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Research Article

Comparitive In-Vitro Evaluation Of Commercially Available Generic And Branded Propranolol Hydrochloride Immediate Release Tablets

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Abstract

The present work describes about the comparative *in-vitro study* of commercially available generic and branded Propranolol Hydrochloride tablets. The generic and branded Propranolol hydrochloride tablets were taken and evaluated for different parameters like weight variation, hardness, friability, disintegration, percentage purity and dissolution studies. According to USFDA, generic drugs are identical and are within the acceptable bioequivalent range to the brand-name counterpart with respect to pharmacokinetic and pharmacodynamic properties. Generics are almost identical to that of branded drugs which are 80% cheaper on average. The generic drugs of various pharmaceutical companies are sold at low cost and are checked for their therapeutic efficacy by comparing with that of branded ones. The *in-vitro* results of both generic and branded were compared and found to be within the limits and claimed that generics are almost equal to branded drugs in all aspects except cost.

Key words: Branded formulations, Generic drugs, Percentage purity, USFDA, Dissolution studies.

INTRODUCTION

In present scenario most of the people are suffering with high blood pressure due to different food habits, stress and lack of exercise, so we focused our work on this aspect and selected Propranolol Hydrochloride as the drug of choice. It is the drug widely used for the treatment of Hypertension. Branded vs Generics: The difference between a brand-name product and a generic one is designed to be transparent. Once the patent life expires on a brand-name drug product, it is eligible to be made into a "generic drug." To do this, the generic drug manufacturer must ensure that the drug they are producing contains the same active ingredient(s) as the brand-name product, in the same dosage form, at the same dose or concentration, and for the same route of administration .The drug may differ in color, shape, taste, inactive ingredients, preservatives and packaging, however. Because of these differences, the generic drug manufacturers are required to submit additional paperwork to the FDA to prove that their product is manufactured in accordance with good manufacturing practices (GMPs), and is as pure and stable as the brand-name product. Additionally, the generic needs to meet pharmacokinetic parameters in the body, which means it must dissolve (in a beaker) at the same rate and to the same extent as the original. This process ensures that the two products are bioequivalent and behave the same inside the body [1-4].

MATERIALS AND METHODS

PROPRANOLOL HYDROCHLORIDE [5, 6]:

Propranolol Hydrochloride is a non-cardio selective sympatholytic beta blocker that crosses the blood brain barrier. It is useful for treating atrial fibrillation and in patients with angina. It is used to decrease the risk of heart death and to manage certain types of tremors.

The generic forms of Propranolol hydrochloride such as Pronol-40, Propochem-40 and branded forms such as Inderal-40, Ciplar-40 were used for the study. These were evaluated for various parameters like weight variation which is done by using Electronic balance. The hardness was tested by Mosanto tester and Friability by Roche friabilator. The Disintegration test was carried out by disintegration apparatus and percentage purity by making use of Systronics UV spectrophotometer. The dissolution studies were carried out by using Dissolution type -2 apparatus.

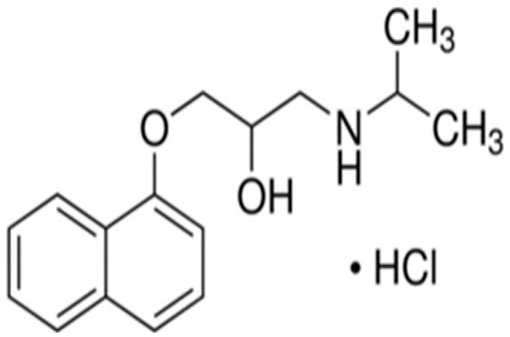

FIG: 1 STRUCTURE OF PROPRANOLOL HYDROCHLORIDE

EVALUATION PARAMETERS [7, 8, 9]

HARDNESS:

Hardness is defined as the "force required to break a tablet in diametric compression test." Hardness is hence, also termed as the tablet crushing strength. The resistance of tablets to breakage, under conditions of storage, transportation or handling before usage depends on its hardness. Tablet hardness was measured using a Monsanto and Pfizer hardness testers. Three tablets from each formulation were tested randomly and average reading was noted.

FRAIBILITY:

Twenty (20) tablets were selected from each batch and weighed. Each group of tablets was rotated at 25 rpm for 4 minutes (100 rotations) in the Roche friabilator. The tablets, were then dedusted and reweighed to determine the loss in the weight. Friability was then calculated using the following formula.

$$\%friability = [(W1-W2)/W1] \times 100$$

where, W1= weight of tablets before test, W2= weight of tablets after test.

DISINTEGRATION:

Disintegration time of a tablet was determined using disintegration test apparatus as per I.P. one tablet was placed in each of the 6 tubes of the basket. Add a disc to each tube and run the apparatus in a beaker containing 0.1N HCl maintained at 37^0 C ± 2^0C. The assembly should be raised and lowered between 30 cycles per minute. The time in seconds taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus was measured and recorded.

