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Review on Generic and Branded drug's-Comparative Analysis of Generic and Branded drugs

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ABSTRACT:The use of generic or branded drug is a great matter of discussion in recent times globally. The government in different countries is also strictly promoting the use of generic drugs in place of branded ones. A generic drug consists of same active ingredient/ingredients as its branded counterpart and found to be equally efficient therapeutically. The cost of generic drugs are much lesser than the branded drugs as they do not need to go through the robust and costly pre-clinical or clinical studies as done in branded ones. The present review enlightens the effectiveness of generic drugs as compared to branded drugs. An attempt is also made to highlight the cost comparison between both classes. Branded drugs are protected by a patent for a particular number of years, generic drugs are not. Generic drugs only have to meet the same bio-equivalence requirement as their branded counterparts. Also, Branded drugs take a lot of time to get approved while generic drugs take a much lesser time. Due to the time taken for the Branded drugs to get approved, the costs used in the development of the drug, branded drugs then to get very expensive in the market while generic drugs are cheaper.

KEYWORDS:
- Generic drugs
- Branded drugs
- Bio-Equivalence
- Cost comparison
- Global prevalence

I. INTRODUCTION:

According to estimates from the World Health Organization (WHO), about 30% of the world's population lacks access to basic medications, and in some African and Asian countries, that number will exceed 50%. The primary barrier to access to medications is the expense of pharmaceuticals, and governments in developing nations appear to be doing relatively little to address this issue.

India's predicament is not all that dissimilar from that of other emerging countries. Both as measured in actual terms and as a percentage of the GDP, healthcare spending in India has been increasing (GDP). It is the line item in healthcare budgets that is expanding the quickest globally, ranging from 20 to 60% in different healthcare budgets of nations. The prescription medicine industry in the United States is anticipated to reach USD 700 billion (B) by 2020, while the market in China will reach USD 260 B. The age-old discussion over how to strike a balance between the cost of innovation in drug research and universal access to the results of that research will be reignited by the rise of the pharmaceutical business globally and its rising role in total healthcare spending. Drugs are any biological or chemical substance, except food, that when eaten alters how the body functions physiologically. It can also be described as a chemical that is used to treat, prevent, mitigate, and cure diseases. These drugs can be classified as:

- Prescription drugs
- Over the counter drugs

Prescription medications: Prescription medications are those that a doctor has prescribed. They are often bought at a pharmacy, prescribed for only one individual, and are only to be used for that one person. Abacavir, Anthralin, Quinapril, and other prescription medications are a few examples.

Over-the-counter medications: Medicines that are typically sold over the counter without a doctor's prescription are also known as non-prescription pharmaceuticals. Analgesics, NSAIDs, decongestants, antacids, anti-fungal medications, cough suppressants (such as expectorants and antitussives), anti-acne medications, and some topical antibiotics (often sold as creams, ointments, powders, sprays, etc.) are examples of over-the-counter medications.

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Defination

Generic drugs

Instead of the innovator drug, which has a brand name under which the chemical composition of the drug is sold, generic drugs refer to the chemical composition of a drug. It usually performs the same function as a proprietary drug in terms of dose, potency, administration method, quality, and action. When referring to household goods, the term "generic" means that the item is less expensive, potentially less effective, and a replica of a name-brand product. But, when it comes to generic medications, they are just as effective and of equal quality to their branded counterparts. The drug's active pharmaceutical ingredient, which is what gives the medication its therapeutic effects, is known by its generic name.

The medication that is bioequivalent to its branded counterpart is known as a generic drug. The active pharmaceutical ingredient is the same, and frequently the inactive ingredients and dosage are the same as in the branded version.

Due to the lack of clinical trials, generic medications are less expensive than their branded counterparts. This makes generic medications a great solution for those looking to cut costs due to its high cost.

The FDA monitors reports of any side effects brought on by the use of generic medications. This guarantees that the manufacturers of these medications do not produce subpar medication.

Branded/ proprietary drugs:

Drugs with a trade name and patent protection are referred to as branded drugs (means that a drug can be manufactured and sold by the innovator company). A pharmaceutical company invests significant funds and resources to create, develop, and discover novel medication substances; as a result, they are granted the only right to produce and distribute the medicine for a predetermined period of time. Many people trust and are familiar with proprietary pharmaceuticals because only the innovator firm can manufacture them during the period of the patent protection.

