Research Article

Comparative *In-Vitro* Equivalence Evaluation of Generic and Branded Warfarin Sodium Tablets

[1]T. Jaghatha*, [2]Dr. J. Jaslin Edward, [3]Abinesha Mol K, [3] Asmi S, [3]Jency Glara J, [3]Siva Prasath C, [3]Anisha S

[1]Associate Professor, HOD, Department of Pharmaceutics, Sun College of Pharmacy and Research Centre, Vellamodi, Tamilnadu, India.

[2]Principal, Department of Pharmacognosy, Sun College of Pharmacy and Research Centre. Vellamodi, Tamilnadu, India.

[3]Student, B. Pharm, Sun College of Pharmacy and Research Centre, Vellamodi, Tamilnadu, India.

***Corresponding author's E-mail:** asmisasi2020@gmail.com

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ABSTRACT

The study on "Comparative in-vitro equivalence evaluation of generic and branded Warfarin Sodium tablets". The objective of this research study is to assess the pharmaceutical quality, dissolution profiles, and bioequivalence of different brands of warfarin sodium tablet available in the local market. Here, we select three brands and generic warfarin sodium tablets and compare the physical and chemical parameters as per the official methods. Warfarin Sodium is a critical oral anticoagulant drug, used for the prevention and treatment of venous thrombosis and thromboembolic complication associated with atrial fibrillation. In this research, we determined their safety, quality and physicochemical equivalence of all brands of tablet through the evaluation of both official and non-official standards such as assay, weight variation, hardness, friability, disintegration, and dissolution rate. To conclude, the present study confirmed that the generic and branded warfarin sodium tablets meet the official specification for quality control analysis.

Keywords: Warfarin sodium tablet, generic, brand, Physiochemical parameters.

1. INTRODUCTION

Comparative evaluation and Quality control (QC) is crucial in pharmaceutical analysis to ensure the safety, efficacy, and quality of pharmaceutical products. Comparative studies play a vital role in evaluating different formulations or brands of a pharmaceutical product to assess their relative quality, efficacy, and safety. One of their primary objectives is to establish bioequivalence, particularly for generic drugs, ensuring that they deliver the same therapeutic effect as their branded counterparts. These studies help evaluate therapeutic efficacy by comparing whether different formulations of the same medication provide similar clinical outcomes, which is especially important in markets with multiple competing brands.[1]

1.1 Generic drugs:

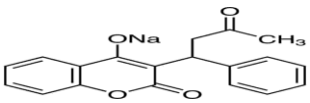
Generic medicines are pharmaceutical drugs that contain the same active ingredient as a brand-name drug that has lost its patent protection. Generic drugs are approved by regulatory authorities, such as the U.S.FDA, after they are proven to be bioequivalent to the original brand name version. Generic drugs are manufactured by companies other than the original developer of the brand-name drug. They are typically less expensive than their brand-name counterparts but are just as effective and safe.

1.2 Branded drug:

Branded drug is a medicine that a pharmaceutical company has invented, developed and marketed. Once the new drug is discovered, the company creates a patent file to protect itself from coping and selling companies from other companies, typically 20 years from the date of patent filling. During this period, no other company can produce or sell the same drug under a different name.[2]

1.3 Warfarin sodium-IP 5 mg

Warfarin, first introduced in the 1950, has now become the most widely prescribed oral anticoagulant. Warfarin Sodium tablet is an oral anticoagulant (vitamin K antagonist) commonly prescribed to prevent and treat bloods clots in conditions such as venous thrombosis and thromboembolic complication associated in atrial fibrillation. It also prevents recurrent transient ischemic attack and to reduces recurrent myocardial risk. Warfarin works by inhibit the synthesis of clotting factors such as II, VII, IX, X, as well as the naturally occurring endogenous anticoagulant C and S. Warfarin is administered orally, typically as a tablet. The bioavailability of warfarin is approximately 100% when taken orally. It also has many interactions with other medication, foods especially those high in vitamin K leafy green vegetables and herbal supplements, which can increase the risk of bleeding or reduce its effectiveness.The warfarin sodium can cause severe adverse effect is bleeding, purple toe syndrome, skin necrosis and hair loss.[3]



Structure of Warfarin sodium

Generic name: Warfarin

Molecular formula: $C_{19}H_{16}O_4$

Molecular weight: 308.3g/mol

IUPAC name: 4-hydroxy-3-(3-oxo-1-phenylbutyl)-2H-chromen-2-one.

