International Journal of Pharmaceutical Research and Applications
Volume 7, Issue 5 Sep-Oct 2022, pp: 106-108 www.ijprajournal.com ISSN: 2456-4494

A Comparative Pharmaceutical Evaluation of Standard vs. Generic Tablets of Amlodipine (5mg).

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Submitted: 05-09-2022 Accepted: 13-09-2022

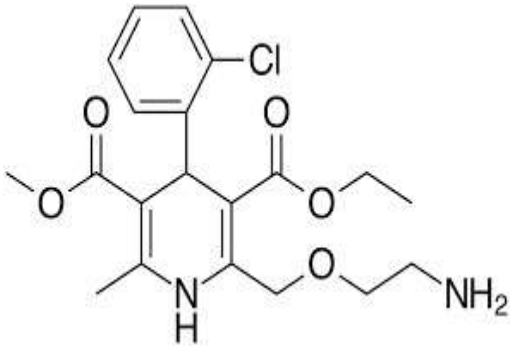
ABSTRACT:
The main goal of the study to identify physico-chemical properties of standard and generic tablets of Amlodipine (5 mg) .The physical and chemical parameters including Hardness, Assay, Dissolution, Thickness, Disintegration etc. The study concluded that standard and generic tablet of Amlodipine besylate showed satisfactory results.
When a pharmaceutical company first markets a new drug ,its usually under the patent .Even after completion of the patent period ,the prices of some standard medicines are still high. Generic medicines contain the same active ingredients with same quantity whose patent is expired ,therefore cost of generic drug are low.
As the difference in prices between branded and generic medicines is high,to eradicate that notion, the attempt was made taking regular usage drugs Amlodipine to compare their quality standards both in branded and generic preparations.

KEYWORDS:
Standard Drugs, Generic Drugs, Physical Assessments, Amlodipine.

I. INTRODUCTION:

Amlodipine is a medication used to treat hypertension and coronary artery disease. It is taken orally and has an effect that lasts for at least a day.Amlodipine is a dihydropyridine calcium antagonist which inhibits the trans membrane influx of calcium ions into vascular smooth muscle and cardiac muscle.

Chemically Amlodipine is a -3-ethyl 5-methyl 2-[(2-aminoethoxy)methyl]-4-(2-chlorophenyl)-6methyl-1,4-dihydropyridine-3,5-dicarboxylate.
Molecular Formula ; $C_{20}H_{25}ClN_2O_5$
Molar mass ; 408.88 g·mol^{-1}



Pharmacokinetic data :
Bioavailability : 63-91 %
Protein binding : 93 %
Metabolism : Liver
Onset of action : highest availability 6 to 12 hours after oral dose
Elimination half life : 30-50 hours
Excretion : Urine

AIMS AND OBJECTIVE

The goal of study is to produce a report on a comparative study / analysis of standard and generic amlodipine formulations and to discuss the realities of generic formulation standards
Do a survey of Hospitals, Medicals and premises to know the opinion of Doctors, Pharmacists and patients about standard and generic tablets of amlodipine.

INFORMATION OF STANDARD AND GENERIC MEDICINES

a) **Standard medicine**

A standard drug undergoes a series of tests and evaluations for its efficacy, safety for human consumption. The branded drugs are well known reliable sort of medicines.

b) **Generic medicines :**

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A generic medicines is one that contains the same chemical substance as the drug that was patented and invented originally. After the patent on the original drug has expired generic drugs can be sold. The active pharmaceutical ingredients in the generic drug is same as in the original drug. There may be difference in the manufacturing method, formulation, excipients, colour, taste, packaging etc.

The active ingredients in the generic product has same type and quantity, but the inactive substances are different. The inactive components includes shape, flavour, texture, smell, and other characteristics but do not help to alleviate health problems.

The generic pharmaceutical sector is expanding and these drugs may become more widely available in the future. Increased education regarding generic medicines and there is no so many difference in branded and generic drugs is urgently needed. Therapeutic bioequivalence testing is also essential to guarantee that generic drugs are safe and have same effect on the body as standard medicines.

EXPERIMENTAL PROCESS :

The comparison of generic and standard drugs , one standard tablet of amlodipine and one generic tablet of amlodipine were choosen.

The selected generic and branded formulation of amlodipine besylate (5mg) were compared for their quality standards based upon different control parameters

1) Physical evaluation
2) Thickness
3) Hardness
4) Friability
5) Disintegration test.

1. Physical parameters

Its includes colour, odour and shape of tablets

2. Thickness / heaviness

A critical quality control test is tablet thickness. The packaging of a thick tablet, whether in a blister or a plastic container, can be affected. The diameter of the tablet is used to determine the thickness of the tablet.

3. Hardness test:

The crushing strength (KgF) was determined with an automatic hardness tester for tablets (8M, Dr. Schleuniger, Switzerland). The force applied to the edge of the tablet was gradually increased by moving the screw knob forward until the tablet was broken. Ten tablets were randomly selected from each brand and the pressure at which eachtablet crushed wasrecorded.

4.Friability test:

10 tablets from each brand were weighed and. subjected to abrasion by employing a Veego friabilator which was operated at 25 Revolution per min for 4 minutes. The Friabilator was made of a plastic chamber divided into 2 parts. During each revolution the tablets were fallen from a distance of six inches to undergo shock. After 100 revolutions the tablets were again weighed. The loss in weight indicated the
friability.

5.Disintegration test:

6 tablets from each brand were taking for the test in distilled water at 37± 0.5 °C using a Tablet Disintegration Tester . As stated by Alderborn , the disintegration time was taken as the time when no particle remained on the basket of the system.

II. CONCLUSION

We had cocluded that the standard medicines undergoes safety studies, efficacy studies and clinical trials , therefore the money require for the studies are high , therefore the cost of standard medicines are very high. On other hand generic medicines did not undergo these studies so the prices of generic medicines are low as compare to standard medicines.

According to the survey

1. The most Doctors prescribe the standard medicines to patient,
2. The most, Druggist and Chemist gives generic medicines to the patient ,
3. The most patient purchase the generic medicines.

In our premises there is more misunderstanding regarding the generic and standard medicines , so we have to arrange the programme related to awareness , gives education about medicines.

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