II. BACKGROUND

A pharmaceutical business will obtain a patent for a newdrug moiety after extensive research, development, and expensive trials in order to prevent any other pharmaceuticalorganisations from copying the same moiety of medication. a brand name drug is a drug that is not a drug. A freshly developed medicine has a twenty-year patent protection period during which the maker is solely responsible for its ownership. No one else is able to duplicate or produce the same therapeutic compound. The health care system saves a lot of money as a result of patents expiring and the entry of numerous generic producers that compete with one another on pricing. Generic drug producers are expected to have saved the American healthcare system between $253 billion and $1.67 trillion over the past ten years. After the original patents have expired, generic pharmaceuticals are medical treatments that can be produced and marketed by companies other than the originator business. These medications have the same active ingredient(s), strength, quality, purity, and efficacy as branded medications. Only when a specific branded drug's patent expires can generic drugs be produced, but this has the advantage that they are much less expensive than their branded counterparts because they do not require the extensive costs for research, development, and testing that are involved in the creation of any new drug. When it comes to effectiveness and safety, generic pharmaceuticals are on par with branded medications. Because they are far less expensive than their branded counterparts, this class of medications also benefits from being simple to obtain by all socioeconomic groups. These generic medications are especially helpful in some nations where poverty is a serious problem and many people die from dangerous diseases that go untreated because they cannot afford the pricey branded medications. The timely and efficient administration of medication can ensure the effective treatment of many illnesses and help patients postpone or eliminate the need for expensive hospital care. Importantly, the use of generic medications has the chance to significantly lower expenses for patients and health care budgets

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while still effectively treating many of the illnesses of today. Branded medications have undoubtedly had a significant impact on how people use medications, but generic medications, which are bioequivalent to their brand-name equivalents, are seen as both safe and affordable alternatives. Economic pressures on medicine budgets have led to a steady rise in the use of generic medications throughout the world. Consumer in this review refers to a person who purchases pharmaceuticals for either personal use or the management of a condition. Given that they are typically less expensive than their brand-name equivalents, generic medications provide the potential for significant reductions in healthcare spending that will benefit both consumers and the government. The availability and use of generic drug substitutes for name-brand medications significantly affects how much money consumers can save on their healthcare. More than 63% of all prescriptions filled in the United States in 2008 were for generic medications. Despite the fact that most prescriptions are filled using generic drugs, these drugs really cost less than 13% less than their branded counterparts. Although lower direct costs are a major benefit of generic drug items, studies have also revealed reductions in hidden costs including compliance and therapy adherence. A generic drug, according to the FDA, is a substance that is equivalent to the pioneer, or reference, drug product (often a branded medication) in terms of dosage form, method of administration, strength, quality, safety, and performance characteristics. The pioneer product that acts as the generic drug's prototype must have the same intended application as the generic medication. Some customers continue to use brand-name prescriptions despite the cost difference because of misconceptions about or prior experiences with generic medications. This may result in higher consumer spending, patient discontent, and eventually a decline in adherence. In order to increase patient satisfaction, adherence, and quality of life, pharmacists play a crucial role in providing patients with information, answering questions, and debating the usage of generic versus brand pharmaceuticals or inactive versus active chemicals. A larger market for generic goods will spur competition, which will ultimately result in reduced drug costs and greater patient access to affordable healthcare. A generic drug, according to the FDA, is a substance that is equivalent to the pioneer, or reference, drug product (often a branded medication) in terms of dosage form, method of administration, strength, quality, safety, and performance characteristics. The pioneer product that acts as the generic drug's prototype must have the same intended application as the generic medication. 