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Research Article

Comparison and Evaluation of Freely Supplied Government and Ethically Marketed Antihypertensive Drug (Atenolol)

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Abstract

The main aim and objective of present research work is to evaluate and compare the standards concerning quality of generic and two branded antihypertensive drug (atenolol). The drugs are evaluated and results showed that branded and generic meet the pharmacopeial specifications. All tablets passed for the test of weight variation, hardness, thickness, friability, disintegration, dissolution, as per pharmacopoeia. Hence, we can say that branded and non-branded drugs of antihypertensive are equal. So, health care professionals are suggested to prescribe generic drugs so that everyone can reach the coast of drugs and maintain health.

Keywords: Atenolol; *In vitro* studies; Physicochemical test

Introduction

In the present framework medical stream has converted into a curative jungle. Pharmaceutical industries are out coming with many new molecules to cure many terrible diseases. The single comprehensive drug is formulating by various pharmaceutical companies by different brand names. In various research studies it is found that especially in rural areas most of the drugs are devour without proper prescription, which is very dangerous activity followed, apart from these few drugs are selling by government as the OTC drugs to treat common diseases. It is found that few small-scale Pharma industries are also following the Pharmacopeial standards which are maintained by pharmaceutical regulatory authorities during the formulation of the drugs. The same generic drug is manufactured by different pharmaceutical companies under different brand names and sold under different coast. The present studies aim to throw away the blind belief of many people that branded drugs show better therapeutic activity than the generic drugs. Hence quality of drugs accessed by qualitative and quantitative analysis of the drug formulation. As per pharmaceutical standards the parameters like weight variation, hardness, friability, disintegration, dissolution and pH of the drug are studied. In the present study we are analyzing antihypertensive drug (atenolol) used for treating hypertension [1-7].

Materials and Methods

Chemicals and reagents

The atenolol tablets were taken from one of the reputed pharmaceutical stores as well as taken from the Government hospital pharmaceutical stores (Table 1).

Table 1.

Brand Name	Cost of Drug (Per 10 Tab)	Manufacturer	Batch No	MFG Date	Expiry Date
A-AtenololIP (Generic)	0.00 Rs/-	Relieflabs P. LTD. (Maharashtra)	16C103	MAR. 2019	Feb-21
HIPRES-50	27.39 Rs/-	Cipla Pharmaceuticals Pvt. Ltd.	390371	Jun-19	May-22
Acord Plus	65.00 Rs/-	Invision Medi Sceinces Pvt. Ltd	LP-046	OCT. 2019	Sep-22

Methodology

Various analytical methods and tests are important for the development and manufacture of pharmaceutical formulations. The evaluation was done according to USP and BP standards.

Evaluation Tests for Tablets

Weight variation

Weigh Sample tablets (20) of each brand individually on electronic analytical balance the average weight and the percentage (%) deviation was determined [8-15].

Table 2: Evaluation Tests for Tablets.

Evaluation Tests for Tablets								
SL N0	**Tablet Name**	**Weight Variation**	**Hardness Test**	**Thickness Test**	**Friability Test**	**Disintegration Test**	**Dissolution Rate (After 60min)**	**Assay**
	Standard as per IP	< 7.5 % for > 300 mg	3-10 kg/cm2	± 5%	< 1%	30min	99-100%	99-101%
1	Atenolol	± 0.605%	4.7	± 4.0	0.48%	19min-44sec	98.10%	100%
2	HIPRES-50	± 0.587%	4.8	± 4.1	0.45%	19min-31sec	98.50%	100%
3	Acord Plus	± 0.586%	4.8	± 4.1	0.45%	19min-14sec	99.01%	99.80%

$$\% \text{ deviation} = \frac{\text{Average weight} - \text{individual weight}}{\text{Average weight}} \times 100$$

Limits-As per I.P generally 10%for tablet weighing is 120mg (or) less than 7.5% for tablet weighing more than 300mg. The results are shown in Table 2.

Hardness test

The hardness of 5 atenolol tablets of each brand was measured by using Monsanto hardness tester. The hardness determines the resistance of tablet for breakage, under conditions of storage, transportation and handling, before usage. Limits-As per I.P 3-10kg.

Thickness test

The thickness of tablet is determined by measuring the diameter of tablet. It is a major quality control test which helps in packaging. The excessive thickness of tablet cause problems during blister or plastic container packaging. Limits-Diameter, % Deviation, greater than 12.5 ± 3%, Less than 12.5 ± 5%.

Friability test

Friability determines the physical strength of tablet upon exposure to mechanical shock and attrition. Roche friabilator was used to measure the friability. The initial weight of 20 tablets was taken as (W_1) and placed in a friabilator for 4 min at a rate of 25rpm for 100. After 100 revolutions the tablets were weighed again and noted as (W_2). The difference between the weight before and after the process is determined as Friability and should not exceed 1%. The percent friability was determined using the following formula.

$$\% \text{ Friability} = [(\text{Initial weight } (W_1) - \text{Final weight } (W_2))/\text{Initial weight } (W_1)] \times 100$$

Limits-As per I.P friability limits are does not cross the more than 1%.

Disintegration test

The disintegration time was performed by apparatus specified in USP at 50rpm. 900ml of buffer pH 7.4 was used as disintegration medium and the temperature of 37± 0.5 ^{0}C and time in seconds was taken for complete disintegration of the tablet.

