Comparative *In-Vitro* Quality Evaluation of Commercially Available Atorvastatin Tablets in Bangladesh

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ABSTRACT

The aim of the present investigation was to evaluate the *in vitro* quality assessment of different marketed brands of Atorvastatin tablets (10mg) available in Bangladesh. Three brands of Atorvastatin tablets were selected and marked as A, B and C. Some quality control tests were performed such as weight variation test, friability test, hardness test, disintegration time, dissolution profile, potency test etc. to assess the quality level of these marketed products. All the brands complied with the official specification for weight variation and friability (below1%). According to the USP specification, disintegration time should be within 30 minutes which is maintained by all of these brands. Specification for the dissolution time of Atorvastatin is 90% or more in 45 minutes. Drug Release of Brand A, Brand B and Brand C were 99.49 %, 99.35%, and 101.06% respectively in 45 minutes. So according to specification all the brands are in acceptable range which indicated the quality products of Bangladeshi pharmaceuticals.

Keywords: Atorvastatin, quality control tests, dissolution study.

INTRODUCTION

Atorvastatin is a lipid lowering agent which decreases the level of low density lipoprotein but increases the level of high density lipoprotein. [1] Atorvastatin has wide range of use in treating heart attack, angina, stroke, myocardial infarction and other heart related complications and usual dose of atorvastatin is 10-80mg once a daily [2] Oral dosage form is considered as the most convenient dosage form. Efficacy of pharmaceutical dosage form relies on the quality of the product. [3] To assess the quality of Atorvastatin tablets (10mg) of Dhaka city, Bangladesh, three brands of tablets were chosen for testing. Current study was performed to find out general organoleptic properties and comparative quality control evaluation test. This study is very much helpful for pharmacist and physicians to find out the interchangeability.

MATERIALS AND METHODS

Three different marketed brands of Atorvastatin tablets (10mg) were collected from the retail pharmacy of Dhaka, Bangladesh and marked as A, B and C. Physical appearance, name of manufacturer, manufacturing date, expiry date, manufacturing license number, D.A.R number was checked properly. Analytical grade chemicals were used in this experiment.

Measurement of diameter, shape and thickness: Shape of tablets was estimated by visual appearance. Digital caliper was used to measure the diameter and thickness of tablets. Five tablets from each batch were used, and the average value is calculated.

Measurement of average weight: Twenty tablets of each brand were weighed in balance and average weight was calculated from there.

Measurement of hardness: Monsanto hardness tester was used to measure the hardness of tablets.

Evaluation of weight variation, friability and disintegration time: Official pharmacopoeia method was followed to evaluate weight variation, friability and disintegration time of the tablets.

Measurement of assay: At first average weight of four tablets of Brand A, B and C were taken individually and then

crushed in mortar and pestle. Then equivalent amount 10mg of Brand A was taken and dissolved in 100 ml of phosphate buffer (pH 6.8) medium and filtered through 0.45 micron membrane filter paper. 1 ml of the filtrate was taken in a test tube and diluted up to 8 ml by using the same medium and absorbance was taken using UV spectrophotometer at 244 nm. Then absorbance value (y) was inputted previous standard curve equation and unknown concentration is measured. Assay was then computed using following formula.

$$Assay = \frac{Con \; X \; Dilution \; Factor \; X \; Total \; Volume \; X \; Average \; Weight \; (mg)}{Sample \; Taken \; (mg) \; X \; Strength(mg)} X \; 100\%$$

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Determination of in-vitro dissolution study: Release rate of marketed samples were determined by using USP II dissolution tester. 900 ml of simulated gastric fluid containing Phosphate buffer pH 6.8 at 37 ± 0.5 ºC was used as dissolution media and 75 rpm was set. Aliquot volume was withdrawn from the dissolution apparatus in a definite period of time and the samples were replaced with fresh dissolution medium. Drug released was determined by using standard calibration curve of pure drug after having the filtration. [4]

RESULTS AND DISCUSSION

Average diameter, shape and thickness of Brand A, B and C are presented in Table-1. Diameter, shape and thickness are very much important as they affect the packaging.

Table 1: Average diameter, shape and thickness of Brand A, B and C.

Brand	Average Diameter		Shape	Thickens (mm)
	Length (mm)	Width (mm)		
A	10.58	5.67	Oval	3.15
B	10.51	5.72	Rectangle	3.05
C	7.44		Spherical	3.73

Physical parameters of Brand A, B and C are tabulated in Table-2. From Table-2, it is clear that weight variation and friability are within official limit. Again, it is observed that Brand A has the greater disintegration time than other. But from the table, it can be said that, the disintegration time of all brands are within 30 minutes according to the USP specification. Assay of different Brands are also within the limit (90%-110%).

Table 2: Average weight, weight variation, hardness, friability, disintegration time and assay of Brand A, B and C.

Code	Average weight(mg)	Weight variation (%)	Hardness (N)	Friability (%)	Disintegration time (min)	Assay (%)
A	182.95	1.66	173.33	0.16	3.23	104.43
B	157.30	1.71	51.67	0.09	2.96	108.21
C	162.25	2.92	59.33	0.18	1.42	108.95

Table 3: Dissolution profile of Brand A, B and C.

Time (min)	Brand-A	Brand-B	Brand-C
0	0%	0%	0%
5	54%	67%	64%
15	69%	73%	72%
30	79%	81%	78%
45	99%	99%	100%
60	111%	106%	108%

Dissolution study is provided to determine whether the tablets dissolved within the desired time. Atorvastatin is an INN drug; no official specification is available in USP. According to FDA specification, % drug release of Atorvastatin should be 99% at 45 minutes. % drug release of all the brands of Atorvastatin met this specification and it is tabulated in Table 3 and presented in Figure 1. From the tables and graphs mentioned above, it can be said that all the brands of Atorvastatin complied with the FDA specification of 90% or more drug release from the tablet at 45 minutes.
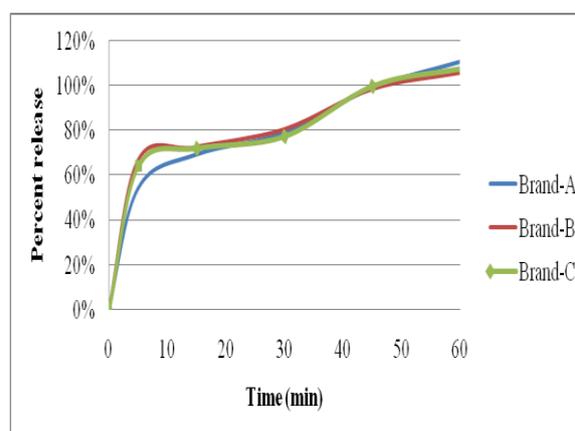
Figure 1: Dissolution profile of Brand A, B and C.

CONCLUSION

From the study, it can be concluded that, all brands of Atorvastatin compiled with the official specification. It will help the pharmacist and physicians to determine the interchangeability while prescribing and dispensing of Atorvastatin brands. It is also a very good fact that, pharmaceutical companies are manufacturing better drugs. Samples size should be taken in larger amount in future tests so as to get further clear idea about the quality of other brands.

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