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Worldwide, the majority of national governments have promoted the use of generic pharmaceuticals, and many healthcare systems have rules that call for the replacement of pricey branded original prescriptions with generic medications. Generic substitution (GS) is a common technique in the United States; by the end of 2012, about 80% of all prescriptions were for generic drugs. This has led to huge savings for the economy and a moderating of the growth in spending on commonly used pharmaceuticals. In the UK, generic prescription has been included into medical school curricula, and GS is now a common practise in hospitals run by the National Health Service (NHS). Generic medications have a significant role in lowering healthcare costs, and this has been known for a while. Several studies have shown that by switching from more expensive original brands to generic versions, consumers can save anywhere from 10% to 90%. 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hospitals run by the National Health Service (NHS). The FDA's authorised drug product with therapeutic equivalence evaluation, also known as the "ORANGE BOOK," contains a list of all approved products, both branded and generic. A comparable product is being marketed as the medicine is FDA and NDA approved (i.e., based on bioequivalence). Usually, these medications are referred to as "branded" or "originator" medications. Other manufacturers may submit an application for the FDA's (U.S. Food and Drug Administration) approval of their own versions of the medication once that protection has expired. Drugs that have lost their initial patent protection for the active ingredient are referred to as "generic." In order to provide patients with more cheap medications as soon as feasible, generic businesses can contest that prior to the patent's expiration. To encourage generics to assume the enormous risk and expense of such patent challenges, Congress has given the first company(ies) to do so the possibility of 180 days of exclusivity. Drugs that are generic are essential to healthcare. The health care system saves a lot of money as a result of patents expiring and the entry of numerous generic producers that compete with one another on pricing. Generic drug producers are expected to have saved the American healthcare system between $253 billion and $1.67 trillion over the past ten years. The cost of procuring necessary medications in India is typically less than the mean International Reference Price (IRP), but access to these medications in the public sector has always been an issue. The bulk of the impoverished are unable to get some of the regularly used medications because of their expensive price at private pharmacies. However, certain generic drugs had a gap between procurement and retail pricing of up to 28 times, indicating an extremely high profit margin given the lack of effective price control systems. In 2012, the government updated the National Pharmaceutical Price Policy in light of this It provided guidelines for determining medicine price ceilings that fall under the 2011 revision to the National List of Essential Medicines (NLEM). It provided a methodology for determining the maximum medicine prices under NLEM using the market-based pricing (MBP) method, accounting for the costs of all manufacturers with a market share of more than 1% on a nationwide level. The Hatch Waxman Act of 1984, also known as the Drug Price Competition and Patent Team Restoration Act, established bioequivalence as the standard for licencing generic medication products. The National Pharmaceutical Pricing Policy was followed by the Drug Price Control Order of 2013, which set a price cap on 348 medications and more than 600 formulations. Several activists who advocate for more affordable medications, however, criticised the measure as being insufficient and called it a sell-out to multinational pharmaceutical firms. We can categorise the brands into innovator brands (IB), most-selling generics (MSG), and least-expensive generics based on the Indian market (LPG).