Action and use: Vitamin K epoxide reductase inhibitor; oral anticoagulant(coumarin)[4]

Mechanism of action

Warfarin sodium is an oral anticoagulant, it acts as a vitamin K antagonist, that work by inhibiting the synthesis of vitamin K-dependent clotting factor. In the liver vitamin K is essential for activating clotting factors II, VII, IX, X, as well as proteins C and S, which help regulate blood coagulation. Warfarin exerts its effect by inhibiting the enzyme vitamin K epoxide reductase. This enzyme is responsible for converting inactive vitamin k epoxide into its active form. By blocking VKOR, warfarin reduces the availability of active vitamin K, thereby impairing the formation of functional clotting factors. As a result, the blood's ability to clot is diminished, which helps prevent the formation of clots in conditions such as deep vein thrombosis, pulmonary embolism, atrial fibirilation.[5,6]

Dosage:

Initial Dosage:

1. **Adults:** 2-10 mg orally once a daily

2. **Elderly:** 1-5 mg orally once daily (due to increased sensitivity)

Maintenance Dosage:

1. Adults: 2-10 mg orally once daily (average dose: 5-7 mg/day)

2. Elderly: 1-5 mg orally once daily[7]

Adverse effects

Severe adverse effects of warfarin sodium include bleeding complications, which can range from minor brushing and nosebleeds to life- threatening haemorrhage. Other potential side effects include purple toe syndrome, skin necrosis, allergic reactions, gastrointestinal issues like nausea, vomiting, abdominal pain, bloating, diarrhea and reversible hair loss, liver enzyme elevation. Warfarin therapy can altered the taste sensation.Warfarin is teratogenic and should be avoided during pregnancy.[8]

2. MATERIALS AND METHODS

Comparative in-vitro quality control parameters of commercially available uncoated warfarin sodium tablet brands, evaluating weight variation, hardness, friability, disintegration time, and dissolution profile. The evaluation is performed through standardized test procedures to assess tablet quality. All the test procedures were performed within the products expiry date.

2.1. Sample Collection

To perform the test, generic and three brands of warfarin sodium 5 mg uncoated tablets were purchased from a local retail pharmacy. Three brands are coded as Brand A, Brand B and brand C for the study.

Table 1: Detail of different brands of warfarin sodium tablets

Trade name	Batch no	Country	Mfg. date	Exp. Date	Cost/tablet
Generic tablet	02320	India	09/2024	08/2026	Rs 18/10 tablets
Brand A	4SB0863	India	08/2024	01/2027	Rs 80.64/30 tablets
Brand B	PT- 33827	India	12/2023	11/2025	Rs 37.70/10 tablets
Brand C	T232879	India	02/2024	01/2026	Rs 26.88/10 tablets

2.2 Chemicals

Chloroform, Hydrochloric acid, Disodium hydrogen orthophosphate, Potassium-di-hydrogen phosphate, Sodium hydroxide and Distilled water. All chemicals are used for analytical grade.

2.3. Equipment

Monsanto Hardness Tester, Roche Friability Apparatus, U.S.P. II Dissolution Apparatus, Disintegration Apparatus, Analytical Balance, Vernier Caliper, UV - visible spectrophotometer, IR spectroscopy.

2.4. Methods

The quality control tests for weight variation, hardness, friability, disintegration time, and dissolution profile were conducted on warfarin sodium uncoated tablet generic and brands A, B and C, following the guidelines outlined in the Indian Pharmacopoeia 2018, to comparatively evaluate their in-vitro quality.

Procedure:

2.4.1. General Appearance[9,10]

A tablet's general appearance, including size, shape, color, odor, and taste, is crucial for consumer acceptance. Tablets should be smooth, unblemished, and uniform in color, with common shapes being biconvex, circular, or flat, depending on the die and punches used.

Organoleptic properties

Color

The color of the tablet serves as a identifier and contributes to consumer acceptance. The color of the tablet must be uniform within a single tablet from tablet to tablet or from lot to lot. Non uniformity is generally referred to as mottling.

Odor

The presence of an odour in a batch of tablet could indicate a stability problem. However, the presence of an odour

could be characteristics of the drug, added ingredients, or the dosage.

