



Choosing Wisely: A Comparative Analysis of Generic and Branded Anti-Hypertensive Drugs Telmisartan And Metoprolol Succinate

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Abstract :

High blood pressure, or hypertension, is a prevalent heart ailment that affects a large proportion of the world's population. High blood pressure medication is commonly used to treat the condition. Antihypertensive drugs are prescribed in medicine with both brand and generic names. The goal of this study is to compare generic and branded versions of two commonly prescribed antihypertensive drugs, telmisartan and metoprolol succinate, based on quality. This study considered a number of evaluation factors, including weight variation, weight uniformity, hardness, brittleness, disintegration, and dissolution. The use of brand-name or generic drugs has recently caused much debate on a global scale. Furthermore, the governments of a number of countries actively encourage the use of generic pharmaceuticals instead of name-brand medications. A generic drug has therapeutic efficacy similar to its brand-name counterpart and includes the same active ingredient or substances. Generic drugs are much less expensive than name-brand medications since they do not have to go through the extensive and costly preclinical or clinical trials that brand-name medications undertake, which significantly raises the cost of those prescriptions. This analysis provides an overview of the comparative effectiveness of metoprolol succinate and telmisartan generics versus name-brand drugs. The objective also attempts to draw attention to the discrepancies in prices between the two categories, as well as the laws and controls surrounding both pharmaceuticals.

Keywords :

Generic drug's , Branded drug's , Safety , Efficacy , Affordability , Cost of therapy for generic drug's , health policy , Scope , Objectives and Definition , Methodology , etc.

Introduction :

A pharmaceutical business that discovers a novel drug after conducting costly trials and significant research and development will file a patent on the drug to prevent other pharmaceutical companies from producing the same molecules of the drug. These medications are known as brand name medications since they are sold on the market under a single trade name. New drug patents are valid for approximately 20 years after which the inventor retains the right to manufacture the product. This facility is the only one that can study chemical compounds in precisely the same manner. Prescription medicines are a different area that I would like to discuss. The active component composition, potency, quality, purity, and efficacy of this medication are all the same as those of its branded equivalent. A patented brand's expiration date determines when generic medications can be produced. However, the risk here is frequently the erratic quality of the medications, which makes many individuals concerned about their efficacy and safety. The goal of this

article is to compare antihypertensive medications, both branded and generic, in India. This study will evaluate the effectiveness, risk-benefit ratio, and overall cost of different medications, revealing their characteristics. The purpose of this in-depth examination of the Indian pharmaceutical market is to assist you in selecting the best blood pressure medications for your next prescription.⁽¹⁾

A thorough comparison of generic and branded antihypertensive medications is essential to ensuring patient safety, efficacy, and best treatment outcomes. It can help with evidence-based prescribing and informed decision-making, taking into account the cost-effectiveness and quality of available treatment alternatives. The medical field has now become a therapeutic jungle. Many pharmaceutical companies are creating new chemicals to cure a variety of dreadful diseases. Pharmaceutical businesses produce the same non proprietary medication (generic) under a variety of brand names. Numerous studies have found that, in many countries, the leading cause of mortality for a huge number of people is not sickness, but rather an inability to pay for the necessary medications. As a result, in order to address the issue that affects the average person, the government should properly monitor generic pharmaceutical manufacture and verify that it meets international pharmaceutical standards. Multiple research investigations have found that the majority of pharmaceuticals are used without a legitimate prescription, which is a dangerous practice, especially in rural areas. Aside from that, our government sells a small number of over-the-counter drugs to treat common ailments. It has been established that only a small fraction of pharmaceutical businesses follow the Pharmacopeial requirements, which are enforced by pharmaceutical regulatory agencies, when manufacturing drugs. Several pharmaceutical businesses manufacture the same generic medication under numerous brand names, which are subsequently supplied across multiple coasts. The current study aims to refute the widespread misperception that branded drugs have higher therapeutic efficacy than generic medications. As a result, both qualitative and quantitative analyses of the medication formulation can be utilised to determine the quality of the medicine. Weight fluctuation, hardness, friability, disintegration, dissolution, and drug pH are the criteria evaluated in our study effort in accordance with P pharmaceutical standards. This is because when a medicine dosage form is taken orally, it first disintegrates, then dissolves, and lastly absorbs into the bloodstream. The different processes that a drug goes through inside the body are explored externally using a variety of techniques including in vitro studies. We are looking at antihypertensive drugs used to treat hypertension.⁽²⁾

Scope , Objectives and definition of generic and branded medicine:

Scope

This study aims to carry out a comprehensive comparative analysis of newly developed and registered antihypertensive drugs in India. It will be an evaluation of these two classes of drugs through several key criteria such as efficacy, safety, affordability and quality .The evaluation also explores the causes behind the choice of pharmaceutical formulations with respect to their relevance and impact on patients' health.