Dissolution studies

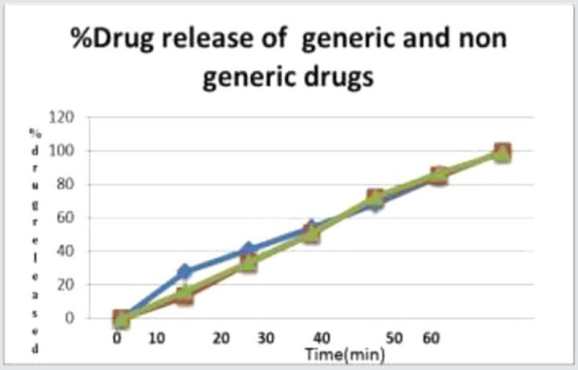

Figure 1: Dissolution profile of Generic and non-generic drugs of Atenolol.

Drug dissolution testing is routinely used to provide critical *in vitro* drug release information for both quality control purposes. The Atenolol tablets are added to 900ml of dissolution media (PH 7.4 phosphate buffer) contained in USP dissolution apparatus II and stirred at a speed of 60rpm at 37 ± 0.5 °C. Ten milliliter aliquots were withdrawn at interval of 10, 20, 30, 40, 50, 60 minute and replaced by 10ml of fresh dissolution media (37 °C). The samples were collected and analyzed after suitable dilution at 252nm using Shimadzu 1700 UV-Visible spectrophotometer (Figure 1).

Assay

The spectroscopic method (UV-visible) is chosen for ascertaining the percentage purity of samples they are

UV Method

Preparation of standard stock solution

The standard solution of Atenolol is prepared by dissolving the weighed 10mg of drug sample into a 100ml volumetric flask and the volume is make up to 100ml to get the concentration of 100µg/ml using methanol as a solvent.

Preparation of calibration curve and λmax of Atenolol determination

From the above prepared standard stock solution fresh aliquots were pipette out and suitably diluted with methanol to get final concentration in the range of 5-30µg/ml. The prepared dilutions were scanned under 200-400nm wavelength range and a sharp peak was obtained at 241nm (Figure 2). Calibration curve was plotted by taking concentration of solution on x-axis and absorbance on y-axis. The λ_{max} is shown in (Figure 3).

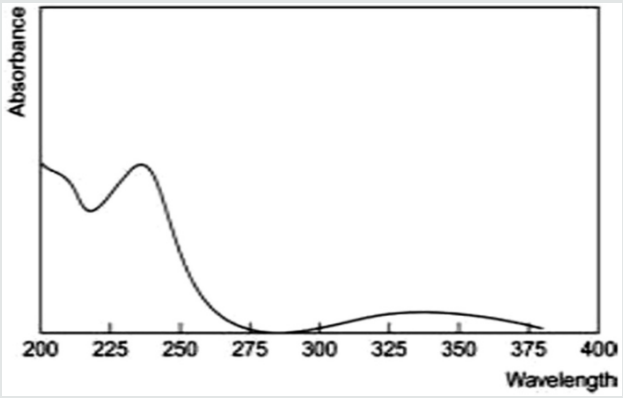

Figure 2: UV spectrum of Atenolol.

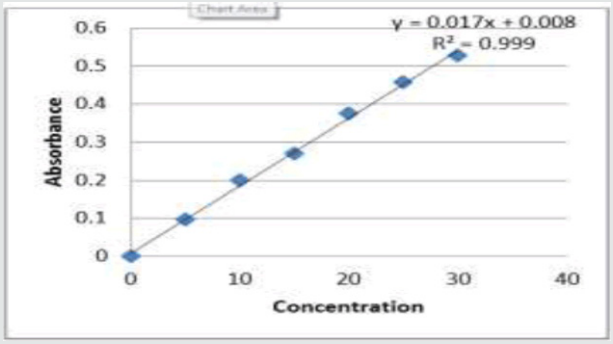

Figure 3: Calibration curve of Standard Atenolol.

Procedure

Weigh about 20 tablets of Atenolol, powdered and weigh equivalent amount of drug about 10mg and transferred into a 100ml volumetric flask. Then add few ml of methanol and make it to dissolve and the final volume were made up to mark with methanol. The solution was then filtered through Whatman filter paper and the absorbance was measured against blank. The amount of atenolol was computed by using the equation referring to the calibration curve data represented in (Table 3).

Table 3: Calibration curve data of Atenolol.

S. NO	Concentration	Absorbance
1	5	0.095
2	10	0.196
3	15	0.268
4	20	0.377
5	25	0.458
6	30	0.53

Results and Discussion

The results of our research work conducted on generic and two different brands of antihypertensive atenolol tablets, met the IP requirements of quality control tests within specified limits. It is carried out in an *in vitro* study. The various physical parameters of tablets like weight variation, hardness, thickness, friability, dissolution, assay and disintegration time are accessed were within the pharmacopeial specifications. Disintegration time of the entire branded and generic tablet was found in the pharmacopeial limit while generic tablet showing little higher disintegration. Drug release of generic tablet was found to be 99.1 % in 30 minutes which is comparatively lesser than the branded tablets which showed drug release 100% in 30 minutes. Hence, it can be concluded that tablets were all found to be as per pharmaceutical specifications.

Conclusion

Finally, study suggests that generic and branded (non-generic drugs) shown equal results. Hence generic form of the drug should be widely prescribed to reduce the medication cost and make the treatment economical. So that general people can also meet the medication cost.

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