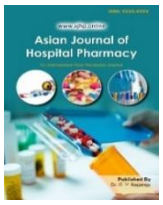
Review Article

Asian Jour Hosp Phar, Vol: 5, Issue: 3, 2025, 7-12

Asian Journal of Hospital Pharmacy

Content Available at www.ajhponline.com ISSN: 2583-0724



GENERIC VS BRANDED MEDICINES: AN OVER-VIEW

Mandapati Swapna*, D.Raji Tejaswini, P. Mohan Vikas, Chandu Babu Rao

Priyadharshini Institute of Pharmaceutical Education and Research, 5th Mile, Pulladigunta, Guntur-522017, Andhra Pradesh, India.

Received: 05 June 2025 Revised: 26 June 2025 Accepted: 02 Aug 2025

Abstract

The Indian pharmaceutical industry is the winner in the form of the most affordable formula in the world. The concept of generic prescription is widely accepted in various parts of the world. Nevertheless, it has failed to gain popularity in INDIA due to factors such as no availability and distrust on the product quality. However, since 2012, the Government of West Bengal, India, has initiated exclusive generic drug outlets called "fair price medicine shop" (FPMS).The concept of generic prescription is widely accepted in various parts of the world Generic drugs offer the same ingredients and same dosage forms therapeutic effect but lower cost and there available after the brand name drug patent expires .Dissolution is the amount of substance that goes into solution per unit time under standardized conditions of liquid/solid interface, solvent composition and temperature. Dissolution is one of the most important tools to predict the in-vivo bio-availability and in some cases to determine bioequivalence and assure interchange ability. Same drug can be sold for different prices under different brand names due to various reasons. Branded medicine is the original product that has been developed by a pharmaceutical company and generic medicine is a copy of the original branded product, marketed after the expiry date of the patent and hence supposed to be of low cost as compared to their branded versions

Keywords: In-vitro dissolution, Absorption, Difference between the branded vs generic medicines, Dissolution Method, IVIVC.

***Corresponding Author**

Mandapati Swapna

DOI: https://doi.org/10.38022/ajhp.v4i3.90

Introduction

The Indian pharmaceutical industry is known globally for its generic medicines and low-cost vaccines. The Indian pharmacy sector holds the 3rd position in the manufacturing of pharmaceutical items and medicines, and this sector has emerged as a vibrant one over the years [1]. The Indian pharmacy sector has grown steadily with a Compound Annual Growth Rate (CAGR) of 9.43% [2]. The pharmacy sector has consistently earned a trade surplus. During more than 120 countries for Hydroxychloroquine (HCQ), 20 countries for paracetamol, and around 96 nations for vaccines globally during the COVID-19 pandemic [3].

Generic and Branded Drugs

Generic medicines are those for which the original patent has expired, allowing other manufacturers to produce them. Different markets may defin e "generi c medicineor "generic drug" differently. But according to the World Health Organization (WHO), it is generally understood to refer to a pharmaceutical product that can be used in place of an innovator product is produced without a license from the innovator company; and is marketed after the patent or other exclusive rights have expired.Are generic drugs equivalent to branded drugs[4].

National list of essential medicines

The National list of essential medicines 2022, which includes 384 medications, was announced by Union Health Minister of India. A medicine is included to the NLEM; a number of factors are taken into account. The regulations state that the medication must be vital and necessary to treat a sickness. Effort helps them retain and grow their customer base by-using the inventory- based model in combination with mobile applications or phone delivery services [5].

Drugs and Cosmetics Rules, 1945

- It has been made mandatory for all online e-pharmacy market players to obtain licenses from the central government licensing authority.E-pharmacy players are required to maintain records of patient details, including written or electronic prescriptions. A mechanism will be provided for complaint redressal regarding the sale of inferior or spurious quality

medicines. Consumers can file complaints about-poor-quality medicines with sector regulators, who are required to take necessary action against the e-pharmacies [6].

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].

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 FF2

Generic drugs are marketed

- After patent and exhibition protection, or
- Patentees waive their rights, and
- FDA requirements have been
- Bio involution Standard
- 90% confidence interval
- Single dose study in healthy volunteers
- EN 20-30 specific

What is Bio equivalence

Generic drugs for brand name drugs are considered bio-equivalents

- ❖ 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 [8].
- Bio involution Standard
- 90% confidence interval
- Single dose study in healthy volunteers
- EN 20-30 specific

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

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 branded comparision.