Objectives

This study was primarily designed to compare the efficacy, safety and affordability of generic antihypertensive drugs used in India. Other objectives are:

- Evaluation of generic drug quality and understanding factors that affect them.
- To determine what lies beneath the selection between adopting generics or sticking to brand name prescriptions by patients.
- To make recommendations for ensuring quality assurance and safety in using generics.

Definition

The generics are indeed just the same drugs from pharmaceutical brands as those of the original manufacturer (brand name or innovator company). They are often cheaper than their equivalents because they do not incur marketing, advertising and research expenses.

On the flipside, branded medicines refer to medications that were manufactured by pharmaceutical companies that have patents on them. These usually cost more than generics due to R&D costs.

Though generics should be equivalents of brand name products, they may differ widely because of differences in manufacturing methods, regulatory controls and market competition.

Antihypertensive drugs

Antihypertensive drugs are required since hypertension, one of the main public health problems in India, is so common. Millions of Indians suffer from this silent killer, also known as hypertension, which is a key contributor to the burden associated with numerous cardiovascular diseases. Antihypertensive drugs are mostly used to treat hypertension in India. These medications are designed to lower blood pressure and lessen adverse consequences like heart attacks, strokes, and renal failure. There are branded and generic versions available, and each has pros and cons of its own. Many people prefer generic drugs since they are less costly than branded ones and contain the same active components. The large variety of quality discrepancies in pharmaceutical products, however, should worry patients and healthcare providers. On the other hand, branded drugs are typically more expensive but appear more reliable and manageable. Those that were accepted early are the main target of their attention. Over the past several years, there has been a notable increase in the availability of more user-friendly and reasonably priced antihypertensive drugs in India (World Health Organisation, 2011). However, there can be differences in these drugs' properties, which begs the question of their safety and effectiveness. The purpose of this article is to provide a comprehensive comparison of antihypertensive branded and generic drugs.⁽³⁾

Safety

Both generic-brand antihypertensive medications present safety concerns for patients and healthcare providers. Both brands have to adhere to the same quality standards including safety and efficacy.

Synthetic drugs if manufactured by reputed companies following proper manufacturing process could be regarded safe though generics may vary greatly with manufacturers and types.

However, Branded medicines are usually characterized by careful and precise management. It is generally considered safe because it is manufactured and tested by reputable pharmaceutical companies.⁽⁴⁾

Efficacy

Efficacy, which implies being able to produce the desired therapeutic action is a term used to describe the ability of a drug to produce. Generic and branded antihypertensive drugs are made to reduce blood pressure and lower the chances of developing complications that come with high blood pressure.

Research has shown that generic antihypertensive drugs have similar effectiveness as their branded versions. The reason for this is because generics contain the same active ingredient as the brands and hence expected to give similar clinical effects.

Nevertheless, factors like patient compliance, treatment adherence and response to medication can also affect the efficacy of a drug.⁽⁵⁾

Affordability

Affordability in India is among the key factors that influence selection of antihypertensive drugs. In case, the generic drugs cost less compared to brand name ones due to minimal marketing, advertising or research expenses.

Increased utilization of generic drugs on account of their affordability has been witnessed in India. However, prices for generic drugs may be so much different depending on who manufactures it and what specific medicine it is as well as market competition.⁽⁶⁾

Branded medications could be more expensive but they may be covered by health insurance plans or governments thus making them cheap for some patients.

The Indian market has been subjected to various studies on the pros and cons of generic and brand-named antihypertensive drugs. These clinical studies have dwelt on different areas like cost-effectiveness, safety, efficiency and patient compliance.

