

Simple UV Spectrophotometric Assay of Atorvastatin API Formulation and their Comparative Study

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Abstract

A rapid, simple, accurate, and economical least time consuming rosuvastatin spectrophotometric method has been developed for the assay of atorvastatin and then compare assay of brand available in Karachi, Pakistan. The assay is based on the ultraviolet UV absorbance maxima at about 244nm wavelength of atorvastatin using methanol as solvent. A sample of drug was dissolved in methanol to produce a solution containing atorvastatin. Similarly, a sample of ground tablets of different brand were extracted with methanol and diluted with the same methanol. The absorbance of sample preparation was measured at 244 nm against the solvent blank and the assay was determined by comparing with the absorbance of available brand. The method can be applied for the routine QC quantitation of atorvastatin in tablet formulation and active.

Index terms— atorvastatin, assay, uv pectrophotometry.

1 Introduction

torvastatin figure 1 is an HMG-CoA reductase inhibitors (3-hydroxy,3-methylglutaryl-CoA), called statins. It was a breakthrough for the prevention of hypercholesterolemia and related diseases.1-3 Cholesterol has an important role in the daily functioning of the body. But, it can also have a negative effect to the development of atherosclerosis. These plaques can block the arteries, disturb blood flow, or may rupturing and causing a clot that increases blockage. The results of these blockages are very serious and can cause angina, claudication, stroke and heart attack.4 Hyperlipidemia and hypertension are correlated to each other and have additional effect on CHD coronary heart disease and associated mortality rate, since CV cardiovascular disease is closely related to some factors such as high cholesterol levels, hypertension or diabetes. In literature there are many evidences which suggest additive beneficial effects of statin combined with losartan in the treatment of hypercholesterolemia, hypertensive patients.5

There are several methods reported by HPLC with the statin 6-10 but there is study found that show the comparison of available brands in market. Because the therapy is very expensive an person who has any cardiovascular disorder take medicine life time when he started. Therefor it is important that they use medicine should not be expensive and give hundred % result.

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The aim of this study is to investigate the assay of commercially available six brands of atorvastatin in Karachi, Pakistan. number and were labeled to conatin atorvastatin 10mg per tablet. All the six brands have 5 year shelf life.

The serial number as an identification of purchased brands are given in Tabel 1.20 tablets of six different brand of atorvastatin from the marketed sample were weighed and crushed uniformly with the help of a mortar and pestle. By calculating the average weighed sample powder equivalent to 10 mg of atorvastatin was transferred into a volumetric flask containing 10mL methanol solvent MeOH. The solutions were sonicated for about 5 min and than make up volume upto 100 ml with water.

2 d) Procedure

After preparation of standard and tablet solutions, strength of solution 100 ppm in 100 ml absorbance of the sample preparation and standard preparation in 1cm cell at the wavelength of maximum absorbance at about 244 nm, using spectrophotometer, using the blank solution. Calculate the quantity in mg, of atorvastatin per tablet.

3 III.

4 Results and Discussions

Pharmaceutical assay was carried out by using spectrophotometer on all brands of atorvastatin tablets during the study. Table-1 shows name brand and % assay of different brands. Table-2 ,3 are showing the descriptive within and between groups and shows result are highly significant with p value 0.000.

Test of hypothesis i-e ANOVA and multiple comparison of different brands of atorvastatin are given in table ?? shows highly significant difference of all brands with each other. The proposed method for the assay of commercially available atorvastatin tablet formulation is very simple, accurate ,least time consuming and rapid. It can be easily used for routine quality control QC for monitoring the assay in the API, inprocess samples and tablet formulation. ANOVA shows between and within group F value 309348.804 with degree of freedom df value5 and 24 and p value 0.00 which shows significant results. ¹



Figure 1: Figure 1 :

Brand Name	Serial no	Average wt of tablet mg	Wt for 100 ppm	Absorbance 244 nm	% assay
Prostatin	ATR-1	16.43	16.43	0.157	104.66
Statin	ATR-2	16.6	16.6	0.137	91.33
Fopsec	ATR-3	15.9	15.9	0.099	66.00
Winstor	ATR-4	15.6	15.6	0.118	78.66
Survive	ATR-5	18.8	18.8	0.059	39.33

Figure 2: Table 1 :

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	13328.351	5	2665.670	309348.804	.000
Within Groups	.207	24	.009		
Total	13328.557	29			

Figure 1

Figure 3: Table 2 :

	%Availability of different brands	
	ATR-1	ATR-2
ATR2	13.30467 *	
ATR3	38.56733 *	
ATR4	25.96600 *	
ATR5	65.29267 *	
ATR6	42.53133 *	
ATR1	-13.30467 *	
ATR3	25.26267 *	
ATR4	12.66133 *	
ATR5	51.98800 *	
ATR6	29.22667 *	
ATR1	-38.56733 *	-25.26267 *
ATR2		-12.60133 *
ATR4		26.72533 *
ATR5		3.96400 *
ATR6		-25.96600 *
ATR1		-12.66133 *
ATR2		12.60133 *
ATR3		
ATR4		
ATR5		
ATR6		
ATR1		
ATR2		
ATR3		
ATR5	39.32667 *	
ATR6	16.56533 *	
ATR1	-65.29267 *	
ATR2	-51.98800 *	
ATR3	-26.72533 *	-39.32667 *
ATR4		
ATR6	-22.76133 *	

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