DRUG CONTENT:

It was performed by using Systronics UV Spectrophotometer with PC based double spectrophotometer of version type 2202.The UV wavelength ranges from 200-300nm and having special band width of 2 nm, measuring mode -% transmittance, absorbance, concentration, K factor, its absorbance = + 2.5 absorbance. The detector used in it is dual di-photo diode (PMT).

Preparation of drug sample dilutions [10]**:**

20 tablets were weighed and powdered in a clean mortar and pestle. Required quantity of powder equivalent to 2mg of Propranolol Hydrochloride was weighed accurately and transferred to a volumetric flask containing 20 ml of distilled water. The volumetric flask was shaken for 10 mins for complete solubility of drug. The volume was further made upto 100ml with methanol and filtered. From the filterate 10ml was taken diluted to 50 ml with methanol and absorbance of solution was measured at 290nm. The percentage purity was calculated taking 222 as specific absorbance.

WEIGHT VARIATION:

20 tablets were weighed individually and the average weight was calculated from the total weight of all tablets. The individual weights were compared with the average weight. The percentage differences in the weight should be within the permissible limits.

CALCULATIONS:

Weight of 20 tablets: x gms.

Weight of 5 tablets: y gms.

Average of 5 tablets: y/5.

Weight to be taken: Avg weight/Label claim X Equivalent weight.

Amount: Absorbance / € *Dilution factor X Conversion factor

%Purity: Amount /label claim X 100

DISSOLUTION STUDIES [11,12]:

Calibration Curve:

Preparation of 0.1N HCl buffer: It was prepared by dissolving 8.5ml of HCl in 1000ml volumetric flask using distilled water.

Preparation of drug solutions: The stock solution was prepared by accurately weighing 100 mg of drug and transferring to a clean volumetric flask containing 100 ml of 0.1N HCl buffer. It gives a concentration of 1000 µg/ml . From that 10ml of the solution was taken and made up to 100ml with 0.1N HCl buffer to produce standard solution of 100 µg/ml. From this solution serial dilutions of 5, 10,15,20,25 and 30 µg/ml were prepared respectively.

Dissolution study:

The dissolution behavior of generic, branded tablets were observed under the following parameters.

Dissolution parameters:

Medium	-	0.1N HCl buffer
Apparatus	-	USP Apparatus 2(paddle)
RPM	-	100 rpm
Quality	-	900ml
Temperature	-	37 ± 0.5^{0}C
Time points	-	5min, 10min, 15min, 20min, 30min, 45min.

The absorbance of the solution was measured by using Systronics UV Spectrophotometer at 290nm.

Table 1: Cost of Generic and Branded formulations of Propranolol Hydrochloride

S.No	Formulations of Propranolol Hydrochloride		Cost per strip (Rs)	Manufacturer
1	Generic	Pronol-40mg	16/-	Knoll Pharmaceuticals LTD
2		Propochem-40mg	20/-	Biochem Pharmaceutical Industries LTD
3	Branded	Inderal-40mg	27/-	Abbott Pharmaceuticals
4		Ciplar-40mg	43/-	Cipla LTD

Table 2: Acceptance criteria for tablet weight variation

Average weight of tablet(mg)	% difference allowed
130 or less than	±10
130-324	±7.5
More than 324	±5

Table 3: Calibration curve

Concentration(µg/ml)	Absorbance
0	0
5	0.1
10	0.211
15	0.324
20	0.452
25	0.578
30	0.690

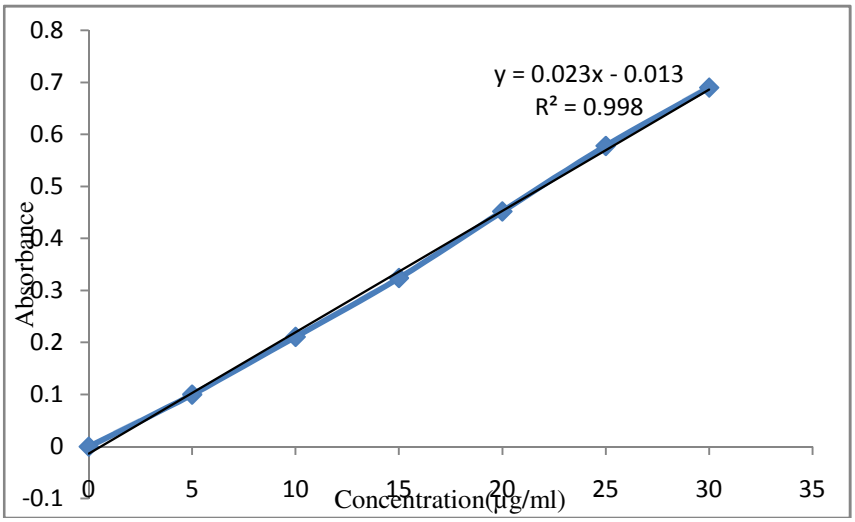

Fig 2: Calibration curve of Propranolol Hydrochloride

RESULTS & DISCUSSION

Table 4: Results of Generic and Branded Propranolol Hyrdochloride tablets

S.no	Commercial product	Weight variation	Hardness Kg/cm²	% friability	Disintegration (sec)	Drug content(%)
1	Pronol-40mg	108±0.02	3.33	0.59	79	97.75
2	Propochem- 40mg	107±0.03	3.23	0.71	85	99.5
3	Inderal-40mg	106±0.04	3.67	0.62	90	98.75
4	Ciplar-40mg	105±0.05	3.33	0.74	96	99