Materials and Methods :

➤ **Marketed preparation of Telmisartan And Metoprolol Succinate – 25 mg**

Telmisartan And Metoprolol succinate – 25 mg were taken from one of the reputed pharmaceutical store as well as taken from the Generic medical by checking their manufacturing license number, production batch number, manufacturing and expiry date.

Table 1 : Marketed preparation of generic and branded drugs

	Generic	Brand 1	Brand 2
Name	Teltan-MT 25	Metosartan-25	Telmikind Beta-25
API	Telmisartan And Metoprolol succinate	Telmisartan And Metoprolol succinate	Telmisartan and Metoprolol succinate
Strength	25 mg	25 mg	25 mg
Company	Ajanta Pharma	Sun Pharma	Mankind Pharma
Batch no.	T3226	SIE 2667A	K55W008
Mfg. Date	8/2023	11/2023	9/2023
Exp. Date	7/2025	10/2025	2/2025

➤ **Instrument :**

UV-Vis spectrophotometer, Disintegration Test Apparatus, Monsanto Hardness Tester, Friabilator, Dissolution Test Apparatus, Digital Balance, Stop Watch.

➤ **Reagents:**

Potassium Dihydrogen Phosphate (KH₂PO₄), Sodium hydroxide (NaOH), 0.1 M HCL, Distilled water.

➤ **Study Design :**

Comparative in-vitro quality control parameters between generic drug and commercially available pharmaceutical brands were studied through the

Evaluation of various parameters like thickness test, weight variation test, hardness test, friability test, disintegration time, dissolution profile and drug content.

➤ **Methodology:**

Various analytical methods and tests are important for the development and manufacture of pharmaceutical formulations. The evaluation was done according to USP and BP standards.

EVALUATION TESTS FOR TABLET

1. Thickness and diameter^{(7) (8)} :-

10 tablets of each brands were taken randomly and the thickness and diameter was determined. Thickness

and diameter of tablets were measured with the vernier calliper that had a scale of 0–25 mm and were capable of differentiating up to 0.01.

2. Evaluation of Weight Variation ⁽⁷⁾⁽⁸⁾:-

20 tablets of each formulation were weighed individually and the mean of weight were determined. According to the USP for tablets with weight more than 324 mg, among 20 tablets; just two tablets can be out of the 5% of the average weight and none deviated by more than twice that percentage. Weight variation test The United State Pharmacopeia (USP) weight variation test was performed by weighing 20 tablets individually calculating the average weight and comparing the individual tablet weight to the average weight.

$$\text{Deviation (\%)} = \frac{\text{Average wt of tablet} - \text{Individual wt of tablet}}{\text{Average wt of tablet}} \times 100$$

3. Hardness test ⁽⁸⁾⁽⁹⁾:-

The resistance of tablets to shipping or breakage under conditions of storage, transportation and handling before usage depends on its hardness. The hardness of tablet of each formulation was measured by Monsanto Hardness Tester. The hardness was measured in items of kg/cm². Hardness or tablet crushing strength is the force required to break a tablet in a diametric compression. The force is measured in kg and the hardness of about 3-5 kg/cm² is considered to be satisfactory for uncoated tablets.

4. Friability (F) test ⁽⁸⁾:-

Friability of the tablet determined using Roche friabilator. This device subjects the tablet to the combined effect of abrasion and shock in a plastic chamber revolving at 25 rpm and dropping a tablet at a height of 6 inches in each revolution. Pre weighted sample of tablets was placed in the friabilator and were subjected to the 100 revolutions. Tablets were dusted using a soft muslin cloth and reweighed. USP limit is 0.5 to 1%.

$$\text{Friability (\%)} = \frac{\text{Initial wt of tablet} - \text{Final wt of tablet}}{\text{Initial wt of tablet}} \times 100$$

5. Disintegration time ⁽¹⁰⁾⁽⁷⁾ :-

The disintegration time of a tablet refers to how quickly it breaks down into smaller particles when exposed to a liquid environment, typically in the gastrointestinal tract. This parameter is important for assessing the tablet's ability to release the active ingredient for absorption. Six tablets from branded and generic Telmisartan and Metoprolol Succinate were employed for the test in distilled water at 37±0.5 °C using a Tablet Disintegration Tester, the disintegration time (DT) was taken as the time when no particle remained on the basket of the system.. To note the disintegration time, a single tablet was placed in each tube of the USP disintegration apparatus. The device is used to move the basket assembly containing of tablet up and down through a distance of 25–32 cycles per minute.

