**International Journal of Research in Pharmacy and Pharmaceutical Sciences**
**ISSN: 2455-698X; Impact Factor: RJIF 5.22**
**Received: 06-01-2019; Accepted: 09-02-2019**
**www.pharmacyjournal.in**
**Volume 4; Issue 2; March 2019; Page No. 01-06**

# Generic vs. brand medicines: An overview

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**Abstract**
The Indian pharmaceutical industry is the winner in the form of the most affordable formula in the world. These & quot; generic & quot; formulations maintain a balance of public interest as a serious disease such as cancer, AIDS, etc. In December 2011, the Indian pharmaceutical market grew by 15.7%. By law, generic drugs can-not be sold until the end of the patent name, which can take up to 10 years or more. Brand names have been defined in cases where current versions are not yet available. The generic pharmaceutical product that refers to the multi-source drug product is considered & quot; substantially identical& quot; or a bi-equivalent for the product of a (brand name) promoter. This document addresses various aspects of generic and branded drugs, their barriers and issues related to generic and brand medicine.

**Keywords:** generic, pharmaceutical, brand, medicine

## Introduction: Legislative history

1906 Food and Drug Act - Regulates the regulation of food and drugs. Food, Drugs and Cosmetics Act of 1938 - creating safety standards.
1962 FDA and C modified Kefauver-Harris repairs - introduction of preventive safety standards and drug efficacy. The Hatch-Waxman Act of 1984 - Compiled briefly with approval of the general copy of all major drugs approved after 1962 [1].

## What is generic medicine?

Generic drugs are used for identical (or biological) purposes on the original drugs, in doses, strengths, EFF accumulation and safely. To approve generic drugs, it is necessary to meet the same quality standards as branded products. Even normal production, packaging and test sites must meet the same criteria. Many generic products are manufactured with the same brand name [2].

## What are the basic requirements of generic medicines?

- The same active ingredient
- Administration same route
- The same dose form
- The same power
- Similar terms of use
- Inactive component already acceptable in a similar NDA [1]

## The US FDA classifies generics based on therapeutic products that meet the following general criteria

1. They are approved as safe and effective;
2. They are a pharmaceutical equivalent, so that they (A) include the same proportion of the same active ingredients of the drug in the same dosage form and in the same mode of administration and (b) the strength, quality, accuracy and recognition;
3. They are biological (a) they do not present known or potential bioinvolution problems and are acceptable in vitro standards or (b) if they present known or potential problems, they are shown to meet the standard appropriate bioinvolution;
4. They have enough labels;
5. They comply with the rules of good production practice in force.

## What are brand names and generic drugs?

*Brand Name* is a drug 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 copying and selling companies from other companies. Tylenol® is an example of pain reduction. The brand name is Tylenol® and the common name is acetaminophen.
*Generic drugs* are similar principles in which brand name drugs have already been approved by the Food and Drug Administration (FDA). Generics are only available after the patent mark has ended on the drug name. Patents can last 20 years on certain drugs. The same company that makes the branded drug can also produce a general version. Or, another company can be formed.

## How do different medicines differ from brands?

The main price of the FDF is the price of generic drugs and brand name drugs. Most producers spend 70% to 90% less than the brand, saving between $ 8 and $ 10 billion a year in pharmaceuticals. Billions are saved by the hospital using more generic. A common drug can also be DFF by brand in terms of size, color or packaging, but the difference lies in the appearance of the drug [2].

## What is the difference between a brand name drug and a generic drug?

### The Similarities

### According to the FDA for a generic change for a brand

- It must contain the same active ingredient (chemical substance used for drug work).
- The dosage should be the same (number of active ingredients, e.g. 20 mg or 40 mg).

- It must be the same dosage form (that is, the original must be available in the same form - for example, liquid, pill, etc.).
- It should have an administrative facility (in the same way that drugs should be introduced into the body).
- It is necessary to bring a large amount of blood into the blood (that is, it must be administered as a brand medicine at the same time in the blood).

