E-ISSN: 2320-1215
P-ISSN: 2322-0112

Research and Reviews: Journal of Pharmacy and Pharmaceutical Sciences

The Facts about Generic and Branded Drugs

Bhanu Prasad. CH
Lalitha School of Pharmacy, Hyderabad, India

Review Article

Received:04-06-2016
Revised: 22-06-2016
Accepted:28-06-2016

***Corresponding author:**

CH. Bhanu Prasad, Lalitha School of Pharmacy (Anurag group of Institutions), Autonomous University, Telangana, Hyderabad, India, 500082; Tel: 7702627935.

Email: bhanu_22226@rediffmail.com

Keywords: Generic Drugs, Branded Drugs, Pharmaceuticals, Medications, Abbreviated New Drug Application (ANDA), FDA.

ABSTRACT

A drug is identical or bioequivalent to a name drug in dose type, safety, strength, route of administration, quality, and performance characteristics and meant use. Though generic medication is with chemicals a dead ringer for their branded counterparts, they're generally sold-out at substantial discounts from the branded worth. In step with the general assembly Budget workplace, generic medication save customers Associate in nursing calculable $8 to $10 billion a year at retail pharmacies. Even a lot of billions are saved once hospitals use generics.

INTRODUCTION

Generic medicine contains equivalent active ingredients, within the exact same strength, as brand-name medicine. Once a drug is initial developed, the drug company that discovers and markets it receives a patent on its new drug. The patent sometimes lasts for twenty years, to allow the originating company an opportunity to recoup its analysis investment. Once the patent expires, a generic version of the drug might become on the market. Generics ar marketed underneath the drug's chemical, or generic, name and meet an equivalent FDA quality and effectiveness standards because the original [1-5].

Is Generic Medication as Effective as Brand-Name Drugs?

A drug is that the same as a drug in dose, safety, strength, quality, the approach it works, and the approach it's taken and therefore the approach it ought to be used. FDA needs generic medication has constant top quality, strength, purity and stability as brand-name medication. Not each drug contains a drug [6-10].

Once new medication area unit 1st created they need drug patents. Most drug patents area unit protected for twenty years. The patent, that protects the corporate that created the drug 1st, does not permit anyone else to form and sell the drug. Once the patent expires, alternative drug firms will begin commerce a generic version of the drug. But, first, they need to take a look at the drug and therefore the agency must approve it. Creating a drug prices numerous cash. Since drug manufacturers don't develop a drug from scratch, the prices to bring the drug to plug area unit less; so, generic medication area unit sometimes more cost-effective than brand-name medication. But, drug manufacturers should show that their product performs within the same approach because the drug [8].

How Generic Medication Approved?

Drug corporations should submit abbreviated new drug application (ANDA) [5], for approval to promote a generic product. Drug corporations gained bigger access to the marketplace for pharmaceuticals, and originator corporations gained restoration of patent lifetime of their product lost throughout FDA's approval method [11-16].

New drugs, like alternative new product, square measure developed beneath patent protection. The patent protects the investment within the drug's development by giving the corporate the only right to sell the drug whereas the patent is in result. Once patents or alternative periods of exclusivity expire, makers will apply to the authority to sell generic versions. The ANDA [5], method doesn't need the drug sponsor to repeat expensive animal and clinical analysis on ingredients or indefinite quantity forms already approved for safety and effectiveness [6].

Standards for a Generic Drug

Health professionals and customers may be assured that agency approved generic medicine have met an equivalent rigid standards because the pioneer drug. It should contain an equivalent active ingredients because the pioneer drug(inactive ingredients could vary) be identical in strength, dose kind, and route of administration, have equivalent use indications, be bioequivalent, meet an equivalent batch necessities for identity, strength, purity, and quality, be factory-made underneath an equivalent strict standards of FDA's smart producing observe laws needed for pioneer product [16-20].

When a drug product is approved, it's met rigorous standards established by the agency with relation to identity, strength, quality, purity, and efficiency. However, some variability will and will occur throughout producing, for each brand and generic medicine. Once a drug, generic or brand, is factory-made, terribly tiny variations in purity, size, strength, and different parameters area unit allowable. Agency limits what proportion variability is suitable. Generic medicine area unit needed to possess an equivalent active ingredient, strength, dose kind, and route of administration because the brand product [21-25].