6. In Vitro – Dissolution Study ⁽¹⁰⁾ :

The drug release rate of branded and generic Telmisartan and Metoprolol Succinate tablets were determined by using United States Pharmacopeia (USP) dissolution testing apparatus type 2 (paddle). The dissolution test was performed by using 900 ml of dissolution medium at 37°± 0.50° C and 50 rpm. In specified time intervals an aliquot of 5ml samples of the solution were withdrawn from the dissolution

apparatus and with replacement of fresh fluid to dissolution medium. The samples were filtered through filter paper of 0.45 μ m. Absorbance of these solutions were measure at 2-max 220 nm of Telmisartan And Metoprolol Succinate by using UV-Visible Spectrophotometer. The drug release of tablet was plotted against time to determine the release of selected generic and branded drugs.

➤ **Methode of analysis**

Dissolution Condition

Apparatus.	: USP Type – II
Rotary Speed Of Bowl.	: 50 rpm
Dissolution Medium	: Phosphate Buffer pH 6.8
Medium's Volume.	: 900 ml
Temperature of dissolution Medium.	: 37°C \pm 0.5°C
Test time	: 45 min
Time points.	: 10, 20, 30, 45, 60 minutes

➤ **UV Spectrophotometer Condition :**

Wavelength : 220 nm

➤ **STANDARD SOLUTION :**

The standard solutions were prepared by transferring 100mg of telmisartan and 100 mg of metoprolol succinate working standards into 100mL volumetric flask. To each, 30mL methanol was added, and the mixture was sonicated to dissolve and make up the volume with methanol.

➤ **TEST SOLUTION :**

Transfer 1 tablet in 900 ml of dissolution vessels and start the apparatus immediately. Withdraw about 10 ml Sample after every time point, filter .

➤ **PROCEDURE:**

Measure the absorbance at 220 nm and calculate the % release.

➤ **CALCULATION :**

$$\% \text{ Release} = \frac{A_t}{A_s} \times \frac{W_s}{50} \times \frac{5}{100} \times 100$$

As. 100. 50. LC

Where

At = Absorbance due the sample.

As = Absorbance due to standard.

Ws = Weight of Telmisartan and Metoprolol Succinate working standard in the Standard solution in mg.

RESULTS AND DISCUSSION:**1) Description of Generic And Branded Tablets :**

Description	Generic	Brand 1	Brand 2
Colour	White	Sunset Yellow	Tartazine
Shape	Shallow Convex	Standard Convex	Standard Convex
Smell	No Smell	No Smell	No Smell
Coat	Uncoated	Coated	Coated
Contain	Telmisartan = 40mg Metoprolol Succinate= 23.75 mg Eq. to metoprolol tartarate 25 mg	Telmisartan = 40mg Metoprolol Succinate= 23.75 mg Eq.to metoprolol tartarate 25 mg	Telmisartan = 40mg Metoprolol Succinate= 23.75 mg Eq.to metoprolol tartarate 25 mg
Brand name	Teltan-MT 25	Metosartan-25	Telmikind Beta-25
Mfg. By	Ajanta Pharma	Sun Pharma	Mankind Pharma

Table 2: Description of generic and branded drugs:

2) Average Weight :

Weigh together 10 tablet selected at random and calculate the average weight.

Tablet No.	Generic	Brand 1	Brand 2
10	3430 mg	2860 mg	3336

Table 3: Average weight of generic and branded drugs

I. Generic Tablet :

Average weight : $w/10 = 3430/10 = 343$ mg

II. Brand 1 Tablet :

Average weight: $w/10 = 2860/10 = 286$ mg

III. Brand 2 Tablet :

Average weight: $w/10 = 3336/10 = 333.6$ mg

3) Uniformity Of Weight Of Tablet:

Selected randomly 10 tablets weight individual tablet determine the weight of each tablet and determine (- &+) deviation.