Requirements of generic drugs have to meet with a branded drug:

The requirements for generic medications are the same as those for their branded counterparts. They should –

1.Contain the same pharmaceutical active components.
2.Use the identical dosage form (oral, topical, intravenous etc.)
3.Have the same strength and purity.
4.Share the same usage guidelines.
5.Share the proprietary counterpart's action and dissolving rate.
6.Be produced in accordance with the tight guidelines established by the Good Manufacturing Practices (GMP) programme of the Food and Drug Administration (FDA) for the patented counterparts.

Drug development and approval process

A new medicine's invention and development is a protracted, expensive, complicated, and risky process, but it offers significant advantages in the commercial world. From the beginning of a project through the release of a drug product, research and development (R&D) for the majority of the medications on the market today has taken 12–24 years for a single new medicine. also necessitates extensive, costly study. Finding a medical need and evaluating the sufficiency of available treatments are the first steps in the drug discovery process (if there are any). Hypotheses on how to potentially improve therapy—specifically, what advancements in efficacy, safety, or mechanically novel aspects will advance the method of drug treatment for patients with the target disease—will emerge from this

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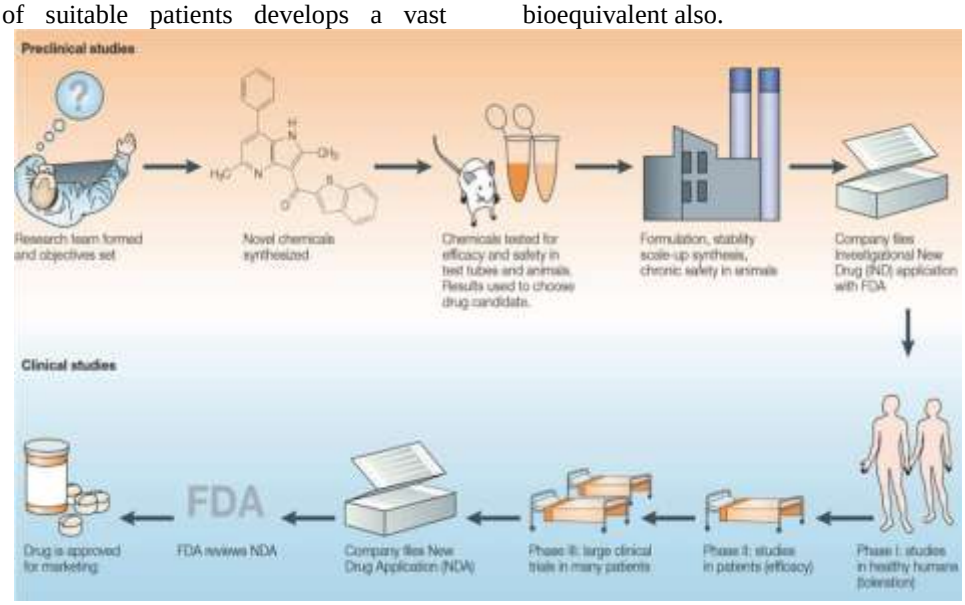
analysis along with an assessment of the state of our knowledge about the target disease. Specific project goals will be established based on these hypotheses. Following that, testing of certain compounds in pertinent biological tests might start.

A structurally novel compound's in vitro biological activity must be determined, followed by the identification of a related compound that exhibits in vivo activity in an appropriate animal model, the optimisation of this activity through the preparation of analogous structures, and finally the choice of one compound as the drug development candidate. Then, as required by law, this drug candidate goes through toxicological testing on animals. The Food and Drug Administration (FDA) in the United States (or a comparable organisation in other countries) receives the compiled research data as an Investigational New Drug Application (IND) if the substance passes all of these tests before clinical trials can begin Phase I of clinical trials in normal human volunteers evaluates toleration, Phase II of clinical trials in patients evaluates efficacy and dose range, and Phase III of clinical trials in hundreds of suitable patients develops a vast database of efficacy and safety (phase3). A New Drug Application (NDA) with all the accumulated research data is submitted for the select few (4–7%) drug candidates that make it through this phase of development trials for a thorough examination by the FDA. The new medication cannot be given to doctors or their patients to treat the condition for which it was created unless they provide their consent. Generic medications are only able to be produced when the patent period of their branded counterparts has expired. A New Drug Application (NDA) is necessary for a new moiety, while an Abbreviated New Drug Application (ANDA), which does not have to meet the same exacting criteria as the NDA, is needed for generic versions. The Hatch-Waxman Act of 1984 in the US, which was primarily responsible for developing the ANDA system, is relevant for the approval of generic drugs beginning in 1962. The significant regulatory requirements for generic drugs are that it should contain the same active ingredient as the innovator drug. It should be similar in strength, dosage form and route of administration. It should be bioequivalent also.



Bio-Equivalence

Bio-equivalence refers to pharmaceutically comparable drug products in which, under adequate and appropriate test settings, the rate of bioavailability of the Active Pharmaceutical Ingredients is almost same to achieve peak blood concentrations. In vivo testing on humans is typically used to determine bioequivalence. When the dose form of a branded drug is the same as that of a generic drug, the bioavailability parameters of the branded drug are determined. The quality, therapeutic efficacy, and safety of generic pharmaceuticals are demonstrated by comparison of the bioequivalence data of those drugs with those of their branded counterparts. If the two sets of data are consistent. According to a drug's concentration time curve or excretion, bioavailability is the pace and degree of absorption from a dose form. Typically, human subjects are used in this bioequivalence assessment together with recognised bioavailability