Generic medicine ought not to contain an equivalent inactive ingredients because the brand product. The drug manufacturer should prove its drug is that the same as (bioequivalent) the brand drug. For instance, once the patient takes the drug, the number of drug within the blood is measured. If the amount of the drug within the blood area unit an equivalent because the levels found once the brand product is employed, the drug can work an equivalent.

Through review of bioequivalence [9] knowledge, agency ensures that the generic product performs an equivalent as its various brand product. This customary applies to all or any generic medicine, whether or not immediate or controlled unharness. All generic producing, packaging, and testing sites should pass an equivalent quality standards as those of name medicine, and also the generic product should meet an equivalent exacting specifications as any brand product. In fact, several generic medicine area units created within the same producing plants as brand drug product [9].

Generics Drugs Works Same as Brand Drugs

A study evaluated the results of 42 published clinical trials that compared diabetic generic drugs to their brand name counterparts. There was no evidence that brand name heart drugs worked any better than generic drugs [10]. The Food and Drug Administration (FDA) requires generic drugs to have the same quality, strength, purity and stability as their brand-name versions. Generic drugs are thoroughly tested to make sure their performance and ingredients meet the FDA’s standards for equivalency [26-30]. Generic drugs work in your body in the same way and in the same amount of time as brand-name drugs.

Both brand-name and drug facilities should meet identical standards; the bureau won’t allow medicine to be created in substandard facilities. The bureau conducts regarding three, 500 inspections a year to make sure standards are met. In fact, brand-name companies are connected to associate degree calculable five hundredth of drug production. They often build generic copies of their own or alternative brand-name medicine, and then sell them with a generic name.

The science of bioequivalence evaluations for generics has been in place in most countries for more than 20 years with an established track record of therapeutic equivalence. These evaluation methods have been so successful in establishing generic drug standards that they are largely consistent between all of the major drug regulators worldwide. Consumers and health professionals alike can be reassured that generic drugs approved under these regulatory frameworks are indeed bioequivalent, and therefore, interchangeable with brand name products [12].

E-ISSN: 2320-1215
P-ISSN: 2322-0112

Why Generic Drugs are Cheaper?

Cheaper doesn't mean lower quality it was a misconception. Actually a generic drug is cheap compared to originals because the generic manufacture not needed to repeat the expensive clinical trials, expensive advertising, marketing, and promotion. Generic drug companies don't have the expense of researching and developing a new chemical entity. There is usually competition among generic drug manufacturers [30-35]. Most of the generic drug manufactures switch to the same product this creates competition within the market place, typically leading to lower costs **(Table 1).**

When a corporation develops a brand new drug and submits it for Food and Drug Administration approval, a 20-year patent is issued, preventing different corporations from mercantilism the drug throughout the lifetime of the patent. As a drug patent nears expiration, any drug manufacturer will apply to the Food and Drug Administration to sell its generic version. As a result of these makers didn't have an equivalent development prices (such as years of high-priced research), they will sell the drug at a reduction. Once generics square measure allowed, the competition keeps the worth down. On average, the price of a drug is 80 to 90% not up to the brand product. In 2011 alone, the employment of FDA-approved generics saved $158 billion, a median of $3 billion weekly [36-40].

Table 1: Price list of generic & branded drugs

Used as	Generic name	price	Branded drug	price
Painkiller	Paracetamol	Rs 2.45	Crocin	Rs 11
			Calpol	Rs 10.70
	Paracetamol syrup	Rs 9.00	Crocin (syrup)	Rs 15
			Febrex	Rs 20.50
	Diclofenac sodium + Paracetamol	Rs 4.4	Diclogesic	Rs 19.40
Antibiotic	Amoxicillin	Rs 13.2	LMX	Rs 40
			Remox	Rs 38.7
	Azithromycin	Rs 41.8	Azee	Rs 107
			Azithral	Rs 128.55
Anti-TB	Ethambutol	Rs 14.8	Myambutol	Rs 15.3
Vitamins	Folic acid	Rs 2.8	Folivite	Rs 11.8
	B-complex	Rs 1.8	Becosul	Rs 11.0
Cardiovascular (Blood Pressure) drug	Atenolol	Rs 7.0	Aten	Rs 23.8