2.4.2. Identification test[11]

Extract a quantity of the powdered tablets containing 0.1 g of warfarin sodium with 30ml of water, add 0.1ml of 2M HCL, filter, wash the precipitate with water and dry. Warm the residue gently with 3 ml of ethanol (95%), filter and add the filtrate to 2ml of water containing 0.1ml of 2M HCl. Filter, wash the precipitate with water and dry it at 105°.

On the residue, determine by IR absorption Spectrophotometry. Compare the spectrum with that obtain with warfarin sodium RS treated in the same manner or with the reference spectrum of warfarin.

2.4.3. Thickness test[10]

The thickness test is used to measure the thickness of tablet to ensure uniformity a consistency in tablet size and weight. In this test, five tablets from each brand are taken and each tablet's thickness was measured using a vernier caliper, and the average thickness was calculated to assess uniformity.

Acceptance criteria:

The acceptable tablet thickness range within a ± 5%.

2.4.4. Hardness test[12]

The hardness test is used to measure the mechanical strength of a tablet specifically, how much force it can withstand before breaking, Monsanto or Pfizer hardness tester used to measure hardness of the tablet. Place a single tablet between two anvils of the tester. Pressure is gradually applied to the tablet until the tablet breaks and record the force required to break the tablet directly from the scale on the barrel of the tester in $kg/cm^{2.}$ The process is repeated for ten tablets and average hardness is calculated.

Acceptance criteria:

Tablet hardness should lie between 5 to $15kg/cm^2$ (result limit: ±5%).

2.4.5. Friability test[13]

Friability testing assesses a tablet's ability to withstand abrasion during handling and shipping. This test is conducted using a Roche friabilator, which has an internal drum diameter ranging from 283 to 291 mm and rotating at a speed of 25 ±1 revolutions per minute (rpm).

For the test, ten tablets from each brand are selected and weighed collectively. These tablets are then placed in the calibrated friabilator and subjected to 100 revolutions over a period of 4 minutes. After completion, the tablets are reweighed, and the percentage of weight loss is calculated to determine friability using the following formula:

$$\text{Percentage friability} = \frac{W_1 - W_2}{W_1} \times 100$$

Where,

W_1 = Weight of tablets before testing.

W_2 = Weight of tablets after testing.

Acceptance criteria:

According to BP /IP= The percentage weight loss should not be more than 0.8% -1.0%.

According to USP = The percentage weight loss should not more than 4%.

2.4.6. Weight variation test[14]

The weight variation test ensures the uniformity of the weight of individual tablets in a batch, which is essential for consistent drug deliver.

To ensure uniformity, 20 tablets are randomly selected and individually weighed. The average weight is calculated, and the individual weights are compared.

Acceptance criteria:

For tablets weighing 80 mg or less, the allowed deviation from the average weight is ±10%. The specification allows for no more than two tablets to deviate from the average weight by more than a specified percentage, and none should deviate by more than twice that percentage.

2.4.7. Content Uniformity Test[15]

Content uniformity test ensure the amount of active pharmaceutical ingredients within a range around the label claim in dosage units. The assay was conducted by using UV spectrophotometer. Twenty tablets were taken from each brand, weigh and power the tablets. Disperse a quantity of the powder containing 20mg of warfarin sodium and shake with 250ml of 0.01M NaOH for 15mins and filtered. To 20ml of the filtrate add 0.15 ml of HCL and extract with 3 quantities each of 15ml pf chloroform. Extract the combined chloroform layer with 3 quantities each of 20ml of 0.01M NaOH. Dilute the combined aqueous layer to 100ml with 0.01M NaOH, filter and measure the absorbance of resulting solution at the maximum at above 307nm.

Acceptance criteria:

The drug content in each tablet should be in the range of 95% - 105% warfarin sodium.

2.4.8. Disintegration test[16,17]

Disintegration test used to determine whether tablets breakdown into smaller particles within prescribed time when place in a in a specified medium (usually water or simulated gastrointestinal fluid) under standardized conditions, ensuring the tablet can release its active ingredients. The Disintegration test was performed using a USP disintegration device. Six tablets were placed in the apparatus containing distilled water at 37 ± 0.2°C. The time taken for each tablet to completely disintegrate was recorded.

Acceptance criteria:

For uncoated tablets the disintegrating time should not be more than 15 minutes.