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 [9].

Branded and common equivalent

The FDA (Foods & Drugs Administration) requires that all drugs be safe and effective. Since generics use the same active ingredients and are shown to work the same way in the body, they have the same risks and benefits as their brand-name counterparts. FDA requires drug companies to demonstrate that the generic medicine can be effectively substituted and provide the same clinical benefit as the brand-name medicine that it copies. The active ingredient in the generic medicine is the same as in the brand- name dru Example of Generic & Branded Drugs:

An example of a generic drug, one used for diabetes, is metformin. A brand name for metformin is Glucophage. (Brand names are usually capitalized while generic names are not.) A generic drug, one used for hypertension, is metoprolol, whereas a brand name for the same drug is Lopressor.

Pradhan Mantri Bhartiya Janaushadhi innovator

Are Generic Drugs are Safe & same as Branded drugs

Yes. The FDA (Foods & Drugs Administration) requires that all drugs be safe and effective

Since generics use the same active ingredients and are shown to work the same way in the

body, they have the same risks and benefits as their brand-name counterparts.FDA requires drug companies to demonstrate that the generic medicine can be effectively substituted and provide the same clinical benefit as the brand-name medicine that it copies. The active ingredient in the generic medicine is the same as in the brand- name drug/innovator drug [10].

Example of Generic & Branded Drugs

An example of a generic drug, one used for diabetes, is metformin. A brand name for metformin is Glucophage. (Brand names are usually capitalized while generic names are not.) A generic drug, one used for hypertension, is metoprolol, whereas a brand name for the same drug is Lopressor.

Pradhan Mantri Bhartiya Janaushadhi Pariyojana: (PMBJP)

A large portion of the Indian population cannot afford-medicines. Branded medicines are more expensive compared to generic medicines, although they are equally effective and safe. To provide quality generic medicines to-the poor and underprivileged, the Prada Mantri Bharat Janaushadhi Pariyojana was launched in 2008. In 2015, the Honorable Prime Minister recommended that Jan Upanishads Kendra s be opened across the country.

As of December 31, 2022, 8,675 Jan Upanishads Kendras are operational. Citizens saved ₹2,500 crores during the 2019-20 financial year through this initiative. These-generic medicines are 50% to 90% cheaper than branded medicines (Pharmaceutical and Medical Devices Bureau of India. In order to maintain a quality control procedure in research and development, dissolution testing has been employed over the past 50 years to detect the Dissolution is defined as the amount of substance that goes into solution per unit time under standardized conditions of liquid/solid interface, solvent composition and temperature Although dissolution cannot be used as a predictor of therapeutic efficiency; it can be used as a qualitative and a quantitative tool, which can provide important information about biological availability of a drug as well as batch-to-batch consistency [11]. In the cases when the in-vitro results fail to predict the in-vivo performance of a drug product, larger clinical studies are needed to assess the product bioavailability, thus additional cost will be added to the drug development expenses Therefore, dissolution is considered one of the most important quality control tests performed on pharmaceutical dosage forms and validation of dissolution methods and is an important part of good manufacturing practice. With modern technology and advancement in research of drug delivery and more emphasis on in

Dissolution is defined as the amount of substance that goes into solution per unit time under standardised conditions of liquid/solid interface, solvent composition and temperature Although dissolution cannot be used as a predictor of therapeutic efficiency; it can be used as a qualitative and a quantitative tool, which can provide important information about biological availability of a drug as well as batch-to-batch consistency. In the cases when the in-vitro results fail to predict the in-vivo performance of a drug product, larger clinical studies are needed to assess the product bioavailability, thus additional cost will be added to the drug development expenses Therefore, dissolution is considered one of the most important quality control tests performed on pharmaceutical dosage forms and validation of dissolution methods and is an important part of good manufacturing practice [12]. With modern technology and advancement in research of drug delivery and more emphasis on invivo predictavibility of therapeutic effect by means of in-vitro test, dissolution tests have been gaining more and more popularity whenever a new solid dosage form is developed or produced, it is necessary to ensure that drug dissolution occurs in an appropriate manner. The ultimate aim of performing dissolution tests is to predict the extent release and absorption of the administered drug in-vivo, i.e. in-vitro–in-vivo correlation.