FDA Monitoring

FDA will take care of the adverse reactions of the drug and regularly monitor the generic products. FDA is stepping in to take control of generic drugs and applying stringent rules for the manufacture regarding the quality of the product. FDA is encouraging the generic industry to investigate whether, and under what circumstances, such problems occur [15].

The monitoring of adverse events for all drug products, including generic drugs, is one aspect of the overall FDA effort to evaluate the safety of drugs after approval. Many times, reports of adverse events describe a known reaction to the active drug ingredient. Reports are monitored and investigated, when appropriate. The investigations may lead to changes in how a product (brand name and generic counterparts) is used or manufactured [16].

Safety of Generic Drugs

There is misconception about the safety of the generic drug that it won't work as the branded product. Generic and brand name drugs have identical active ingredients, and generic drugs must meet standards for bioequivalence.so people can take the generic drug without any fear [41-45].

FDA doesn't permit a 45% distinction within the effectiveness of the drug product. When it involves worth, there's a giant distinction between generic and brand medicine. U.S. trademark laws do not permit generic medication to appear precisely the same as another drug already on the market. For that reason, the colour and form of a generic pill could also be completely different than the brand-name. Typically it'll have a distinct coating or flavor. Variations in style or look don't have an effect on the drug's safety or effectiveness [18].

CONCLUSION

You can use generics with confidence. Although they may look different from their brand-name versions, generics are safe and effective. As always, any medication changes must be discussed with your physician and pharmacist [19].The savings related to policies that encourage the employment of cheap generic prescribed drugs create them a plain selection within the struggle to contain health care prices. However, policymakers and researchers ought to address the queries close the therapeutic equivalence of generic medication; develop ways of encouraging generic utilization among all consumers; and make a statutory pathway for the approval of generic biological drugs. Additionally, given the inherent complexness of the health care system, it's probably variety of generic utilization policies ought to be combined in an exceedingly a lot of comprehensive approach before drug utilization are often maximized [46-50].

It is the government's task to supply health professionals with correct info concerning generic medicines. Completely different initiatives, like visits from government representatives, audit and feedback on prescribing knowledge or pharmacotherapeutic discussion teams (with physicians solely or physicians and pharmacists) have, therefore, been enforced in some European countries. These activities ought to inform physicians concerning the benefits of generic medicines and purpose them at the cost–consequences of their prescribing behavior. Health care professionals' information and perception of generic medicines were absolutely influenced by these activities.

This demonstrates the necessity of continuous medical education for each physicians and pharmacists [51]. People ought to remember of each the brand-name and generic versions of a medicine. So as to assist them perceive that the drugs share a similar active ingredients. As a result of generic medicine usually take issue in look or packaging from their brand-name equivalents, suppliers ought to additionally clear up any confusion patients could have by reminding them that these visual details don't have any impact on a drug's safety or effectiveness [18,21].

REFERENCES

1. Salim M, et al. The Current Perspective of Community Pharmacists towards Pharmacovigilance. J Pharmacovigil. 2015;3:180.
2. Manoj Kumar Sethi. Pharmacovigilance: Challenges in India. J Pharmacovigil. 2016;4:194.
3. Gildeeva GN and Yurkov VI. Pharmacovigilance in Russia: Challenges, Prospects and Current State of Affairs. J Pharmacovigil. 2016;4:206.
4. Reis CD, et al. Pharmacovigilance in Cabo Verde: Measuring the Awareness and Knowledge of Consumers. J Pharmacovigil. 2016;4:200.
5. Sanaa A, et al. Awareness and Perception of National Pharmacovigilance Center among Lebanese Medical Staff. J Pharmacovigilance. 2016;4:199.
6. Karampola MI and Emmanouilides CE Pharmacovigilance for Biosimilars. J Pharmacovigil. 2016;4:196.
7. Mishra H and Kumar V. Pharmacovigilance: Current Scenario in a Tertiary Care Teaching Medical College in North India. J Pharmacovigilance. 2013;1:108.
8. Wertheimer AI. The Curious Path of Pharmacovigilance. J Pharmacovigilance. 2013;1:e109.
9. Preda A.Pharmacovigilance and Beyond. J Pharmacovigilance. 2013;1:e114.
10. Agrawal P. Drug Discovery and Development: An Insight into Pharmacovigilance. J Pharmacovigilance. 2014;2:e120.