2.4.9. Dissolution test[18]

Dissolution test to measure the rate and extent to which the active pharmaceutical ingredient is released from a dosage form under controlled conditions, simulating the body's environment to assesses drug absorption and bioavailability.

The test was conducted in 900ml of phosphate buffer, pH 6.8 was used as dissolution medium and maintain 37 ± 0.5°C, with the agitation rates of 50, 75 and 100 rpm are tested. Sequential sampling using 0.45µm nitrocellulose filters occurred over 30 minutes at regular 5 minutes interval with 6 replicates. The amount of dissolved warfarin sodium was determined from UV absorbance at the wavelength of maximum absorbance at about 308nm.

Specification: Warfarin Sodium tablets must release 80% of the drug within 30 mins.

Acceptance criteria:[19]

Stage 1 (S1): Test 6 units. Each unit must release not less than Q + 5%, where Q is the specified amount of drug to be dissolved (usually within 30 or 45 minutes, depending on the monograph).

Stage 2 (S2): If one or more of the first 6 units fail to meet the S1 criterion but none is less than Q – 15%, test 6 additional units (total 12). The average of the 12 units must be equal to or greater than Q, and no more than 2 units are allowed to be less than Q – 15%.

Stage 3 (S3): If S2 criteria are not met, test 12 more units (total 24). The average of all 24 units must be ≥ Q, not more than 2 units are less than Q – 15%, and none is less than Q – 25%.

3. RESULT AND DISCUSSION

In present study, both generic and three brands of warfarin sodium tablets are evaluated based on various physiochemical parameters. The results are summarized below:

3.1. Identification test:

The IR spectra for the generic and branded warfarin sodium tablets were analysed and compared based on the key functional groups. The spectra confirm the presence of warfarin sodium through characteristic functional groups absorptions as per standard warfarin sodium spectrum. The observed peaks correspond to characteristic functional group vibrations such as N-H, O-H, C-H, alkyne and alkenyl stretches. The observed spectrum is provided in fig 1,2,3,4. The observed results mentioned in the table 2.

3.2. Visual Inspection:

Generic and branded tablets are visually inspected, the texture, colour, and shape of tablets are presented in table 3.

Table 2: Interpretation of IR spectra of generic and branded warfarin sodium tablets.

Wave number	Type of vibration	Generic	Branded		
			Brand A	Brand B	Brand C
3200-3400 cm^{-1}	N-H stretch	3285	3289	32876	3286
3200-3400 cm^{-1}	O - H stretch	3352	3351	3350	3348
3300 cm^{-1}	Alkyne	3302	3303	3304	3301
	C -H stretch				
>3000 cm^{-1}	alkynyl	3055	3057	3056	3054
	C - H stretch				