Generic drugs: According to FDA “a drug product that is comparable to branded product is dosage form strength route of administration, quality and performance, characteristics, and intended use. It is a copy of branded drug whose patent has expired which has no rexclusive rights to produce and distribute medicines.

Branded drugs: It is the original product that has been developed by pharmacy a period of time (patent). A brand name drug is a small medicine that's discovered developed marketed, by pharmaceutical company. One's a new drug is discovered, the company files for a patent to protect against other companies making copies and selling the drugs. At this point the drug has two names - a generic name and a brand name to make it stand out in the market [13]

Generic Drugs Vs Branded Drugs: View of Public

It must contain same active ingredients & It must have same dosage form.

- They have same quality and performance & It must have same route of administration
- A generic drugs are safe as branded drug & It has same bioavailability
- These all are public view of branded vs generic drugs.

Basic Requirements for General Drug Approval

- 90% confidence interval
- Single dose study in healthy volunteers

EN 20-30 specific Generic drug review process

During the COVID-19 pandemic, the pharmaceutical sector has faced challenges and played an important role in combating the infection caused by COVID-19. Through collaboration with major firms and industries, the sector has enabled itself to develop and refine production processes that ensure the supply of medicine during times of crisis such as Favipiravir, Remdesivir, Ivermectin, Hydroxychloroquine, Dexamethasone, and Tocilizumab. Relief has been given to more than 120 countries for Hydroxychloroquine (HCQ), 20 countries for paracetamol, and around 96 nations for vaccines globally during the COVID-19 pandemic.

Generic and Branded Drugs Generic medicines are those for which the original patent has expired, allowing other manufacturers to produce them. Different markets may define "generic medicine" or "generic drug" differently [14].

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.

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 [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 [16].

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.

Cost: Unlike generic drugs, branded drugs incur high cost due to high investment research & development.

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 [17].

Result

We approached 116 generic medicine users of whom 100 agreed to participate, given correspond rate of 7.41%. The correspond rate among branded medicine users was 9.91% to achieve 100 who agreed to participate. The

demographics, morbidity, and drug use profile of the two study groups are presented and compared Evidently, age and gender distributions and primary disease duration were comparable. However, branded medicine users were better educated, had a higher per capita monthly family income and used more drugs and doses per day. They also bore higher medication cost for their prescriptions. The medication adherence score, as measured through DAI-10, indicated moderate to good adherence in both groups with the mean score showing no statistically significant difference. Branded drug users had a mean DAI-10 score of 6.3 (SD 2.61) while the value for generic drug users was 6.3 (SD 2.80). Sociodemographic, disease- and drug-related variables compared between generic and branded drug users.

Apart from common chronic diseases such as hypertension, type 2 diabetes, and chronic airway diseases, there were also patients with dyslipidemia, ischemic heart disease, hyperuricemia, epilepsy, osteoporosis, and chronic dyspepsia who have been clubbed into the others category. All were receiving medication for prolonged periods [18].

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.

Author contributions

All authors are contributed equally

Financial support

None

Declaration of competing interest

The authors have no conflicts of interest to declare.

