EUROPEAN JOURNAL OF BIOMEDICAL AND PHARMACEUTICAL SCIENCES
http://www.ejbps.com

ISSN 2349-8870
Volume: 10
Issue: 7
154-158
Year: 2023

A COMPARATIVE PHARMACEUTICAL STUDY OF GENERIC AND BRANDED TABLET'S QUALITY CONTROL TESTS ACCORDING TO PHARMACOPOEIAS

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Article Received on 24/04/2023 **Article Revised on 14/05/2023** **Article Accepted on 04/06/2023**

ABSTRACT
Generic medications are pharmaceuticals that are therapeutically equivalent to an original off patent drug. Both authorized generics and branded generics are the versions of generic medications. Generic supply medications having quality of branded drugs at lower prices and this establishes their recognition among the masses who earlier has limited options to buy only brand-name drugs. In India people have many myths about generics due to lack of knowledge and awareness. Even Doctors generally not prescribed the generics drug because of they are more doubtful about quality and safety. Pharmacist not dispenses generics because of less commission on sale of generics and less demand by peoples. So this study is taken to remove this myth from their mind set. The Present study deals with a brief overview of the comparative study of quality requirements for finished products (generic and branded) quality control Tests for tablets according to Pharmacopoeias (IP/BP). For this purpose a set of 5 different tablets from generic and branded source are taken. Quality control tests were conducted on those tablets. The pharmacopoeias have laid down the specified limits within which the value should fall in order to be compliant as per the standards. However the parameters and standards differ to some extent from each other. Hence an attempt is being made to compare the quality of the each branded and generic medicines.

KEYWORDS: Generic Medicines, Branded Medicines, Quality control, Pharmacopoeias.

INTRODUCTION
The goal of all Pharmaceutical industry is to make a good quality product. Most of the Standard products of pharmaceutical companies are the patented drugs, when a pharmaceutical company innovates or discovers new drug they file a patent for the same and only they have the rights to manufacture the drug for around 20 years. After 20 Years when the patent is expired other companies can also manufacture that particular product, which is termed as branded generics. This means generics are the copy of branded drugs manufactured by different companies. In India there are lots of myths about quality of generic products because of different types of packaging and labelling of products.

Many people consider generics as lower quality products because of lack of knowledge and not very well known manufacturers. So in this article we did comparative study of generic and branded products to understand whether generics maintain good quality and have same efficacy as that of standard drugs.

In 2008, the government of India started "jan Aushadhi" the program contemplates making unbranded quality medicine available to the patient at affordable price through retail store.

In November, 2016, to give further impetus to the scheme, it was again renamed as "Pradhan Mantri Bhartiya Janaushadhi Pariyojana" (PMBJP).

Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) is a campaign launched by the Department of Pharmaceuticals to provide quality medicines at affordable prices to the masses. PMBJP stores have been set up to provide generic drugs, which are available at lesser prices but are equivalent in quality and efficacy as expensive branded drugs.

The Hon'ble Minister of Finance while presenting the Budget for the year 2016-17 in Parliament, made a special mention on PMJAY. The excerpt of the Budget Speech of Hon'ble Finance Minister is reproduced below:

"Making quality medicines available at affordable prices has been a key challenge. We will reinvigorate the supply of generic drugs. 3,000 Stores under Prime Minister's Jan Aushadhi Yojana will be opened during 2017."[1]

The MCI (Medical Council of India) in October 2016 has recommended that every physician prescribed drug with generic drug name.

Generic drugs: According to FDA "a drug product that is comparable to branded product in 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 longer exclusive rights to produce and distribute medicines.[2]

Generic drugs are the pharmaceuticals that are similar in active ingredients, dosage form, route of administration, strength, safety, quality to an already approved brand name drug. They can contain different inactive ingredients and look different than their branded counterparts. They can cost up to 95% less than the brand name drugs and can be afforded by almost all the sections of the society.[3]

Branded drugs: It is the original product that has been developed by pharmaceutical company. It has sole right to manufacture and distribution for a period of time (patent). A brand name drug is a small medicine that's discovered, developed and 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 place.[2]

Brand name medicine is originally discovered and developed by a pharmaceutical company. Brand name medicine is approved by FDA by submitting a New Drug Application along with data regarding proof of characteristics of dosage form, manufacturing, chemistry, stability, efficacy, safety, labelling and packaging. After approval by FDA only, the innovatory company can exclusively market this brand name medicine for a period of patent protection (about 20years or as specified). Brand name medicine is generally sold at high cost to cover expense in research and development of drug.