Tablet No.	Generic (mg)	Brand 1 (mg)	Brand 2 (mg)
1	342	287	334
2	347	289	337
3	349	282	342
4	340	290	341
5	347	285	337

6	347	284	341
7	340	289	342
8	338	288	331
9	336	281	339
10	344	284	338
Average weight	343	285.9	338.2
(-) Deviation	2.04	1.71	2.12
(+) Deviation	1.74	1.43	1.12

Table 4: Uniformity weight of generic and branded drugs

4) Thickness of tablets :

Select 10 tablets randomly and determine the thickness each individual tablet using Vernier Calliper and calculate average weight.

Tablet no.	Generic (mm)	Brand 1 (mm)	Brand 2 (mm)
1	0.16	0.19	0.17
2	0.16	0.19	0.17
3	0.16	0.19	0.17
4	0.16	0.19	0.17
5	0.15	0.19	0.17
6	0.16	0.19	0.16
7	0.16	0.19	0.17
8	0.16	0.18	0.17
9	0.17	0.19	0.17
10	0.16	0.19	0.18
Average	0.16	0.18	0.17
Max. limit	0.46	0.48	0.47
Min. limit	0.40	0.12	0.13

Table 5: Thickness of generic and branded drug

5) Diameter of tablet

Select 10 tablets randomly and determine the diameter of each individual tablet using Vernier Calliper and calculate average weight .

Tablet no.	Generic (mm)	Brand 1 (mm)	Brand 2 (mm)
1	9.7	8.0	9.5
2	9.6	8.0	9.5
3	9.7	8.1	9.6

4	9.7	8.1	9.5
5	9.6	8.0	9.4
6	9.7	7.9	9.5
7	9.7	8.0	9.6
8	9.8	8.1	9.5
9	9.7	8.1	9.4
10	9.7	8.0	9.4
Average	9.6	8.0	9.1
Max. limit	9.9	8.6	9.9
Min. limit	9.3	7.7	8.8

Table 6: Diameter of generic and branded drugs

6) Friability of generic tablet

Table 7 : Friability of generic tablet

Data	Generic Tablet (uncoated)
Initial weight	3430
Final weight	3400
Friability %	0.87

Friability = $\frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$

Friability % is not more than 1.0 %

7) Dissolution Test:

	Generic	Brand 1	Brand 2	Dissolution Condition	
Names	Teltan-MT-25	Metosartan-25	Telmikind Beta 25		
API	Telmisartan and Metoprolol Succinate	Telmisartan and Metoprolol Succinate	Telmisartan and Metoprolol Succinate	Medium	Phosphate Buffer pH-6.8
Strength	25 mg	25 mg	25 mg	Appratus	USP Type-II
Batch No.	T3226	SIE2667A	K55W008	Temperature	37.0° C±0.5°C
Mfg. Date	08/2023	11/2023	09/2023	RPM	50
Exp. Date	07/2025	10/2025	02/2025	Time	45 min

Table 9: Dissolution test of generic and branded drugs

Sr.no	10 min			20 min			30 min			45 min			60 min		
	G	B1	B2	G	B1	B2	G	B1	B2	G	B1	B2	G	B1	B2
1	63.3 5	66.6 3	66.5 4	66.1 0	68.5 1	68.5 0	83.0 0	86.2 5	86.0 9	88.9 3	89.0 2	88.9 8	89.3 7	90.9 3	90.7 9
2	63.4 7	66.4 5	66.5 2	65.6 1	68.5 4	68.0 0	82.9 8	86.3 6	86.1 8	88.8 6	89.1 5	89.0 4	89.5 1	92.2 8	90.7 0
3	63.9 9	66.7 6	66.4 5	65.4 8	68.6 7	67.8 3	83.1 9	88.7 1	86.2 7	88.0 2	90.7 0	89.2 9	89.6 0	92.2 1	91.0 6
4	63.7 7	66.4 5	66.3 2	64.4 2	68.5 4	67.9 2	83.0 7	86.3 6	86.0 5	89.0 9	90.6 6	89.0 2	89.6 3	91.0 8	90.8 6
5	64.4 2	66.4 8	66.3 0	66.1 7	68.6 9	68.6 7	83.1 1	88.8 0	86.3 2	88.9 6	90.7 0	88.8 4	89.5 2	90.1 5	88.7 1
6	64.1 2	66.5 4	66.0 5	66.2 5	70.9 8	68.5 8	83.1 5	88.3 6	86.2 5	88.8 4	89.5 1	88.9 8	89.3 7	91.5 9	91.4 1
Avg.	63.8 5	66.6 3	66.3 6	65.6 7	68.9 8	68.2 5	83.0 8	83.6 2	86.1 9	88.9 5	89.9 5	89.0 2	89.5 0	91.5 4	90.5 8

