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DECISION TO CHOOSE: BRANDED OR GENERIC DRUGS

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ABSTRACT

Generic medicines are those where patent protection has expired, and which may be produced by manufacturers other than the innovator company. Some patients have misperception that generic drugs are inferior to brand name drugs. Use of generic medicines has been increasing in recent years, primarily as a cost saving measure in healthcare provision. Generic medicines are typically 20 to 80% cheaper than originator equivalents. Our objective is to provide a high-level description of what generic medicines are and how they differ, at a regulatory and legislative level from originator medicines, their similarities and drug development. Often the question is raised about the safety and efficacy of generic drugs / formulations comparing their branded products. All over the world this aspect is being debated and more so in recent times since the cost of treatment is sky-rocketing. The points of debate have always been the "bioequivalence" i.e. whether it is similar in form, strength, safety, dosage, route of administration, bioavailability and effectivity to that of its branded siblings. We also need to educate our patients about generic drugs so that they can make an informed decision about their treatment.

KEYWORDS: Generic name, Brand name, Drug Development, Bioequivalence, Price difference, Education etc.

INTRODUCTION

Generic Medicines[1]

Generic medicines are those where the original patent has expired and which may now be produced by manufacturers other than the original innovator (patent-holding) company. The term "generic drug" or "generic medicine" can have varying definitions in different markets, however the term is commonly understood, as defined by the World Health Organisation (WHO), to mean a pharmaceutical product which:

- Is usually intended to be interchangeable with an innovator product.
- Is manufactured without a licence from the innovator company.
- Is marketed after the expiry date of the patent or other exclusive rights.

Bioequivalence[4]

The FDA's formal definition of bioequivalence is: the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.[4] Therefore, bioequivalent drugs are pharmaceutical equivalents whose rate and extent of absorption are not statistically different when administrated to patients or subjects at the same molar dose under similar experimental conditions.[2]

Difference between brand name and generic drugs.

The Similarities	The Differences
It must contain the same active ingredients. It must have the same dosage strength It must be the same dosage form	They look different. They could have different sizes, shapes, colors or markings. They have different names.
It must have the same route of administration It must deliver similar amounts of the drug to the bloodstream	They might have different inactive ingredients. Drugs are made up of both active and inactive ingredients. The generic costs less than the brand name drug. Generics can cost between 20 and 80 percent less.

Drug Development:[1,6]

Development of new drugs is a complex and costly process. It generally takes 10–15 years. Research and Development involves discovery and development of New Chemical Entities also known as New Molecular Entities.

Pre-Clinical Research

The earliest stage of development of a new drug begins with the synthesis and purification of the new chemical moiety, or the screening of existing compounds for potential use as drugs. The aim of pre-clinical research is to determine whether the drug is reasonably safe for potential use in humans, and sufficiently effective against a disease target in chemical tests or animal models. During pre-clinical studies, the pharmacology of the new drug in addition to its pharmacokinetics & half-life, pharmacodynamics estimates of therapeutic effects, are assessed. Initial studies relating to toxicology including carcinogenicity, teratogenicity are also carried out, as are efficacy studies on animals.

Clinical Trials

Once permission has been received from the appropriate regulator to administer a new drug to humans, clinical studies may commence. Clinical studies required to bring a new drug to market generally take place over three phases as follows:

- Phase 1: Safety studies on healthy volunteers. Typically involve 20–80 healthy volunteers The emphasis is on drug safety and on the building of a safety profile for the drug in humans.
- Phase 2: Clinical studies on a limited scale to determine efficacy of the drug. Typically involve 100– 300 individuals who have the target illness. Patients receiving the drug are compared to similar patients receiving a placebo or another drug, and safety evaluations continue.
- Phase 3: Comparative studies on a large number of patients. Typically involve 1000–3000 patients. The emphasis is on safety and effectiveness and studies investigate different populations and different dosages as well as evaluating the new drug in combination with other drugs. Data gathered in a phase 3 trial are used to determine the risk versus benefit profile of the drug. Following successful completion of clinical trials, the entirety of the information about the drug is compiled into an application and submitted to the relevant competent authority. The competent authority reviews this application, and additional information may be sought from, or discussions held with, the applicant before the regulator makes its decision. The regulator will, after assessing the scientific data pertaining to the new drug, either allow it to be marketed or deny approval to the applicant.

Post-Marketing Surveillance

Post-market surveillance studies of the drug continually assess the safety of the drug in the marketplace. This may include reporting and investigation of the incidence and severity of rare adverse reactions, cost-effectiveness analyses, comparative trials, and quality of life studies.

Why do brand name drugs cost more than generics?[1,5]

It takes several years, costly scientific development and many clinical studies to get a drug approved. Manufacturers of new brand name drugs (also called "pioneer drugs") usually take on the research and development costs for new medications. These research and development costs, along with marketing costs, account for most of the higher prices we pay for most brand name drugs. In contrast, generic drugs have less research and development costs since the original manufacturer has already done many studies to make sure the drug is safe. These savings are passed on to the consumer. However, while the brand name form is still protected by its patent, no generics can be produced. And, if a brand name drug has only just recently lost its patent, there may only be one generic form available. Usually, when there's only one generic option available, it will be more expensive.