Quality

Quality is a broad term which includes suitability of drugs and products for their utilization which is decided by their efficiency and safety, according to label claim, or as promoted or publicized, their conformity to specifications about identity, purity and other characteristics. Quality gives importance to test the product for defects and reporting the same to the management. Management makes the decision to investigate or deny the release. According to the International Standard of Organization (ISO) quality control is the operational techniques and activities that are used to fulfil requirements for quality. Because of In-process quality control for the entire products producer fulfils all the requirements. Amongst them main requirement is that the product must be safe. In-process control tests should be carried out before the manufacturing process is completed. The function of in-process quality controls is to monitor and if necessary, adaptation of the manufacturing process in order to comply with the specification. This may involve control of equipment and environment too.[4]

In the pharmaceutical industry, total quality of the product must be ensured in order to prevent the kind of product which does not comply with the specifications laid down by the Pharmacopoeias, and at the same time it is also necessary for controlling the errors during the production process. Quality can be defined as the suitability of the goods or service to the determined qualifications. Quality control emphasizes testing of products for defects and reporting to management who makes the decision to investigate or deny the release. Both the in process and finished product quality control tests help to ensure the total quality of the product. The entire dealing process (In process and finished product quality control tests) involves stringent quality control tests to make products totally flawless before they are released into the market.

View of Professionals

Doctors

Doctors generally not prescribed the generic because they are not completely satisfied about safe and effectiveness as compared to branded medicines. They have no any commission from manufacturer for prescribing generics like commission on branded. Doctors are also differ in their belief towards and experience with different medications, medical history, preference may also influence doctor's decision. When the doctor prescribed generic medicines they do not give patient health result as compared to branded medicines.

Pharmacist

They get minimum profits on sale of generics drugs as compared to branded medicines. There is also an availability issue of generic drug in Indian market. Less demand of generics by consumers due to less quality and result. Patient strictly follow the prescription which mostly contain branded medicines. The pharmacist can dispense any brand of the drugs when the prescriber writes the generic name on a prescription.[2]

MATERIALS AND METHODS

QUALITY CONTROL TESTS FOR TABLETS

Tablets are solid dosage forms usually prepared with the aid of suitable pharmaceutical excipients. They may vary in size, shape, weight, hardness, thickness, disintegration and dissolution characteristics and in other aspects

depending on their intended use and method of manufacture.

Most tablets are used in the oral administration of drugs. Many of these are prepared with colorants and coatings of various types. Other tablets, such as those administered sublingually, buccally or vaginally are prepared to have features most applicable to their particular route of administration.

The Tablet quality control (TQC) tests are
• Weight variation test
• Hardness test
• Friability test
• Disintegration test.

Weight Variation Test
These test is carried out to ensure that the tablet contain the perfect amount of the drug. The 10 tablet are weigh individually using analytical balance then the average weight was calculated after that individual tablet weight was compare with average weight and percentage weight variation is calculated by using following formula.
Weight Variation = (Iw - Aw)/Aw X 100%

Where,
Iw = Individual weight of tablet
Aw = Average weight of tablet.

Limits for weight variation test as per IP.[5]

Average mass (mg)		Percent Deviation (%)
IP/BP	USP	
80 mg or less	130mg or less	±10 %
More than 80mg or less than 250mg	130mg to 324 mg	±7.5%
250 mg or More	More than 324 mg or More	± 5%

Digital Weighing Balance.

Hardness Test
For this test tablet hardness tester is use to check the hardness of the tablet. Monsanto, Pfizer Schleuniger these are the examples of hardness testers. Monsanto hardness tester consists of a barrel containing a compressible spring held between two plungers. The lower plunger is placed in contact with the tablet and zero reading is taken. The upper plunger is then forced against a spring by turning a threaded bolt until the tablet fractures. As the spring is compressed, a pointer rides along a gauge in the barrel to indicate the force. The force of fracture is recorded in kilogram. Ten tablets are crushed and measure their hardness and the allowable range is between 4 - 6 kg (40 - 60 N) unless otherwise specified.

Hardness Tester[Pfizer]

Friability Test
Friability of a tablet can determine in laboratory by Roche friabilator. For this test twenty tablets are weighed and placed in the friabilator and then operated at 25 rpm for 4 minutes. The tablets are then dedusted and weighed. The difference in the two weights is used to calculate friability and the value of friability is expressed in percentage. It is calculated by the following formula:
Friability = (Iw – Fw)/ Iw x 100%

Where,
Iw = Total Initial weight of tablets
Fw = Total final weight of tablets.

As stated by USP, if conventional compressed tablets that loss less than 0.5 % to 1 % (after 100 revolutions) of their weight are generally considered acceptable.

Rotation: 25 rpm or 100 Rotation in 4 min.[6]

Friability Tester.

Disintegration Test
The USP disintegration apparatus consist of 6 glass tubes that are 3 inches long, open at the top, and held against a 10-mesh screen at the bottom end of the basket rack assembly.

To test for disintegration time, one tablet is placed in each tube and the basket rack is positioned in specified medium at 37 ± 2 °C such that tablet remains 2.5 cm below the surface of the liquid on their upward movement and descend not closer than 2.5 cm from the bottom of the beaker.