**The difference**

**Here is what generic and branded drugs are different**

- They look different. (Federal law requires it.) - They can have different sizes, sizes, colors or symbols. They have different names.
- They may have different inactive content. - Medications consist of active and inactive components. Some people may be sensitive to passive factors. For example, there are reactions to certain colors used in some drugs.
- The brand costs less than drugs. - Cash prices and co-payment of insurance are generally low. Generators can spend 20 to 80% less, but remember that price is a factor to consider when investigating drugs that are right for you.
- Generators Generic Builders are different, which means that you can get a different version depending on where you buy your medicines and the type of generic
- Distributed. Various drugs are very generic. - Even the same pharmacy can change general provider [7].

**Are generic brands as effective?**

Yes The Food and Drug Administration (FDA) must have an active ingredient, a branded product, a diet, a dosage form and a method of administration. The FDA ensures that bioequivalent data is fully reviewed and reviewed [2].

**Why are generic drugs cheap?**

Original drugs are expensive because they do not compete to reduce their costs. But when there are patents on the expiry mark name, other producers can ask the FDA to sell the common version. Generic drug companies are not required to reimburse expensive clinical trials and generally do not spend advertising or marketing, they are able to sell very little of their productivity. On the contrary, companies producing brand name drugs have spent considerable amounts on research, development and advertising. They should spend a considerable amount of medicine to pay back their expenses and adjust their costs. In addition, when several companies manufacture a general version of the drug, it creates competition in the market and reduces prices. This saving is given to customers in a smaller format [2].

**Why are brand-name drugs more expensive than generics?**

It takes several years to approve drugs, expensive scientific development and many clinical courses are needed. New brand name drugs (also known as "pioneering drugs"), producers spend their time researching and developing new drugs. With the cost of this research and development, as well as marketing expenses, we are spending a large portion of the jewelry purchased for the highest prices.

On the contrary, generic drugs cost less in research and development because the original creators have already done many studies to ensure the safety of drugs. These savings are available to customers.

However, no generic product can be produced when the form of the brand name is still protected by its patent. And, if a brand has recently lost a patent, only a general form would be available. Generally, when only one common option is available, it will cost more.

**How can I get general medications? Will my doctor write to them?**

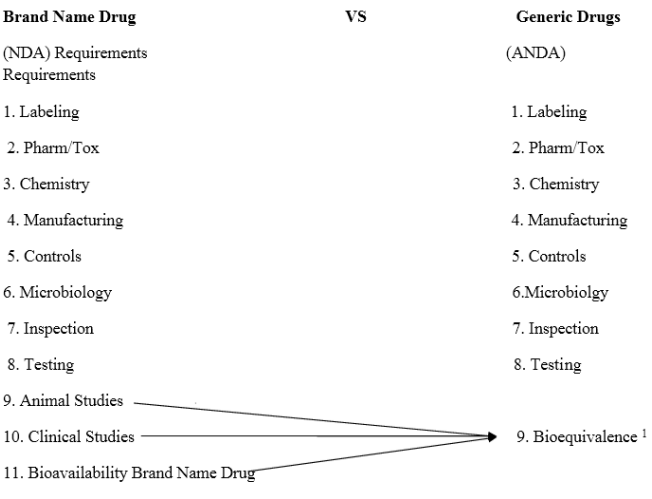
United States General Rule changes vary from one law to another. The pharmacy has made generic drug replacement laws mandatory by some state boards, in which pharmacists will generally be available for brand name drugs. Some states require the patient's consent prior to the generic change of the mark. Medications prescribed as the normal version may be distributed automatically, or only if you or your application for approval. Private and allows use of generic drugs generally cost less to government insurance companies. In addition, doctors are more appropriate for generic drugs decide their votes should be sure that brand drugs and iephaepha of drugs, but an order more FF [2].