11. De Wolf J, et al. Evolution of Drug Utilization in Nursing Homes in Belgium. Clin Pharmacol Biopharm. 2014;3:124.
12. González EM, et al. In Vitro Antioxidant Capacity of Crude Extracts and Acetogenin Fraction of Soursop Fruit Pulp. Pharm Anal Acta. 2016;7:484.
13. Permender R, et al. Novel Statistically Designed Qbd Methodology for Quantitative Analysis of Nisoldipine in Pharmaceutical Dosage Forms. Pharm Anal Acta. 2016;7:489.
14. Abass SAE, et al. Development and Validation of Spectrophotometric and Pre-column Derivatization HPLC Method for Determination of Famotidine in Pharmaceuticals by Reaction with Sodium Nitroprusside; Application to Combined Tablets. Pharm Anal Acta. 2016;7:476.
15. Ranjna C, et al. Pharmaceutical Analysis and the Growing Disciplines. Pharm Anal Acta. 2016;7:478.
16. Sohel D, et al. Bioavailability Study of Sustain Release Preparations of Three Widely used NSAIDS Available in Bangladesh. Pharm Anal Acta. 2016;7:482.
17. Lee S, et al. Lifetime Assessment of POCT Strips through Accelerated Degradation Test. Pharm Anal Acta. 2016;7:475.
18. Kogawa AC, et al. Quantification of Doxycycline in Raw Material by an Eco-Friendly Method of Infrared Spectroscopy. Pharm Anal Acta. 2016;7:463.
19. Shimodaira S, et al. Quality Verification of Dendritic Cell-Based Cancer Vaccine. Pharm Anal Acta. 2016;7:465.
20. Hassali MA, et al. Role of Pharmacists in Health Based Non-Governmental Organizations NGO: Prospects and Future Directions. Pharm Anal Acta. 2016;7:467.
21. Vergeire-Dalmacion G. Usefulness of Cost Effectiveness: Evidence versus Applicability. Pharm Anal Acta 2016;7:456.
22. Wang C. Application of In Vitro Models in Developmental Neurotoxicity and Pharmaceutics Research. J Mol Pharm Org Process Res. 2015;3:e122.
23. Lyubchenko YL. Nanoimaging for Molecular Pharmaceutics of Alzheimer's and other Neurodegenerative Disorders. J Mol Pharm Org Process Res. 2013;1:e107.
24. Skalko-Basnet N. Note on the "Molecular Pharmaceutics and Organic Process". J Mol Pharm Org Process Res. 2013;1:e104.
25. Foldvari M. Nanopharmaceutics Innovations in Gene Therapy: Moving Towards Non-Viral and Non-Invasive Delivery Methods. J Nanomedine Biotherapeutic Discov. 2014;4:e135.
26. Qumbar M, et al. DOEBased Stability Indicating RP-HPLC Method for Determination of Lacidipine in Niosomal Gel in Rat: Pharmacokinetic Determination. Pharm Anal Acta. 2014;5:314.
27. Abbas-Aksil T, et al. Matrix Tablets from Algerian Lyophilized Berries LB Arbutus unedo L. Date Phoenix dactylifera L.0020Nat Prod Chem Res. 2016;4:207.
28. Oshizumi Y et al. Dynamics of Swallowing Tablets during the Recovery Period following Surgery for Tongue Cancer. Otolaryngology. 2016;6:218.
29. Sanaa A, et al. Awareness and Perception of National Pharmacovigilance Center among Lebanese Medical Staff. J Pharmacovigilance. 2016;4:199.
30. Tolentino MJ. Macular Supplements Containing Zinc and Vitamin A Should Be Replaced with Meso-Zeaxanthin, Lutein and Zeaxanthin: An Ophthalmic Need for Pharmacovigilance. J Pharmacovigil. 2016;4:195.
31. Toklu HZ, et al. The Knowledge and Attitude of the Healthcare Professionals towards Pharmacovigilance and Adverse Drug Reaction Reporting in Northern Cyprus. J Pharmacovigilance. 2016;4:193.
32. Obara T, et al. Knowledge of and Perspectives on Pharmacovigilance among Pharmacists in the Miyagi and Hokkaido Regions of Japan. J Pharmacovigilance. 2016;4:192.
33. Magyar I. An Overview on the Third Annual Pharmacovigilance Forum. Clin Pharmacol Biopharm. 2015;5:e122.
34. Kaur I, et al. Effective Reporting by Pharmacist in Pharmacovigilance Programme of India. Adv Pharmacoepidemiol Drug Saf. 2015;4:197.
35. Hama R. The Mechanisms of Adverse Reactions to Oseltamivir: Part II. Delayed Type Reactions. Clin Microbiol. 2015;4:224.