Table 5: Comparative dissolution study of both Generic and Branded Propanolol Hydrochloride tablets

Time(min)	Amount Release of Pronol-40mg	Amount Release of Propochem-40mg	Amount Release of Inderal-40mg	Amount Release of Ciplar-40mg
0	0	0	0	0
5	9.654	9.469	8.836	9.327
10	14.563	12.678	14.113	15.095
15	23.645	21.873	23.277	21.763
20	28.186	26.334	26.263	27.327
30	32.277	30.091	29.945	30.518
45	33.218	32.947	33.095	33.106

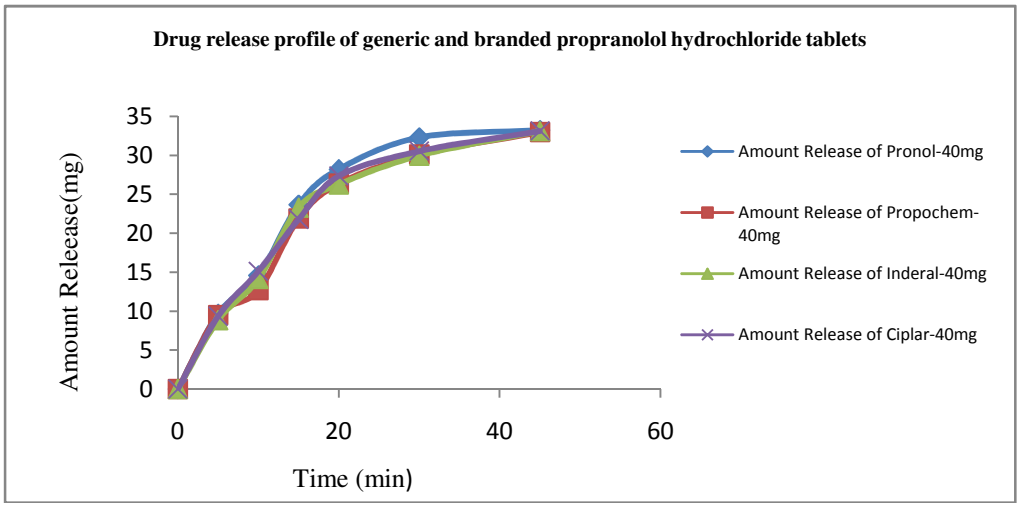

Fig 3. Comparative amount release of both Generic and Branded Propranolol Hydrochloride Tablets

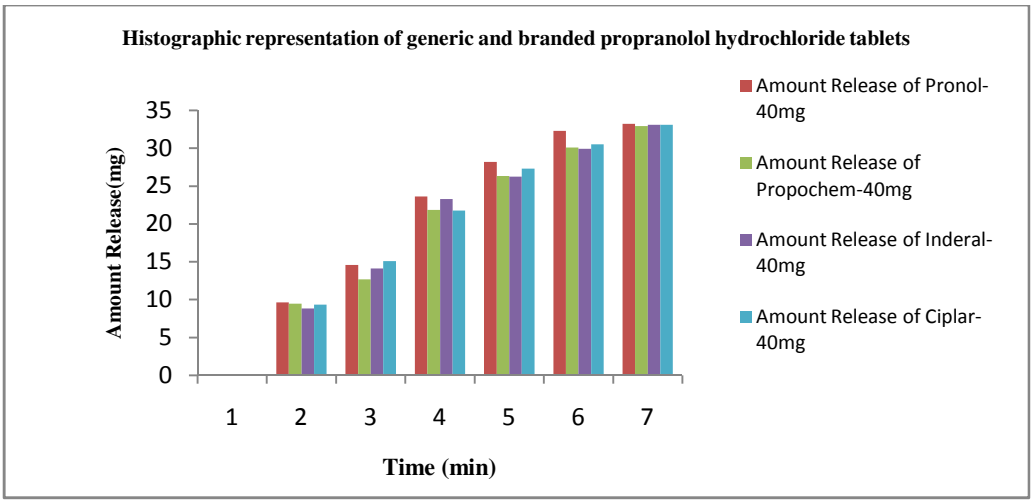

Fig 4. Graphical representation of amount release of Generic and Branded Propranolol Hydrochloride tablets.

Note: By comparing the amount release of both the generic branded tablets of Propranolol Hydrochloride, the amount released at 45min for both the generic and branded was found to be similar. The generic drug Pronol-40mg showed high drug release with 33.218mg when compared with Propochem-40mg and other two brands like Inderal-40mg and Ciplar-40mg.

CONCLUSION

From the above results, we had concluded that generic drugs of Propranolol Hydrochloride showed similar results in weight variation, friability, hardness, percentage purity and drug release profile like the branded drugs. So as a pharmacist we can prefer generic drugs than branded forms as they are cost effective and equally active as branded ones.

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