**Generic drugs are marketed?**

- After patent and exhibition protection, or
- Patentees waive their rights, and
- FDA requirements have been met [1]

**Basic Requirements for General Drug Approval**

Bioinvolution Standard
90% confidence interval
Single dose study in healthy volunteers
EN 20-30 specific



**Generic drug review process**

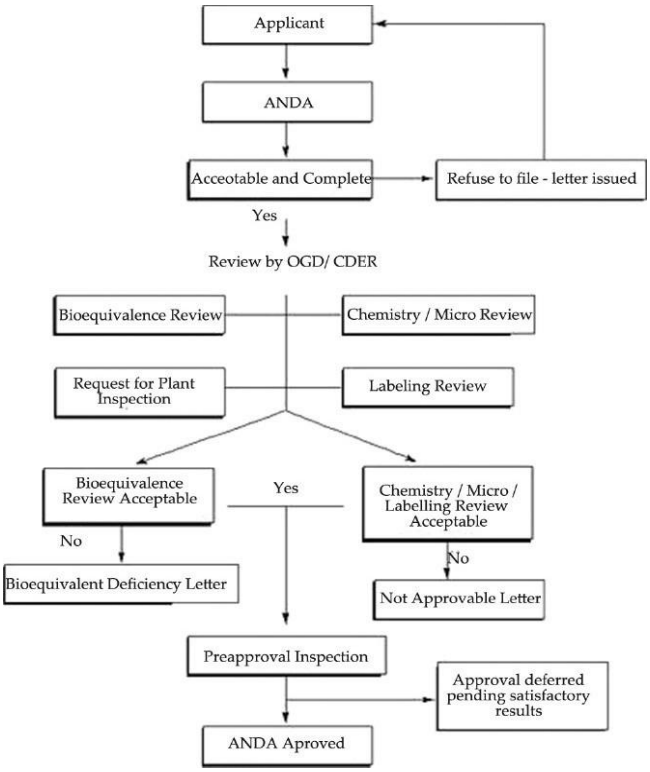



**Fig 1**

**What is Bioequivalence?**

Generic drugs for brand name drugs are considered bioequivalence:

- The quantity and the limit of absorption do not show any significant differences between the listed drugs.
- The degree of absorption shows no significant differences and no difference is intentional or non-medically important [1].

**Marketing issues**

**Applicant's problem**

- Submit the complete application - Avoid "refusing to receive"
- Attempts to accept electronic submissions are ongoing.
- Appropriate patent and specification certificate - Search for pairs
- All master drug files (DMF) are correctly referenced and guarantee that the agency has submitted
- Make sure all facilities are ready for inspection

**Serious Way Initiative**

- The development of medical production is becoming increasingly difficult, inefficient and expensive
- There is a need to update the tools used to assess safety and effectiveness
- The "toolbox" should be new powerful scientific and technological methods to improve forecasting and performance, from the experimental design to a serious commercial production circuit.

**Exam based on questions**

- Specific benefits based on customer benefit - Limit non-scientific controls that are not worth the product quality
- Product Specific Risk Assessment - Productive Supplements - Effectively Utilize FDA Resources
- Keep abreast of developments in the science of creation and formulation
- Quality by design
- Application analytical technique

**The quality of the design**

- Understand the product as developed and designed
- Understand the serious attributes
- Strengthen the process of production and processing of these properties
- Know what happens to these qualities when changing products
- Provide tools to use a risk-based approach

**Analytical process technology**

The design, analysis and control of the measurement process in a timely manner (i.e. during the process) is done by process in order to ensure the critical quality and performance characteristics of the raw content and unsecured and the quality of the final product.

**International Council for Harmonization (ICH)**

- Define the technical guidelines and requirements and compile the application
- Reduce or eliminate duplicate tests during research and development in participating countries

**Approach to facilitate the review process**

- Reduce the number of revision cycles
- For improved / improved communication - Communications Explication-Phone on mobile phone
- Dissolution of the applicant (Internet) and access to information on bioinvolution (thus freeing up the reviewer's time [1].