Acknowledgement

None

References

1. Roberts R, Maldonado S. FDA center for drug evaluation and research (CDER) pediatric plan and new regulations. Drug information journal. 1996 Oct;30(4):1125-7. https://doi.org/10.1177/009286159603000430
2. Hwisa NT, Gindi S, Rao CB, Katakam P, Rao Chandu B. Evaluation of Antiulcer Activity of Picrasma Quassioides Bennett Aqueous Extract in Rodents. Vedic Res. Int. Phytomedicine. 2013;1:27. https://doi.org/10.1002/bmb.20934
3. Mutlu A. Comparison of two different techniques of cooperative learning approach: Undergraduates' conceptual understanding in the context of hormone biochemistry. Biochemistry and Molecular Biology Education. 2018 Mar;46(2):114-20. http://e-currentscience.com/journal/e/CTPPC
4. Gindi S, Methra T, Chandu BR, Boyina R, Dasari V. Antiurolithiatic and invitro anti-oxidant activity of leaves of Ageratum conyzoides in rat. World J. Pharm. Pharm. Sci. 2013 Feb 8;2:636-49. https://doi.org/10.24092/CRPS.2019.090402
5. Cameron A, Mantel-Teeuwisse AK, Leufkens HG, Laing RO. Switching from originator brand medicines to generic equivalents in selected developing countries: how much could be saved?. Value in health. 2012 Jul 1;15(5):664-73. https://doi.org/10.1016/j.jval.2012.04.004
6. Nikam NR, Vakhariya RR, Magdum CS. Generic Vs. Brand Medicines: An Overview. Asian Journal of Pharmaceutical Research. 2019;9(2):109-15. https://doi.org/10.24092/CRPS.2019.090402
7. Bera A, Mukherjee A. The importance of generic drugs in India. Int J Pharm Chem Biol Sci (IJPCBS). 2012;2(4):575-87. https://doi.org/10.30574/wjbphs.2021.7.2.0086
8. Arora K, Singh S, Singh PK. A review on Generic and Branded Drugs-Competence of generic drugs in comparison to branded drugs. Current Research in Pharmaceutical Sciences. 2019:63-6. https://doi.org/10.24092/CRPS.2019.090402
9. Midha KK, McKay G. Bioequivalence; its history, practice, and future. The AAPS journal. 2009 Dec;11:664-70. https://doi.org/10.1177/009286159903300215
10. Mathew P. Generic drugs: Review and experiences from South India. Journal of family medicine and primary care. 2015 Jul 1;4(3):319-23. https://doi.org/10.1177/0972063417747747
11. Nagappa AN, Kavya HB, Chikkamath V, Naik VB. S generic-value based pricing for pharmaceutical in India. Juniper Online J Case Stud. 2017;4:2-4. https://doi.org/10.1185/030079907X233395
12. Singal GL, Nanda A, Kotwani A. A comparative evaluation of price and quality of some branded versus branded-generic medicines of the same manufacturer in India. Indian journal of pharmacology. 2011 Mar 1;43(2):131-6. https://pubmed.ncbi.nlm.nih.gov/21572645/
13. Kipgen J. Sex-Selective Abortion in India: Social Structures, Women's Agency, and Media Discourse. University of Kansas; 2020. https://doi.org/10.1007/978-3-031-44176-9_1
14. Mutlu A. Comparison of two different techniques of cooperative learning approach: Undergraduates' conceptual understanding in the context of hormone

biochemistry. Biochemistry and Molecular Biology Education. 2018 Mar;46(2):11420 **https://iubmb.onlinelibrary.wiley.com/doi/full/10.1002/bmb.21097**

15. Agarwal DS, Chairman DT. Central drugs standard control organization. New Delhi. 2017. https://doi.org/10.37022/jpmhs.v3i2.21
16. Jenei K. The Political Economy of the World Health Organization Model Lists of Essential Medicines. The Milbank Quarterly. 2025 Mar. **https://doi.org/10.1111/1468-0009.70001**
17. Sharma AK, Shrivastava TP, Singh MA, Ahuja J, Goyal RK. Regulations in India. InGlobal Regulations of Medicinal, Pharmaceutical, and Food Products 2024 (pp. 133-152). CRC Press. **https://doi.org/10.62823/EXRE/2024/01/01.5**
18. Alfaqih MA, Khader YS, Bashir N, Nusair Z, Nuseir Q, Nusier M. Attitude of Jordanian Sphysicians toward biochemistry and genetics. BioMed Research International. 2019;2019(1):3176951. **https://doi.org/10.62823/EXRE/2024/01**
19. Nama S, Chandu BR, Awen BZ, Khagga M. Development and validation of a new RP-HPLC method for the determination of aprepitant in solid dosage forms. Tropical Journal of Pharmaceutical Research. 2011;10(4):491-7. **https://doi.org/10.62823/EXRE/2024/01/01.5**
20. Kiranmai M, Renuka P, Brahmaiah B, Chandu BR. Vitamin D as a promising anticancer agent. **http://e-currentscience.com/journal/e/CTPPC**