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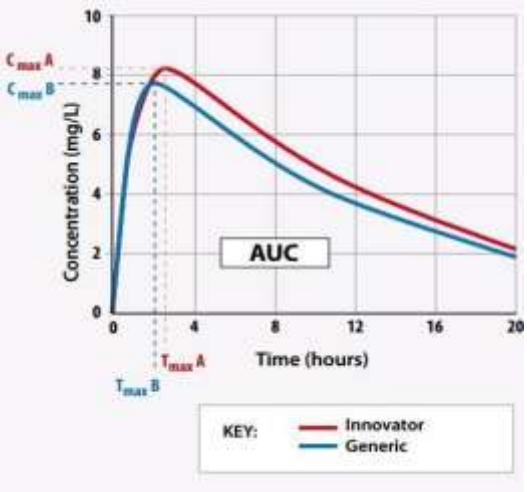
metrics. To determine the pharmacokinetic characteristics and bioequivalence information, sophisticated High performance liquid chromatography (HPLC), Gas chromatography (GC), and Mass spectroscopy (MS) techniques are being employed to measure the plasma drug concentration of both types of medications. According to FDA regulations, generic medications must be bioequivalent to their branded counterparts, and only those with established bioequivalence and efficacy are permitted to access the market. The FDA's requirements for equivalency are rigorously assessed on generic medications to ensure that their presentation and constituents are equivalent. So, we could infer that generic pharmaceuticals are just as effective as branded ones from these effective measures and approval methods. The primary components of bioavailability are:

1.The term "area under the curve" (AUC) describes the blood concentration from time t=0 to time t=infinity.

2.Cmax, which stands for the highest drug concentration in the blood.

3.Tmax, or the time needed for a medication to reach its Cmax.



Advantages and disadvantages of generic drugs:

Advantages of generic drugs over proprietary ones: The Major advantage of generic medication is the

Cost Benefits: Drugs that are generic cannot be sold for more money than those that are proprietary. Due to the high cost of some medications, it may be challenging for patients to take their prescription for the full course of their treatment. This inexpensive medication makes it financially easier for patients to carefully follow a dosing plan. Because the firm producing the generic drug did not include the costs of the original research, testing, or marketing, the price of the generic drug is lower.

Bio Equivalent: Since generic medications adhere to tight standards, they provide the same amounts of Active Pharmaceutical Ingredients to the body at the same times as branded medications.

Disadvantages of generic drugs over proprietary counterparts:

Contamination: Sometimes, generic medications are made at facilities using subpar labour, poor storage practises, and incorrect GMPs (Good Manufacturing Practices).

Consumer Confusion: A medication that patients can find confused because of its various names and appearance. This means that in order to prevent a certain drug from being confused for another during prescribing and dispensing, both the generic names and proprietary names must be distinct.

Reactions: Although the Active Pharmacological Components in generic medications are the same, the Inactive Pharmaceutical Ingredients might vary and affect the rate of absorption. A chemical is transformed into a usable medicinal product by the inactive pharmaceutical ingredients. Although inactive chemicals are not toxic and do not affect the body, they can trigger serious allergic reactions in a small number of persons. For this reason, branded pharmaceuticals may be more favoured than generic ones. Example: Asthmatic allergic reactions have been linked to the preservative bisulphates (e.g., sodium metabisulphites), which is typically utilised in numerous items.

Advantages and disadvantages of branded drugs:

Advantages of branded over generic drug:

1.They are patented drug in their class.

2.They might possess a newly found medicine with advantages.

3.Not all medicine are available in generic form.

4.It might be simple to memorise and write brand names.

Disadvantages of branded drugs over generic drugs:

Branded products' only drawback is their high price. Because we haveto pay for the drug's purchase, development, safety testing, marketing, and transportation charges, proprietary medications are more expensive.

The medications are quite expensive to purchase due to these costs. This will be seen in the estimated cost difference between generic and branded medications.

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Comparative analysis of generic drugs over branded drugs on the basis of cost:

S. No.	Generic drug	Class of drug	Manufacturer	Market price (Rs)	Branded drug	Manufacturer	Market price(Rs)
1.	Aceclofenac Tablets IP 200 mg	NSAID	Edmund Healthcare Pvt Ltd,Chandigarh (Punjab)	10	Aceroc	Wockhardt	29.10 (10 Units)
2.	Acyclovir 400 mg Tablets	Anti-Viral	Vega Biotech Pvt Ltd,Vadodra (Gujrat)	31.6	Acivir DT	Cipla	60.99(5 Units)
3.	Metformin Hcl 1000 mg SR Tablets	Anti-Diabetic	Care Formlation Labs Pvt Ltd, New-Delhi	11.05	Geminor-M Forte	Macleods Pharmaceutical Ltd	60.50 (10 Units)
4.	Omeprazole 20 mg Capsules	Proton Pump Inhibitor	Schwitz Biotech,Ahmedabad	7	Acichek	Sanofi Aventis Pharma India	29.75 (10 Units)
5.	Folic Acid Tablets IP 5 mg	Anti-Anaemic	Alpha Pharmaceuticals, Faridabad(Haryana)	2.9	Folitab	Intas Pharmaceutical Ltd	30 (30 Units)
6.	Montelukast Sodium Tablets IP 5 mg	Antiasthmatic	Curelife Pharmaceuticals, Ambala (Haryana)	12	Singulair	MSD Pharmaceuticals Pvt Ltd	84 (7 Units)
7.	Lansoprazole 30 mg Capsules	Proton Pump Inhibitor	Actiza Pvt. Ltd,Surat,Gujrat	42	Lanzol-30	Cipla	54
8.	Alendronate Sodium 70 mg	Biphosphonates	Radix Pharmaceuticals,	94	Osteofos	Cipla	116 (4 Units)
9.	Cefuroxime Injection 750 mg	Antibacterial	Talent Healthcare,Ahmedabad (Gujrat)	64	Supacef Injection	GlaxoSmithkline	114
10.	Gabapentin Capsules USP 300 mg	Antiseizure	Dycott Healthcare,Baddi,DisttSolan(HP)	23	Gabator 300 mg	Torrent Pharmaceuticals Ltd	98.75
11.	Tenofovir Tablets 300 mg	Nucleotide reverse transcriptase inhibitor	Million Health Pharmaceuticals, Chennai	178	Tenvir-EM	Cipla	2000
12.	Vincristine Injection IP 1 mg	Anti-Cancerous	Lexicare Pharma Pvt. Ltd, Ankleshwar, Gujrat	25	Oncocristin -AQ	Sun Pharmaceuticals	52 (1 ml)
13.	Oxaliplatin Injection 50 mg	Anti-Cancerous	Revacure Lifesciences, New-Delhi	430	Dacotin	Dr Reddy's Laboratory Ltd	4,938
14.	Progesterone 200 mg SR Tablets	Progestins	Tissue Overseas, Surat, Gujrat	163	Algest	Cadila Pharmaceuticals Ltd	187
15.	Orlistat 120 mg Capsule	Lipase Inhibitors	Fortune Healthcare, Vadodara, Gujrat	130	Olisat	Biocon Ltd	380
16.	Temozolamide 100 mg Capsule	Anti-Cancerous	NetcoPharma,Telangna	1,330	Temolon	CelonLaboratories Ltd	9,200
17.	Leflunomide Tablet IP 20 mg	Anti-Arthritic	Tai Pharmaceuticals Ltd, Rajgad, Maharashtra	66.38	Arava	Sanofi Aventis Pharma Ltd	1,384
18.	Efavirenz Tablet IP 600 mg	Anti-Retroviral	Medchem International Ltd,Hyderabad	423	Odivir	Cipla	1,070

Comparison between Generic and Branded drug's:

Features	Generic drug's	Brand name drug's
Patent	Off patent	Patent protected
Trade Name	Marketed under the generic original trade name of drug	Marketed under a unique branded name given by company
Manufactured by	Manufactured by several pharmaceutical companies	Developed manufactured by an innovator company
Animal and clinical study	Not required to perform	Essential to perform
price	Cheaper	Costly than generic drug
Appearance (colour, shape, size)	Look different from relevant brand name drug	Unique look as design during product development
Name variation	Same generic drug name in any country	Same or different brand names
Excipient	Same or altered but acceptable excipient	Uses acceptable excipient
Availability	After expiration of patents and exclusivities	From product launch after proving the safety and effectiveness
Examples	Paracetamol	Tylenol, Para, NAPA, Mapap