**Choosing the best medicines**

According to the Equity Master Report, the value of the Indian drug market is the largest and the thirteen largest. The Indian pharmaceutical market (IPM) accounts for approximately 1.4% of the global pharmaceutical industry and 20% by volume. [4]Generic drugs are currently gaining the highest median of the Indian pharmaceutical industry and contributing 70% of the market revenue. Over-the-counter drugs account for 21% of turnover and patented medicines 9% [5]. The Drug brand name is essentially discovered by the pharmaceutical company.

Normal drugs and brand name drugs may be similar in formulations, but their size, release mechanism, packaging, accents, expiry date / time, and other special features, such as labeling and labeling. Retail storage conditions, vary. After the expiry of the Patent Term Expenses Act 1984 and the restoration of the patent term, this patent was also recognized as a hat-wax law for the approval of general copies of many recognized drugs.

Due to lack of development, general medications are cheaper than branded ones. In India, 90% of branded generics participate in a 1 million rupee market. [6] India is the largest supplier of generic medicines, with more than 200 exporting countries. Faced with the growth of the general market generating 20% of world exports, India is struggling with good drugs [7].

The global generic drug market is expected to grow at a compound annual growth rate of 10.53% between 2016 and 2020. In fact, according to one report, the global generic drug

market represents $ 150 billion worth of patented medicines expired in 2020 [8]. This will attract generic drug companies around the world. Prescription by generic names is justified because if the brand name is used and this mark is not available in pharmacies, the pharmacist refers to drug indexes such as CIMS, etc. (CIMS-Current Index of Medical Specialties) to find the ingredient and then distribute it from the available stock. This would result in a waste of time and could also lead to errors in the wrong ingredient of the drug [9].

India is a country with a dense population. The cost of drugs in India is a big problem. In India, where very few people offer health insurance, 70% of Indians pay health expenses out of their own pockets. With the cost of increasing health care, the interest of generic drugs is a world of rich or poor, whether it is global growth. There is also a big difference between generic drugs and brand name drugs in India. India is known to have imported low-cost generic drugs in more than 200 countries.

The National Pharmaceutical Price Directorate (1997), which currently reports to the Chemicals and Fertilizers Department of the Department of Pharmaceutical Products (DOP), has been responsible for drug policy, drug price controls, drug price controls and related issues. The Central Institute for the Control of Drug Standards (CDSCO), under the Ministry of Health and Family, is the main authority responsible for monitoring drug-related problems in India. In order to provide quality generic medicines at lower prices than the market brand, the "Phase Campaign" was launched by the Indian Government's Pharmaceuticals Department in April 2008. In the 2016-17 budgets, the Indian government has created 3000 "public stores" all over the country.

On October 12, 2012, the Indian government issued instructions that drugs be sold under their common name in relation to their brand names. 8 This question has confused the choice of branded generics because almost 90% of medicines in India are known by their common names. Instead of refining Indian Prime Minister Narendra Modi instead of brand credits, doctors should make medical treatment mandatory.

The Indian Ministry of Health has now started to improve the law of medicines and cosmetics. The Ministry of Health has progressively published a draft notice on gadgets, so pharmaceutical companies must keep common drugs for at least two policies per brand. Apart from this, the ministry has ordered all public hospitals of the Indian Medical Council (MCI), state government and central government, that doctors write handwritten [10].