Table 10: Telmisartan and Metoprolol succinate % release against time

TIME POINT	GENERIC	BRAND D 1	BRAND D 2
0	0	0	0
10	63.85	66.63	66.36
20	65.67	68.98	68.25
30	83.08	83.82	83.19
45	88.95	89.95	89.02
60	89.5	91.54	90.58

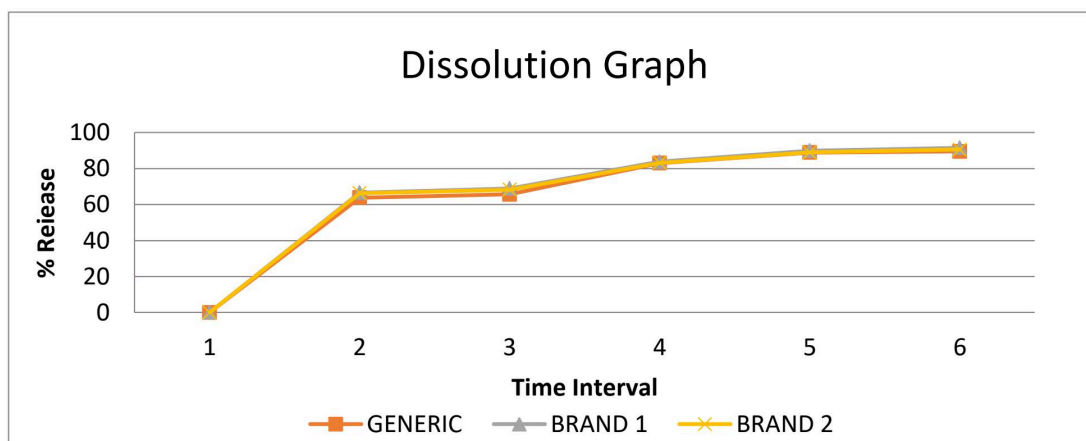


Fig. : Dissolution Rate of Generic and Branded Telmisartan and metoprolol succinate in phosphate buffer pH6.8

Discussion :

In the present study I have attempted to demonstrate the efficacy of generic and other brand versions of the commonly used antihypertensive medication, telmisartan and metoprolol succinate, in the current study. Numerous businesses in the local, national, and international markets also produce and market the medications. The investigation is limited to comparing several brand parameters with pharmaceutical standards. It is done by in vitro research. The pharmacopoeial specifications apply to the several physical parameters of tablets, such as weight fluctuation, hardness, thickness, friability, dissolving, assay, and disintegration time. The whole branded and generic tablet's disintegration time was found to be within the pharmacopoeial limit, with the generic tablet exhibiting somewhat higher disintegration. In comparison to branded tablets, which demonstrated 100% drug release in 30 minutes, the drug release of generic tablets was determined to be 99.1% in 30 minutes. Therefore, it can be said that every tablet was discovered to be in compliance with pharmaceutical requirements.

Conclusion :

The aim of the current study was to compare the price and tablet evaluation tests of Branded and Generic tablets. Telmisartan and metoprolol succinate, two fast-moving antihypertensive drugs, have been chosen for this investigation. Weight variation, hardness, friability, thickness, disintegration, and dissolution results were all observed to be constant and both values were determined to be within the acceptable ranges. Drug Release Rate Kinetics value the better drug release of both medications based on the In-Vitro dissolution studies. First order kinetics was the drug release mechanism used for both branded and generic medications. The two "paired" medications' brand- and generic-name tablets were of the same caliber and met all Indian pharmacopoeia requirements.

In the end research indicates that branded (non-generic) and generic medications yield comparable outcomes; therefore, generic versions of the drugs should to be administered more frequently in order to

lower prescription costs and make therapy more affordable. So that, in the end, we may see individuals as the healthiest rather than the wealthiest, and so that regular people can also afford the cost of their medications

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