36. Kowalski CJ and Mrdjenovich AJ. Pharmacovigilance Observed: Why Watchful Waiting will Work. J Clin Diagn Res. 2015;3:114.
37. Calapai G, et al. Systematic Review of Tranexamic Acid Adverse Reactions . J Pharmacovigilance. 2015;3:171.
38. Marisol HSO, et al. Implementation of a Robust Pharmacovigilance Method for Filgrastim Non-Innovator Products in Cancer Patients in Routine Clinical Practice Complying With Mexican Regulations for Biocomparables. J Pharmacovigilance. 2015;3:174.
39. Reis CD, et al. Illegal Market of Medicines in Cabo Verde: Characterization for Action. J Pharmacovigil. 2015;3:178.
40. Napoleone E and Scasserra C. Pharmacovigilance in Pediatric Age: The Role of Family Pediatricians-Medicines for Children Research Network (FP-MCRN). J Pharmacovigilance 2015;3:168.
41. Abjaude SAR, et al. Strategies to Stimulate Actions for Pharmacovigilance Decentralization 2015;3:165.
42. Kalaivani M, et al. Direct Consumer Reporting of ADRs to PvPI, a Position Paper of Indian Pharmacopoeia Commission. Adv Pharmacoepidemiol Drug Saf. 2015;4:184.
43. Kalaiselvan V, et al. Indian Pharmacopoeia Commission's Partners for Promoting Public Health. Adv Pharmacoepidemiol Drug Saf. 2015;4:181.
44. Swain S and Patra CN. Impact of Pharmacovigilance in Healthcare System: Regulatory Perspective. Pharmaceut Reg Affairs. 2014;3:e143.
45. Shankar PR, et al. Teaching pharmacovigilance to medical students and doctors. Indian J Pharmacol.2006;38:316-319.
46. Swart J, et al. OP0217 Adjudication of Infections in The Pharmacovigilance in Juvenile Idiopathic Arthritis Patients (Pharmachild) Treated with Biologic Agents and/or Methotrexate. Ann Rheum Dis. 2016;75:139.
47. Jourde-Chiche N, et al. Antimalarial ototoxicity: an underdiagnosed complication? A study of spontaneous reports to the French Pharmacovigilance Network. Ann Rheum Dis 2012;71:79
48. Simon LS. Pharmacovigilance: towards a better understanding of the benefit to risk ratio. Ann Rheum Dis 2002;61:88-89.
49. Pirmohamed M, et al. Pharmacovigilance in developing countries: requires collaboration between stakeholders to develop novel models of funding. BMJ. 2007;335: 7618.
50. Lareb. Inhaled and intransal fluticasone propionate and haematoma. Internet Document. 2008;5:100-104.
51. Hasford J, et al. Pharmacovigilance and Patient Safety — Results of the German Net of Regional Pharmacovigilance Centers. Drug Safety. 2008;10:885–885.