**In India, barriers to generic drugs**

a. In developed countries like the United States, only patented medicines are sold under brands that are related to their relationship with the doctor. Non-patented drugs are sold as pure generics, without any brand name. This helps make the pure credits cheaper. But most drugs in India are sold under brand names (generic brand).
b. Sales of brand-name drugs are high for all actors in the supply chain. As the price of generic drugs is very low, the performance achieved by all actors in the supply chain is low. In India, suppliers avoid generic government changes.
c. In addition to strict price controls, large pharmaceutical companies spend huge sums of money on marketing and promoting their medicines. Since the use of drugs in India is not allowed, companies or medical representatives push their products in exchange for gifts, junkets and promotions via doctors, pharmacists and distributors.
d. In India, the generic brand name is not considered equivalent to the drug. To achieve quality standards for brand name drugs, general producers must invest in equipment and approvals to increase the cost of general practice.
e. In addition, in developed countries such as the United States, community pharmacists play an important role in the supply of drugs and, as a result, their price awareness becomes important. But in India, the concept of a company pharmacist does not exist and the doctor must therefore take medication to reduce the price of the selection of drugs, and the doctor has a lower price for different brands. This can lead to the sale of generic financial drugs.
f. If the doctor decides only the common name, the chemist will be released to determine the specific shocks of the mark. In addition, if generic manufacturers do not have a government policy on providing appropriate penalties, they can provide disconcerting quality. In addition, doctors may have difficulty associating drugs or drugs containing many substances in the name of the prescribed drug [4].

**Availability of generic drugs in the Indian market**

The availability of generic drugs is very low in the Indian market. These are given only for government and other hospitals or for medical dispensaries. For more profits, doctors generally encourage branded drugs; branded generics are sold at the maximum retail price. But they buy generic branded drugs from distributors offering a discount of 13 to 15% of the recommended retail price. In the current situation, consumer patients do not benefit and retail pharmacists make huge profits [11].

**Comparative practice**

World prices are available at cheap prices around the world. These 'generic' formulations Cancer, AIDS, etc. Balanced public customs such as serious illnesses. The FDA does not allow a difference in efficacy of 45% of the generic product. The average difference between the general name and the brand name was 3.5%.Some of the generics have been absorbed in small amounts. Expect these differences and accept them, even if they are tested on another lot of the same brand for a lot named Brand. In fact, there were studies in which branded drugs were compared to themselves as well as to a generic. In general, the difference between the generic comparison and brand name drug (brand name drug and brand name drug) is about the same as that of brand-to-brand comparison.

This can be seen in some cases, where some people may experience side effects by switching from original medications to normal formulations or from generic drugs to other drugs. The FDA is actively engaged in all regulated products - generic drugs - safe. If certain formulas are problematic, the FDA wants to know if it has been linked to specific products. The FDA encourages the general industry in such a situation, and under what circumstances, to check that.

The industry does not have the resources to conduct independent diagnostic studies and sufficient regulatory authority to conduct such a study. The FDA maintains

unwanted program reports for generic drugs. Reviewing adverse events for all drugs, including generic drugs, is part of the FDA's overall effort to assess the safety of the drug after approval. In most cases, reports of adverse events reflect a known reaction to the drug's active ingredients. If it is correct, reports are reviewed and verified. Inspection leads to changes in the way the product (brand and common equivalent) is used or produced [11].

**Prescription checklist for eliminated clients**

Use the following checklist for the following options to help you make the most of your decision. If you and your doctor want a brand name drug.

- Your doctor should be advised of a doctor for a brand name medicine.
- Tell the pharmacist that you do not specify what your doctor has prescribed with a doctor.
- Make sure the medicines you receive are brand-name drugs.
- Cover costs
  - Ask your doctor if you are trying new drug samples.
  - Ask your doctor for any coupon or coupon program.

**If you and your doctor want the generic drug:**

- Know the name of the brand and its common name.
- Learn to identify general items from a label on your medicine bottle.
- Learn about common appearances (colors, shapes, shapes, signs), especially if they are different or if you use a daily or weekly Pil bach box. Check with your medications that you are getting the right medicine.
- Ask your doctor what differences you might find common [12].