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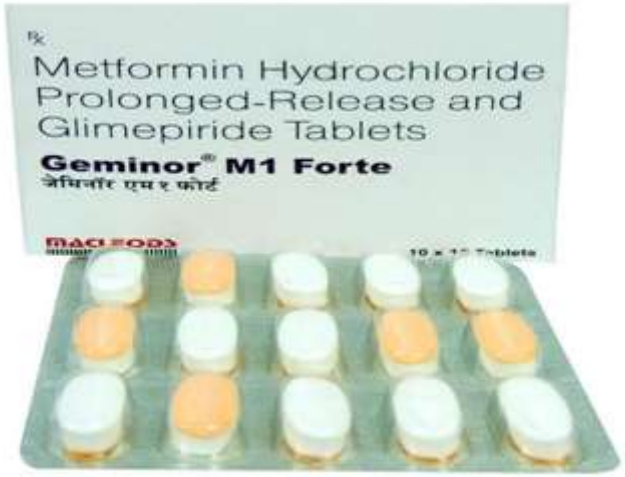
		Nortemp ,Acamol ,Acetalgin, Dexamol , Dolex ,Calpol, Febridol.

Marketed preperation of generic and branded drugs:
Generic drug

Branded drug



Global prevalence:

The pharmaceutical industry's largest segment, original branded drugs, are anticipated to account for 56% of global spending (2021). The market share of generic drugs, which includes both branded and non-branded generic medications, is also expanding considerably more quickly. Increasing demand for low-cost generic alternatives in the pharmaceutical industry is a major factor driving the growth of the generic medicine market. Both the growth and the share are included in this. Also, branded generics in developing nations are probably going to be a major factor in the expansion of the generic market as a whole. The top four generic medication producers worldwide, which together account for 40% of the market, are Teva, Sandoz, Mylan, and Watson. Throughout the past two decades, both brand-name and generic medications have become more globally distributed. The countries that produce the most generic drugs are India, China, and Israel, whereas South Korea, Brazil, the Middle East, Russia, and Southeast Asia are the regions with the fastest-growing pharmaceutical manufacturing facilities. In comparison to the U.S. average of 86%, generic medicine consumption rates are below 30% in Australia, France, Greece, Japan, and Switzerland.

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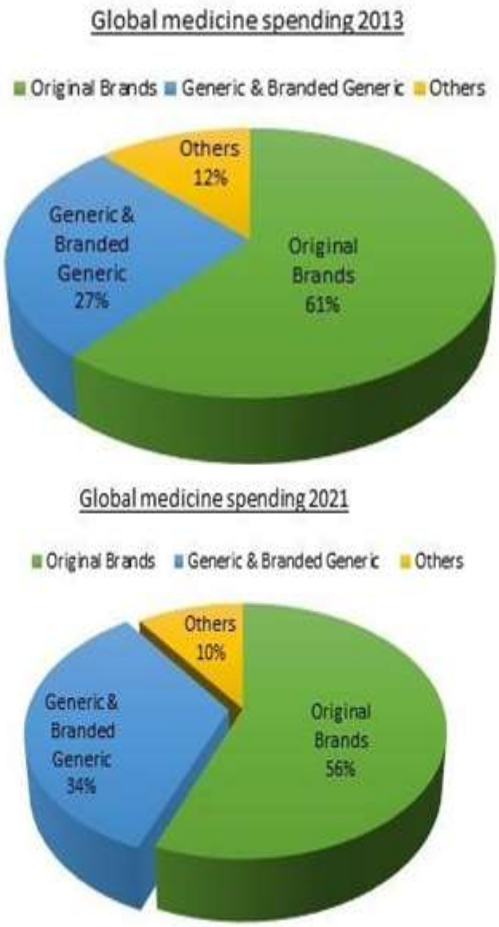

III. CONCLUSION

When compared to branded medications, generic pharmaceuticals are an appropriate alternative that is safe and effective. These medications are an affordable option for medication because they are bioequivalent, secure, and far less expensive than their branded counterparts. The use of generic medications is currently the focus of developing country governments, and great attention is placed on educating the general public about the appropriate use of generic medications. People's misconceptions about the safety, efficacy, and competency of generic medications are starting to fade, at least to some extent. Based on how they were created, generic medications were compared to proprietary drugs in a comparative analysis. The approval process for proprietary medications is lengthy because each new substance drug must pass numerous tests (pre-clinical as well as clinical testings). The analysis was also built on the costs. As can be seen from the cost estimate above, branded medications cost more. Generic medications are a more affordable option, especially for chronic conditions

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