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Comparative *InVitro* Evaluation of Commercial Atenolol Tablets.

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ABSTRACT

The main purpose of an oral tablet is to deliver to the human body a certain and defined amount of drug through the gastro intestinal system. Studies on the bioavailability of drugs from a given dosage form revealed that, in many situations, tablet with the same drug and drug content did not give the same therapeutic effect. Formulation additives in the tablet, physical form of the drug used in the tablet and tablet manufacturing process vary from manufacturer to manufacturer, which is responsible for the variation in the observed dissolution profiles and therapeutic effect. Pharmaceutical bioavailability or *in-vitro* availability is one of the aspects of drug bioavailability. Of the tests that can be performed on tablets, the dissolution test is considered to be sensitive, reliable and rational for predicting *in vivo* drug availability behavior. Thus the present study has been under taken to evaluate & compare the various *in-vitro* quality control parameters (both official & unofficial) such as appearance, thickness, diameter, weight variation, friability, hardness, content uniformity (assay), disintegration & dissolution of commercially available different brands of atenolol tablets.

Keywords: Tablets, formulation, bioavailability, atenolol*, invitro*.

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INTRODUCTION

The main purpose of an oral tablet is to deliver to the human body a certain and defined amount of drug through the gastro intestinal system. Studies on the bioavailability of drugs from a given dosage form revealed that, in many situations, tablet with the same drug and drug content did not give the same therapeutic effect. Formulation additives in the tablet, physical form of the drug used in the tablet and tablet manufacturing process vary from manufacturer to manufacturer, which is responsible for the variation in the observed dissolution profiles and therapeutic effect.

Pharmaceutical bioavailability or *in-vitro* availability is one of the aspects of drug bioavailability. Of the tests that can be performed on tablets, the dissolution test is considered to be sensitive, reliable and rational for predicting *in-vivo* drug availability behavior.

Thus the present study has been under taken to evaluate & compare the various *in-vitro* quality control parameters (both official & unofficial) such as appearance, thickness, diameter, weight variation, friability, hardness, content uniformity (assay), disintegration & dissolution of commercially available different brands of atenolol tablets.

EXPERIMENTAL METHODOLOGY

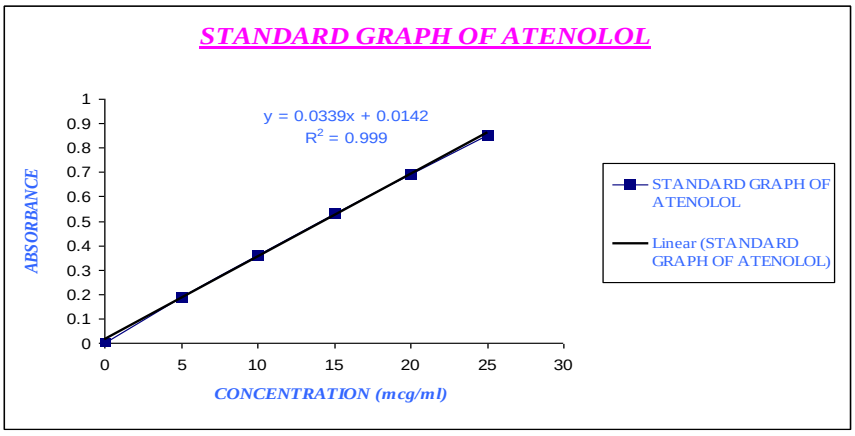
The present study consists of the following steps [1-4]: 1. Preparation of standard curve for the selected drug atenolol. 2. Evaluation of various *in-vitro* quality control parameters (both official & unofficial) such as appearance, thickness, diameter, weight variation, friability, hardness, content uniformity, disintegration & dissolution of commercially available five different brands of atenolol tablets. 3. Comparing the evaluation of various *in-vitro* quality control parameters (both official & unofficial) of the five various marketed atenolol tablets.

RESULTS AND DISCUSSION

Analytical Method for Estimation of Atenolol

A number of methods are reported in the literature for estimation of Atenolol. These methods include colorimetric method, spectrophotometric method and HPLC methods. In this work a spectrophotometric method was used for estimation at 275nm and is described below.

A stock solution of atenolol containing 1 mg/ml was prepared in methanol. From the stock solution different concentration of atenolol were prepared by diluting with the distilled water and their absorbance were measured at 275nm, using double beam U.V. Spectrophotometer. This procedure was carried out in triplicate and the results are given in the below table. A graph was plotted by taking concentration of atenolol (µg/ml) on X-axis and absorbance on the Y- axis.



Graph I: Standard graph of atenolol

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Table 1: Spectrophotometric method of estimation of atenolol

S.No.	CONCENTRATION (µg/ml)	ABSORBANCE (Avg. of 3 trials)
1.	5	0.191
2.	10	0.360
3.	15	0.532
4.	20	0.690
5.	25	0.851

Test for Content of Active Ingredients (Assay)

The assay results for five different marketed brands of atenolol tablets were given in below table-2. Based on the below data, it was inferred that the content of atenolol in tablet of different brands except brand B was within the limits prescribed by I.P. On comparing all the brands the content of atenolol is highest in brand E.