**Brand V/S Generic: price based on the value of Pharmaceuticals in India**

Generic costs are much lower than those of the brand, and innovation is likely to give the brand competitive price competition. The engineer will be able to reduce or leave a normal version of the innovative new innovator. In general, the general bioavailability and bio-identification (BA / BE) are generally considered well-known brand equivalents. It is thought that the common version will be similar to brand name drugs. The Indian Pharmacological Region is the largest manufacturer and supplier of generic versions in North America, the European Union, the United Kingdom, Japan and Australia. Britain is a highly regulated market with North America, the European Union, Japan and Australia. They are of good quality and are committed to ensuring that citizens of this country get standard medicines; As a result, regulators are active and generally check product quality. Regulators have also decided not only products, but also production facilities and human resources. Send their audit team to ensure that the regulatory agencies have manufactured the product according to the standards set by the regulatory agency [13].

**Problems with brand name drugs**

Indian brand medicines are registered in each state with the state-run drug control department. After mandatory verification of the data, licenses are issued for the production bearing their mark. There are so many authorized executives who can license branded medicines in India. This confers a benefit to the brand manufacturer for the registration of the product in a product and for the sale of the product anywhere in the country.

Most products do not have the capacity to produce for the whole of India and their marketing activity limits them to three or four states. These brands are composed of about 600 pharmacopoeia components. In most developed countries, only new manufacturers are allowed to register the trademark and others must provide recognized services after the end of the patent period. The number of brands has negative effects on health care and poses problems.

"A similar sound and sound" Many drug problems are at the origin of brands and there is a risk of medical recourse for the safety of doctors and patients. Apart from this, each company has insulted the obsolete products, set the offer to push the product to the market, the main problem of the list of waste and the concept of capital loss. Retail pharmacists and doctors have faced competition. Encourage the doctor to get extra income and buy specific brands of medicine available with him In the case of minor drugs; there is a considerable amount of medication**.** [14] They are licensed for about one million trademarks registered and marketed outside of India. This has created a mess in the pharmaceutical market. Pharmaceutical manufacturers are classified in small, medium and large companies. Smaller industries limit their marketing activities to the regions, for example, the manufacturer may market the district's product department. When medium-sized manufacturers sell products in a region like the State of South India or North India. The big product is marketed with the right marketing network. Large-scale products must compete with their small businesses and medium-sized products. In addition to price competition, cold chain logistics and the prices of large drugs also pose logistical challenges [15].

**Problems with general drugs**

Generic drugs are less popular and have less profile in the pharmaceutical market. They seem to be low in open markets, such as chemists and druggists, although they are relatively cheap, they are very cheap and of low quality. When the Indian government launched the "Jan Audhuti Yojana" in 2008, the government is committed to developing alternative medicines as brand-name medicines. Generic drugs are manufactured by the public sector like Hindustan Antibiotics Limited and Karnataka Antibiotics Private Limited. The government's main goal is to improve accessibility by highlighting high drug costs and reducing them. Price and Affordable Under the authority of the Ministry of Chemicals and Fertilizers, the Government of India passed the Janaushodi Law in 2008. Recently, the Prime Minister's Office was named "Janaushodi Kendra" after obtaining the protection of that country. In general, with capital letters, doctors who promise the public awareness center and warn a doctor, while promoting the "Centers", are a shocking event like the monstrosity. The government was shocked to promote generic drugs. It is considered a danger and a risk for the Indian commercial market because it is mandatory to write the drugs under generic names [16].

**Conclusion**

In the current situation, generic drugs are looking for the best option for India, but in the gradual changes, it is necessary to apply this fact to the Indian mentality. Patient care should focus on accessibility, health care, and quality infrastructure. Incentives and tax cuts are needed for research to promote

human health. By using cost-effective and sustainable technologies and methods, entrepreneurs need to reduce the cost of drugs. From this article, we collected information on general and branded medicines, their comparative study, general and brand-name drug problems, medications, and so on.

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