3.1.1. Identification Test for Generic Tablet

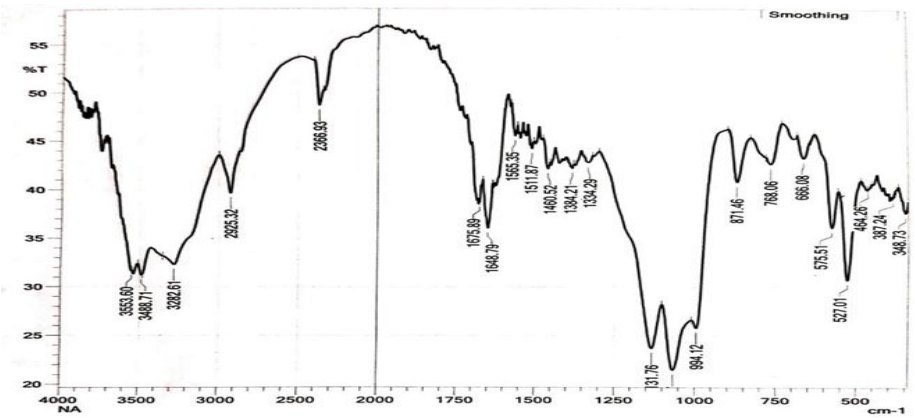


Figure 1: IR spectra of Generic tablet

3.1.2. Identification test for Brand A Tablet

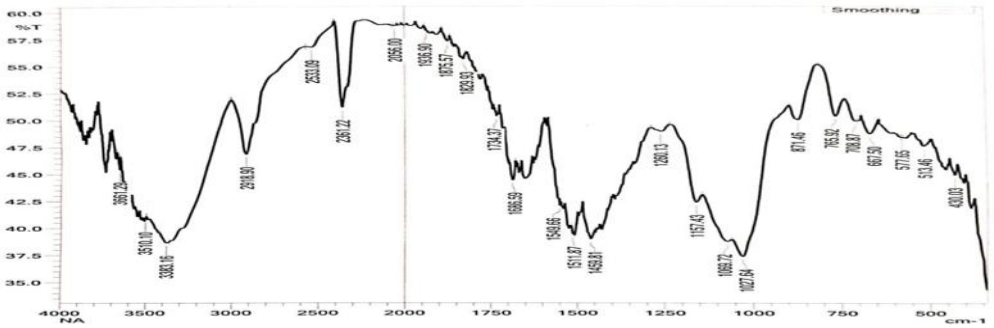


Figure 2: IR spectra of Brand A Tablet

3.1.3. Identification test for Brand B tablet

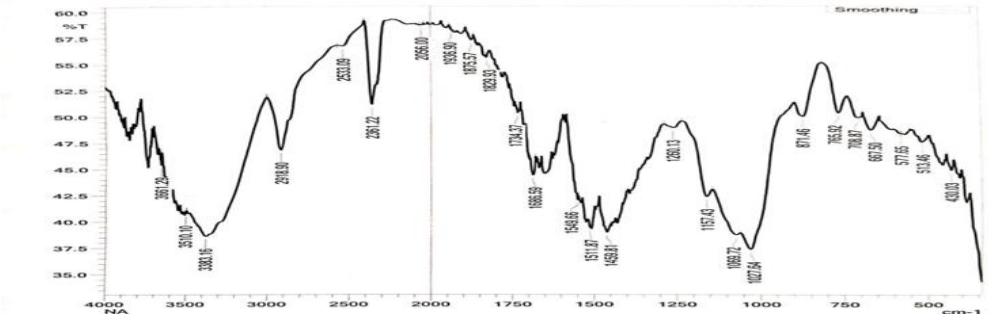


Figure 3: IR spectra of Brand B Tablet

3.1.4. Identification Test for Brand C Tablet

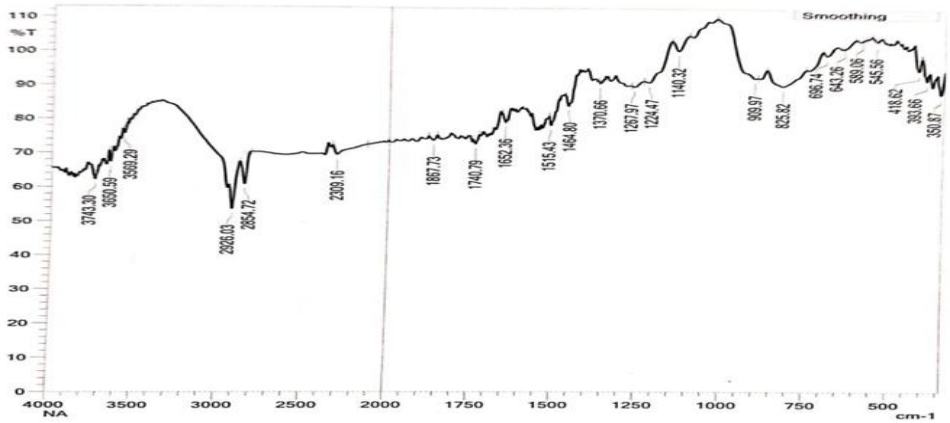


Figure 4: IR for Brand C Tablet

Table 3: Visual inspection of tablets

S.no	Brands	Colour	Shape	Texture
1	Generic Tablet	Off white	Round	**Rough**
2	Brand A	Off white	Round	**Rough**
3	Brand B	Off white	Round	**Rough**
4	Brand C	Off white	Round	**Rough**

3.3. Hardness Test:

Hardness test measure the resistant to breakage or crushing of tablet. The hardness of warfarin tablets was evaluated by using a Monsanto hardness tester. The data are presented in table 4.

3.4. Thickness Test:

The Thickness and diameter of all brands of warfarin sodium tablets were measured using vernier Caliber. Five tablets of each brand were used to determine the thickness and diameter, and average values were calculated. The results are presented in Table 4.