Table 2

Code	Brand	Content of Atenolol in each tablet (in mg)	% drug content in each tablet
A	Tenolol	47.36	94.7
B	Ziblok	45.9	91.8
C	Itel	47.29	94.5
D	Atecard	47.9	95.8
E	Tenormin	49.6	99.2

Test for Uniformity of Weight

The weight variation test results for five different marketed brands of atenolol tablets were given in below table - 3.

Table 3

Code	Brand name	Average weight of 20 tablets, gm	Number of tablets falling outside the range ±10%
A	Tenolol	0.196	Nil
B	Ziblok	0.205	Nil
C	Itel	0.174	Nil
D	Atecard	0.187	Nil
E	Tenormin	0.21	Nil

From the above data, it is inferred that all the brands of tablets passed the weight variation test as prescribed by I.P. According to I.P., if the tablets are uniform in weight; it is likely that the tablets will be uniform in drug content. As all the brands passed the weight variation test, it is concluded that all the tablets are uniform in drug content also. Hence content uniformity test was not carried on the tablets.

Test for Friability of Uncoated Tablets

The friability test results for five different marketed brands of atenolol tablets were given in below table - 4.

Table 4

Code	Brand name	% Friability
A	Tenolol	0.10
B	Ziblok	0.10
C	Itel	0.46
D	Atecard	0.10
E	Tenormin	0.3

Based on the above data, it was inferred that the selected tablets of different brands had a friability of less than 1% as specified in I.P. Therefore all the tablets of different brands passed the I.P. friability test.

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Test for Disintegration

The disintegration test results for five different marketed brands of Atenolol tablets were given in below table - 5.

Table 5

Code	Brand name	DT time in minutes (average of 20 tablets)	Standard deviation
A	Tenolol	13.5	0.1
B	Ziblok	8.5	0.14
C	Itel	10.8	0.1
D	Atecard	14	0.22
E	Tenormin	10.5	0.70

Based on the above data, it was inferred that the selected tablets of different brands are disintegrate within 15 minutes in GIT. Therefore all the tablets of different brands passed the I.P. disintegration test. However there was variation in disintegration time from brand to brand as shown in table – 5.

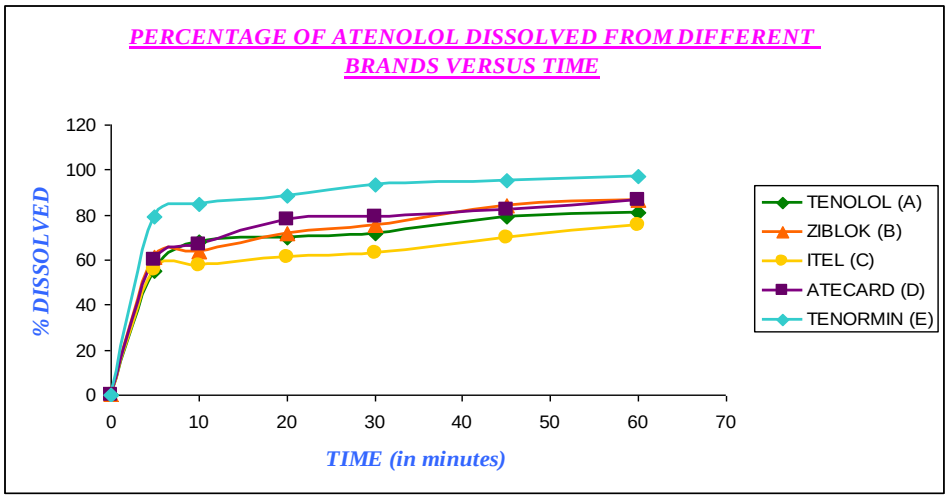
Test for dissolution

The dissolution test results for five different marketed brands of atenolol tablets were given in below table - 6.

Table 6

Code	Brand name	K_1/minute	$T_{50\%}$ minutes ($t_{1/2}$)	$T_{90\%}$ minutes
A	Tenolol	0.04	17.32	3.625
B	Ziblok	0.02	34.65	07.25
C	Itel	0.01	69.3	10.5
D	Atecard	0.02	34.65	7.25
E	Tenormin	0.08	30.11	1.31

Based on the above data, it was inferred that all the brands except C of atenolol tablets passed the dissolution test as prescribed by I.P. Even though all brands passed the dissolution test as prescribed by I.P. there was variation in atenolol dissolution rate from brand to brand. On comparing the first order rate constant (K_1/minute) in table – 6, associated with dissolution of atenolol from each brand of tablets, it was highest with brand E (Tenormin tablets - 0.08/minute), while it was lowest for brand C (Itel tablets – 0.01/minute). It indicates that the onset of action is quick in brand E when compared with other brands. The variation in dissolution profiles of atenolol from different brands is shown in the following graphs II & III.



