percentage of friability in all formulations decreases noticeably as tablet hardnessrises. The percentage of friability will therefore be lower on harder tablets and vice versa. Tablet weight fluctuation or content consistency issues can be exacerbated bythe tendency of tablets to powder, which can also have an impact on the tablet's aesthetic appearance and customer acceptability. [20]

Table 5. Percentage Friability

Sr. No	Tablet	Friability (%) (Mean)(N=20)
1	A	0.5801%
2	B	0.5524%

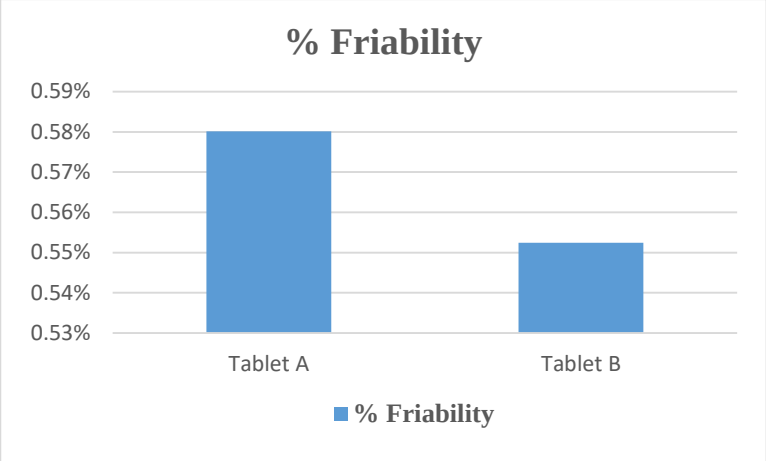


Figure 3. % Friability

5. WEIGHT VARIATION

The weight variation of tablets serves as a reliable indicator of the corresponding variation in the drug content and is a crucial part of the tablet evaluation procedure inside the manufacturing process. A significant weight variance prevents excellent content consistency between dose units, whereas a modest variation does not guarantee good content uniformity across dosage units. [18,21] Each pharmacopoeia has its own specification for this weight variation test. The Indian Pharmacopoeia states that the allowable limit for the weight deviation of tablets with an average weight of 250 mg or more should not exceed 5%. All three brands of azithromycin tablets passed this test. [2]. Some brands may use different excipients than others, which could account for the variation in mean weights across all brands.

Table 6. Weight Variation

Sr. No	Tablet	Weight Variation (mg) (Mean ±SD)(N=20)
1	A	439.55±2.3553
2	B	380.1±1.5132

6. DISINTEGRATION TEST

The process of breaking down a tablet into smaller pieces is called disintegration, and it comes before dissolution. The disintegration test calculates how long it takes for a pill to break down into smaller pieces when it comes into touch with digestive juices. As a technique for quality control with traditional dose forms, the test is helpful. The disintegration time affects both the rate of medication absorption and the drug's therapeutic efficacy. Disintegration is known to be influenced by the kind and quantityof excipient used in tablet formulation as well as the manufacturing process. [22].

Azithromycin tablet disintegration times 7.23 min (A) and 7.12 min (B) minutes on average,as Table 4 illustrates. Within 5 to 30 minutes, tablet that are film-coated should dissolve. [2] The permitted limits were therefore met by all types of Azithromycin tablet.

Table 7. Disintegration time

Sr. No	Tablet	Disintegration time (min) (Mean)(N=6)
1	A	7.23
2	B	7.12

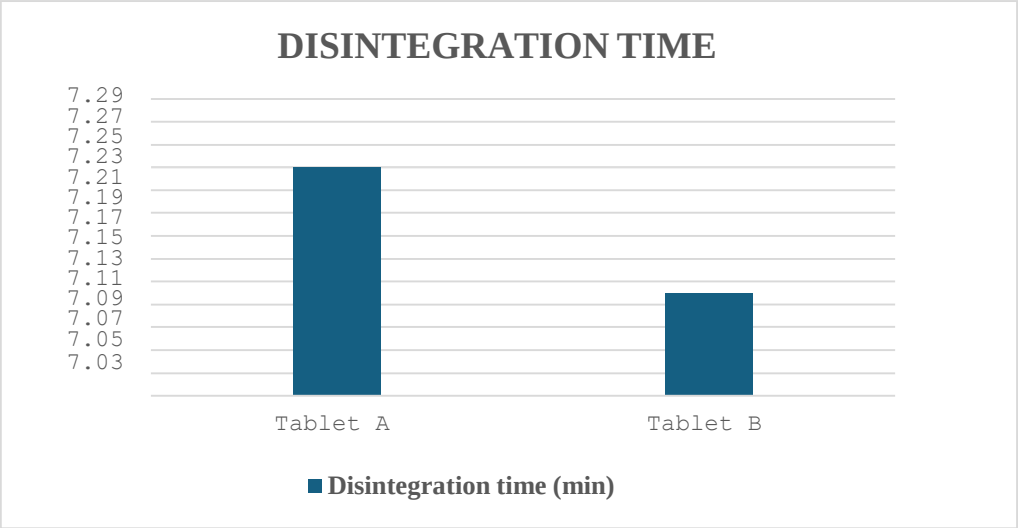


Figure 4. Disintegration time

7. DISSOLUTION

Dissolve is thought to be a crucial indicator of in vivo bioavailability and has been utilized to establish bioequivalency, permitting interchangeability. The FDA frequently views dissolution testing as having greater discriminating power than in vivo testing. The findings showed that the dissolution profiles of all brands' tablets met the requirements set forth by Pharmacopoeia, which say that after 45 minutes, atablet's dissolution profile should include no less than 75% of the active ingredient.

Table 8. Dissolution test

Time in min	Absorbance		Percent of drug release	
	Tablet A	Tablet B	Tablet A	Tablet B
10	0.105	0.102	75.9	75.5
20	0.147	0.135	82	80
30	0.227	0.215	98	99

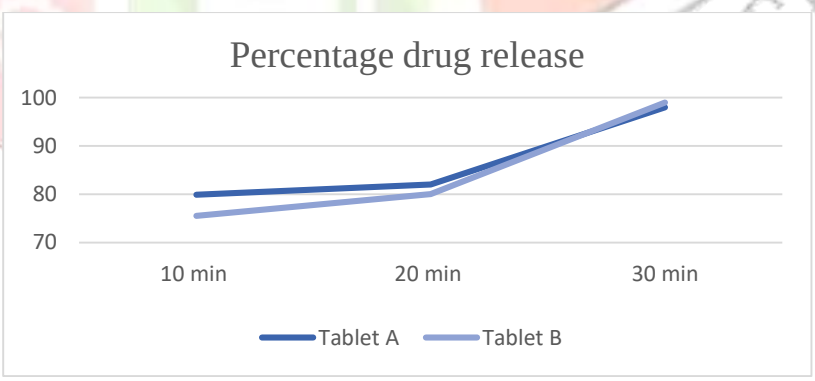


Figure 5. %drug release

CONCLUSION

Based on the comparative study of different marketed brands of Azithromycin 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 across all brands of Azithromycin tablets to safeguard public health.

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