A standard motor driven device is used to move the basket assembly containing the tablets up and down through distance of 5 to 6 cm at a frequency of 28 to 32 cycles per minute. Perforated plastic discs may also be used in the test. These are placed on the top of tablets and impart an abrasive action to the tablets. The discs are useful for tablets that float. Operate the apparatus for the specified time (15 minutes for uncoated tablet unless otherwise justified and authorized).[6]

The tablet complies with the test according to USP, if all of the tablets have disintegrated completely. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12additional tablets. The requirement is met if not less than 16 of the total of 18 tablets tested are disintegrated.[6]

Type of capsule		**Disintegration time**
Uncoated Tablets		15 minutes
Coated Tablets	film-coated	30 minutes
	other coated tablets	60 minutes
Enteric-coated Tablets	*0.1M hydrochloric acid*	Should not disintegrate in 120 minutes
	mixed phosphate buffer pH 6.8,	60 minutes.
Dispersible and Soluble Tablets		within 3 minutes
Effervescent Tablets		5 minutes

Disintegrating Apparatus

RESULT

Name of the Tablets	**Type of Medicine**	**Weight variation Test**	**Hardness Test (Kg/cm^2)**	**Friability Test (%) Less than 1%**	**Disintegration Test (min)**
Paracetamol	Branded	0.59±0.02	3.0±0.29	0.16	8.0±0.57
	Generic	0.57±0.02	4.5±0.29	0.35	5.9±0.03
Aspirin	Branded	0.19±0.01	4.6±0.2	0.51	3.7±0.02
	Generic	0.20±0.01	4.0±0.3	0.69	4.5±0.04
Albendazole	Branded	0.62±0.03	5.65±0.05	0.31	2.1±0.01
	Generic	0.69±0.03	5.60±0.02	0.22	1.8±0.02
Ibuprofen	Branded	0.28±0.02	6.73±0.8	0.18	3.20±0.03
	Generic	0.32±0.02	8.61±1.2	0.15	4.05±0.02
Metformin	Branded	0.59±0.03	7.2±0.1	0.18	8.7±0.01
	Generic	0.57±0.02	4.5±0.3	0.46	8.6±0.01

Both Branded and Generic Medicines lies within the pharmacopoeial limits and Thereby we conclude that Generic medicines are pharmaceutically equivalent to Branded medicines[above report justifies this statement].

Our study results showed that all the selected generic formulation have low cost than the branded formulation. Hence in terms of cost-effective generic drugs may be preferred over branded.

DISCUSSION

Globally, the generic drug formulations are accepted as equivalent to the branded formulation. The Indian government also started campaigning for the same but the general population has some misconception. We attempt to evaluate physical or pharmaceutical differences between branded and generic drugs. We evaluated all the generic and branded tablets for physical parameters like Weight Variation, Hardness, Friability and Disintegration. There was a little variation in the category for the parametric test which is not significant and may not affect the efficacy of the drug. Although generic drugs are cheaper than the branded, they are equivalent in terms of physical pharmaceutical aspects.

In countries like US only patented drug are sold under a brand name which is marketed through their ties to doctor. Off patent drugs are sold as only as a pure generic, without use in any brand name. It helps to making pure generic cheaper. But in India most of the generic drugs are sold as their brand name drugs (brand generics). Commission on sales of brand name drug is much higher for everyone in the supply chain. In India quality of generic drugs is not considered at par as brand name drugs. For obtaining quality standards of brand drugs, generic producers will have to invest in equipments and necessary approval process which may increase the cost of generics drugs. But in India, the concept of community pharmacists doesn't exist and hence the onus for cost reduction, from the point of view of drug selection, lies with doctors and doctors have poor

knowledge of cost of different brands. This can reduced sells of economic generic drugs.

CONCLUSION

All the samples including generic and branded products were evaluated as per tests and standards mentioned in IP/BP. The results indicated that most of the generic products are having comparable quality with the branded products.

The patient with chronic disease is in trouble due to long-time heavy prescription cost containing branded drugs. The present study indicates that the generic the drug is cheaper in cost and equivalent with branded drug hence reduce the cost of prescription even OTC and increases patient survival.

Hence, considering the above pharmaceutical similarity and per capita income of the people generic drugs are a good choice instead of a branded one.

It may be concluded that use of generic products should be encouraged to make affordable medicines available to all. At the same time substantial regulatory and quality checks must be implemented to ensure good generic products in market.

Workshops and seminars with doctors to disseminate and sensitize them on promotion on protection of low priced generic drugs.

FUTURE ASPECTS

Nowadays, the community pharmacy is filled with improper workers/ staffs i.e. Other than pharmacist. Those pupil can easily understand brand names and dispense it easily, this can be avoided if the physician prescribes the drug in generic name because generic names are tougher than brand names and only proper educated pharmacist can dispense it. This leads to increase in job opportunities for pharmacy graduates and increase in dispensing of generic drugs.

We have to increase the concept of community pharmacist in India which plays important role in dispensing of medicines, for increase the sales of generic drug in India by increasing the commission on sale of generic drugs can increase the use of generics in India. By increasing the quality control department for testing and controlling the quality of generics in India can increase the doctors and pharmacist opinion towards the generic medicines.

ACKNOWNLEDGEMENT

The authors would like to thank the teaching faculties of SS INSTITUTE OF PHARMACY for their guidance and support to finish this comparative study. And the authors would also like to thank the lab assistants for their constant support.

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