Different states have different laws and regulations on generic substitutions.

US FDA classifies generics as therapeutically equivalent those products that meet the following general criteria:[3]

(1) They are approved as safe and effective,
(2) They are pharmaceutical equivalents in that they (a) contain identical amounts of the same active drug ingredient in the same dosage form and route of administration (b) meet compendia or other applicable standards of strength, quality, purity, and identity
(3) They are bioequivalent in that (a) they do not present a known or potential bioequivalence problem, meet an acceptable in vitro standard (b) if they do present such a known or potential problem , shown to meet an appropriate bioequivalence standard
(4) They are adequately labeled
(5) They are manufactured in compliance with Current Good Manufacturing Practice regulations.

The two, generic and branded drugs may be identical in formulations but differ in certain other characteristics such as shape, release mechanisms, packaging, excipients (including colors, flavors,preservatives), expiration date/time and minor aspects of labeling and storage conditions The FDA also allows for a 20% - 25% variance in bioavailablity. Then there are (1) pure generics sold by its original name (2) the branded generics (Lipitor for Atorvastatin), the generic manufacturer giving a separate name to its product (3) the authorized generics when the branded drugs disguised as generics.

OBJECTIVE

The objective of present study was to evaluate different parameters like weight variation, Hardness, Friability, Disintegration and Dissolution test of various marketed formulation of Glimepride tablet and generic tablet of same.

MATERIAL AND METHODS

Brands of Tablet	**Evaluation Test**
A	Weight Variation
B	Hardness
C	Thickness
Generic Tablet	Friability
D	Disintegration
	Dissolution

Table 1: List of Equipment / Instruments used.

Sr. No	**Equipment / Instruments**	**Make**
1	Hardness Tester	Monsanto
2	Vernier Caliper	Mitutoyo
3	Friability Test Apparatus	Rochae
4	Disintegration Test Apparatus	Maumps
5	Uv visible Spectrophotometer	Shimadzu
6	Electronic Balance	Elder
7	Dissolution Test Apparatus	Electrolab

Parameters for Dissolution

USP Apparatus : Type 2	Speed : 75 RPM	Medium : Phosphate Buffer P^H 7.8
Volume : 900 ml	Time : 5,10,15,20,25,30 min	
Drug Release Profile	Conc. = Absorbance – Intercept / Slope	
	Drug Release = conc.×Volume of medium ×Dil.Factor / 1000	
	Percent Drug Release = Drug Release / Label Claimed ×100	

RESULT AND DISCUSSION

Table 2: Observation of Weight Variation Test.

Sr. No	**Formulation**	**Average Weight of 10 tab (mg)**	**+ 7.5 % deviation (mg)**	**-7.5 % deviation (mg)**
1.	A	1810	1945.75	1674.2
2.	B	1400	1505	1295
3.	C	1840	1978	1702
4.	D	1800	1935	1665

Table 3: Observation of Friability Test.

Sr. No	**Formulation**	**Standards for % Friability**	**% Friability**
1.	A	Not more than 1%	0.71 %
2.	B		0.57 %
3.	C		0.83%
4.	D		0.86 %

Table 4: Observation of Hardness, Thickness and Disintegration Test.

Sr. No	**Formulation**	**Hardness (kg/cm^2)**	**Thickness(inch)**	**Average Disintegration Time (sec)**
1.	A	3.16 ±0.5	0.317	85
2.	B	3.85±0.5	0.276	85
3.	C	1.83±0.5	0.320	84
4.	D	3.66±0.5	0.324	75

Table 5: Observation of Dissolution Test.

Time (min)	Percent Drug Release (%)			
	Formulation			
	A	B	C	D
0	0	0	0	0
5	18.64	21.34	18.24	32.28
10	40.21	45.36	40.68	59.56
15	56.47	60.21	62.28	78.45
20	68.54	78.25	74.56	81.26
25	82.36	86.32	84.21	86.20
30	90.23	94.02	92.02	92.14

CONCLUSION

Comparative study of various marketed formulation was carried out by different parameters, from this result it was concluded that generic tablet shows results near to branded tablets. Hence we can use generic tablet.

Both the branded and branded-generic versions of the five "paired" medicines had identical quality and they fulfilled all the criteria prescribed by the statutory standards. Hence, the general notion and doubt regarding the quality of the branded-generic version of medicines needs to be erased conducting more such studies and publishing them widely. Suitable changes in the drug price policy may be made to have lower prices for branded-generic versions. Transparency in fixing the MRP by the manufacturer and clear guidelines for mark-ups at least for branded-generics is required in pharmaceutical trade.

The government must take up generic promotional schemes, general awareness programs on quality of generics to build confidence among prescribers, pharmacists, and consumers. Availability of generics or branded-generics in the market with lower price tag and assured quality is essential to make the medicines affordable. With many medicines hitting the so called "patent cliff", generic drug usage, already trending upwards, is likely to continue to increase in the coming years, with generic medicines now being, primarily for economic reasons, a reality of modern healthcare systems.

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