3.5. Friability:

The friability test was conducted on six tablets from each brand of warfarin sodium tablets using a Roche friability device. The friability test revealed that the tablets are robust and can withstand handling and transportation. Data of friability test are presented in table 4.

3.6. Weight variation test:

The weight variation uniformity test was conducted on four brands of warfarin sodium tablets. The weight variation test ensures the uniformity of the weight, which is essential for consistent drug deliver. The weight of individual tablets are presented in table 4.

3.7. Disintegration Test:

Better bioavailability, improved absorption, and improved therapeutic effectiveness are all dependent on disintegration. The results of disintegration test indicates that both generic and branded warfarin tablets dissolve in less than 10minutes. Table 4 displays the duration required for each tablet to dissolve.

3.8. Content Uniformity Test:

The content uniformity test explains the drug potency in tablets ensure the presence and the stability of the active ingredient. The test was performed following the Indian Pharmacopoeia (IP) method using the UV spectrophotometer using a reference standard to determine the amount of warfarin sodium tablet present in each brand. The percentage result are presented in table 4.

Table 4: Hardness, Thickness, friability, weight variation and content uniformity value of generic and branded warfarin sodium tablet

Test		Generic tablet	Brand A	Brand B	Brand C
Hardness Test		6.4 kg/cm^2	12.1 kg/ cm^2	5.5 kg/cm^2	5.1 kg/cm^2
Thickness test	Thickness	0.22cm	0.22cm	0.22cm	0.22cm
	diameter	0.8cm	0.7cm	0.7cm	0.7 cm
Friability test		0.60%	0.40%	0.685	0.50%
Weight variation test		0.1615	0.20%	0.14%	0.17%
Disintegration test		20sec	56sec	61sec	52 sec
Content uniformity test	Absorbance	0.49	0.591	0.619	0.58
	%drug content	93.20%	97.80%	95%	96.70%

Table 5: Dissolution Profile of Generic and branded warfarin sodium tablet

S.no	Tablet Name	Time interval	Absorbance	Amount of Drug released	% Drug Release
1	Generic	5 mins	0.295	2.041	40.82%
2		10 mins	0.325	2.25	45%
3		15 mins	0.415	2.87	59.46%
4		20 mins	0.449	3.108	632.16%
5		25 mins	0.525	3.634	72.68%
6		30 mins	0.634	4.389	87.78%
1	Brand A	5 mins	0.271	1.91	32.20%
2		10 mins	0.347	2.402	48.04%
3		15 mins	0.412	2.852	57.04%
4		20 mins	0.489	3.38	657.70%
5		25 mins	0.602	4.167	83.35%
6		30 mins	0.65	4.5	90%
1	Brand B	5 mins	0.286	1.98	39.60%
2		10 mins	0.338	2.34	48.80%
3		15 mins	0.421	2.19	58.20%
4		20 mins	0.498	3.44	68.90%
5		25 mins	0.513	3.96	79.33%
6		30 mins	0.652	4.56	91%
1	Brand C	5 mins	0.25	1.737	34.75%
2		10 mins	0.388	2.686	53.78%
3		15 mins	0.475	3.288	65.76%
4		20 mins	0.518	3.586	71.72%
5		25 mins	0.601	4.16	83.21%
6		30 mins	0.64	4.43	86.61%

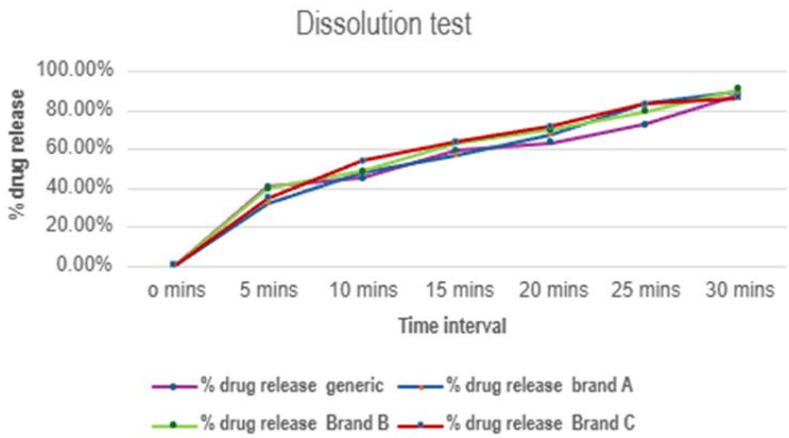


Figure 5: Comparative dissolution Profile of Generic and brands of warfarin sodium tablets

3.9. Dissolution Test:

The Dissolution study, a critical quality control parameter, assessed the release rate and directly related to the absorption and bioavailability of a drug. The study revealed that at different time intervals drug release rate was better. The data of dissolution test are presented in table 5 and the graphical representation of the dissolution value is presented in fig 5.