Graph II

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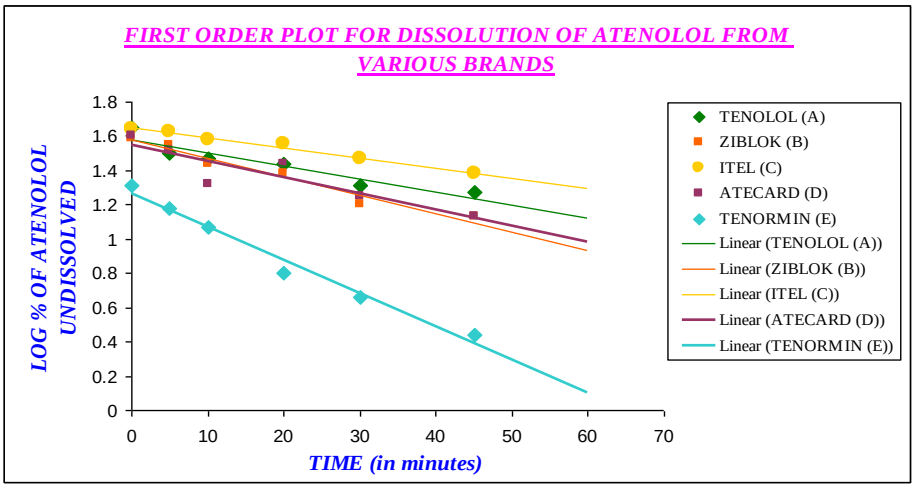

Graph III

Evaluation of Appearance

From the evaluation of appearance for five different marketed brands of atenolol tablets the following was determined.

Table 7

Code	Brand name	Manufacturer	Surface texture	Color	shape
A	Tenolol	IPAC Laboratories Ltd.	Smooth	White	Spherical
B	Ziblok	FDC Limited	Smooth	White	Spherical
C	Itel	Noel pharma	Smooth	White	Spherical
D	Atecard	Alembic Limited	Smooth	White	Spherical
E	Tenormin	Primal healthcare Ltd.	Smooth	White	Spherical

Based on the above data, it was inferred that the selected tablets of different brands are white in color, spherical in shape and having smooth surface texture.

Test for tablet thickness

The thickness test results for five different marketed brands of Atenolol tablets were given in below table - 8.

Table 8

Code	Brand name	Average thickness of 10 tablets, mm
A	Tenolol	0.4
B	Ziblok	0.3
C	Itel	0.3
D	Atecard	0.4
E	Tenormin	0.4

Based on the above data, it was inferred that almost all the brands of tablets were having uniform thickness.

Test for tablet diameter

The diameter test results for five different marketed brands of atenolol tablets were given in below table - 9.

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Table 9

Code	Brand name	Average diameter of 10 tablets, mm
A	Tenolol	0.8
B	Ziblok	0.85
C	Itel	0.82
D	Atecard	0.84
E	Tenormin	0.8

Based on the above data, it was inferred that all the brands of tablets were having uniform diameter.

Hardness Test

The hardness test results for five different marketed brands of Atenolol tablets were given in below table - 10.

Table 10

Code	Brand name	Average hardness of 6 tablets, Kg/cm^2	Standard deviation
A	Tenolol	4.13	0.16
B	Ziblok	3.9	0.07
C	Itel	4.53	0.08
D	Atecard	4.1	0.04
E	Tenormin	3.5	0.04

Based on the above data, it was inferred that all the brands of tablets were having good hardness.

CONCLUSION

In the present work, 5 different marketed brands of atenolol tablets of strength 50mg were selected. Attempts were made to evaluate & compare the various in-vitro quality control parameters (both official & unofficial) such as appearance, thickness, diameter, weight variation, friability, hardness, content uniformity, disintegration & dissolution of commercially available different brands of atenolol tablets. The content of atenolol in tablet of different brands except brand B was within the limits prescribed by I.P. and the content of atenolol was highest in brand E. All the brands of tablets passed the weight variation test as prescribed by I.P. The selected tablets of different brands had a friability of less than 1% as specified in I.P. The selected tablets of different brands are disintegrated within 15 minutes in GIT. Therefore all the tablets of different brands passed the I.P. disintegration test. All the brands except C (Itel) of Atenolol tablets passed the dissolution test as prescribed by I.P. The first order rate constant was highest with brand E (Tenormin tablets - 0.08/minute), indicates that the onset of action is quick in brand E when compared with other brands. The selected tablets of different brands are white in color, spherical in shape and having smooth surface texture. Almost all the brands of tablets were having uniform thickness, diameter and good hardness. The results obtained were satisfactory and within the specified limits.

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