4. DISCUSSION

To perform the test, generic and three brands of warfarin sodium 5 mg uncoated tablets were purchased from a local retail pharmacy evaluating weight variation, hardness, friability, disintegration time, and dissolution profile. The evaluation is performed through standardized test procedures to assess tablet quality. All the test procedures were performed within the products expiry date.

The IR spectra for the generic and branded warfarin sodium tablets were analysed and compared based on the key functional groups. The spectra confirm the presence of warfarin sodium through characteristic functional groups absorptions as per standard warfarin sodium spectrum. The observed peaks correspond to characteristic functional group vibrations such as N-H, O-H, C-H, alkyne and alkenyl stretches.

The hardness of warfarin tablets was evaluated by using a Monsanto hardness tester. The result showed that all chosen brands had suitable crushing strength or hardness. All these brands of tablet's crushing strength are between 4 and 15 kg/cm^2, indicating that they passed the hardness test and are resistant to breakage or crushing.

The friability test was conducted on six tablets from each brand of warfarin sodium tablets using a Roche friability device. All the tested brands had impressive friability values ranging from 0.4% to 0.68% w/w. According to IP, the results showed that the tablets' friability percentage met the IP requirement with a weight loss of less than 1%, all the brands passed the test. This indicates that the tablets are robust and can withstand handling and transportation without significance damage.

The weight variation uniformity test was conducted on four brands of warfarin sodium tablets. According to the test results, all the four brands of tablet warfarin sodium met the IP requirements for weight uniformity, with none brand deviating more than ±5% from the mean value. This indicates that the tablets have consistent weights, ensuring reliable dose.

The content uniformity test explains the drug potency in tablets ensure the presence and the stability of the active ingredient. The test was performed following the Indian Pharmacopoeia (IP) method using the UV spectrophotometer using a reference standard to determine the amount of warfarin sodium tablet present in each brand. That the active content of all brands was found to range from 92.68% to 100.1%. The result indicates there was no significant variation in content of active moiety in their dosage form among the four brands and all within the USP specification of 100 ±10%.

Better bioavailability, improved absorption, and improved therapeutic effectiveness are all dependent on disintegration. The results of disintegration test indicates that both generic and branded warfarin tablets dissolve in less than 10minutes, which is shorter than the typical disintegration time. This indicates that all these brands of warfarin tablets satisfy the pharmacopoeia's quality control requirements.

The Dissolution study, a critical quality control parameter, assessed the release rate and directly related to the absorption and bioavailability of a drug. The study revealed that at different time intervals drug release rate was better. The results showed generic tablet and all brands of warfarin tablet (A, B, C) release at least 80% of drug wtablets30 minutes, so these all brands of warfarin tablet passed USP specifications.

5. CONCLUSION

The purpose of this research was to find out the quality and the physicochemical equivalence of branded and generic warfarin sodium tablet. The present study revealed that the generic and branded warfarin sodium tablets complied with the official specification for weight variance, friability, disintegration and dissolution. All the studied branded and generic warfarin sodium of passed the various quality control parameters including friability test showed less than

1% weight loss, hardness values of all brands range within 5-15 kg/cm^2, all the evaluated tablet released of about 80% of warfarin sodium within 30 minutes as specified in the pharmacopeia, the percent drug content of generic and branded warfarin sodium tablets in within the 90-105%. From the obtained result we were concluded that the Brand B warfarin sodium tablet taken for comparative evaluation of their quality assessment gives higher bioavailability efficacy from each other but not crosses the limits given in official book. The result indicated that the generic and branded tablets fulfilled the required official specification and thus assures that the generic drugs are also bioequivalent to ethical drugs if all the quality control parameters are being maintained. Overall, the result suggest that the generic warfarin sodium tablet is pharmaceutically equivalent to the branded formulation. Therefore, the generic version tablets can be considered as effective alternatives to branded versions, providing cost effective treatment without compromising therapeutic efficacy.

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