Global Journal of Medical research: B
Pharma, Drug Discovery, Toxicology and Medicine
Volume 14 Issue 2 Version 1.0 Year 2014
Type: Double Blind Peer Reviewed International Research Journal
Publisher: Global Journals Inc. (USA)

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

By Dr. Safila Naveed

Jinnah University for Women Karachi, Pakistan

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.

Keywords: *atorvastatin, assay, uv pectrophotometry.*

GJMR-B Classification: *NLMC Code: QV 55, WB 330*

Strictly as per the compliance and regulations of:

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

Dr. Safila Naveed

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.

Keywords: atorvastatin, assay, uv pectrophotometry.

I. Introduction

Atorvastatin 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.

Author: Faculty of Pharmacy Jinnah University for Women Karachi.
e-mail: safila117@yahoo.com

There for in the mind of this I have checked the % assay of different brands available in the market .

The aim of this study is to investigate the assay of commercially available six brands of atorvastatin in Karachi, Pakistan.

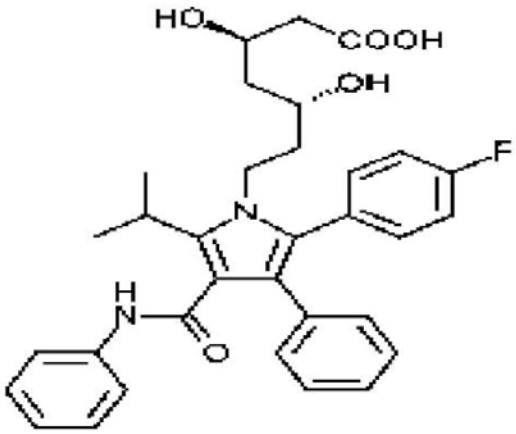

Figure 1 : Structure of Atorvastatin

II. Experimental

UV visible 1601 Shimadzu double beam spectrophotometer was used to measurement of spectra. The solvent which are used for the assay was spectroscopic-grade methanol.

a) Wavelength Selection

About 100 ppm of atorvastatin was accurately prepared in spectroscopic-grade methanol . This solutions were scanned in the 200-400 nm UV region. The wavelength maxima (λmax) was observed at 244 nm and this wavelength was adopted for absorbance measurement.

b) Standard Stock solution

Accurately weighed 10 mg of atorvastatin standard was transferred to a volumetric flask and add add suffi-cient methanol to produce 100 ml. This was sonicated 5 min to dissolve it.

c) Sample Preparation

The six different brands were purchased from different Public medical store located in Karachi, Pakistan. All tablets of each brand have same batch

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.

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 a spectrophotometer, using the blank solution. Calculate the quantity in mg, of atorvastatin per tablet.

III. 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 3 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, in-process 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.

References Références Referencias

1. Tobert, J. A. Nat. Rev. Drug Discov. 2003, 2, 517-526.
2. Jones, P. H.; Davidson, M. H.; Stein, E. A.; Bays, H. E.;McKenney, J. M.; Miller, E. Am. J. Cardiol. 2003, 92, 152-160.
3. Caslake, M. J.; Stewart, G.; Day, S. P.; Daly, E. Atherosclerosis 2003, 171, 245-253.
4. McKenney, J. M. Am. J. Health-Syst. Pharm. 2005, 62,1033-1047.
5. Koh, K. K.; Quon, M. J.; Han, S. H. J. Am. Heart Assoc.2004, 110, 3687-3692.
6. Sultana N, Arayne MS and and Safila Naveed (2010) Simultaneous Determination of Captopril and Statins in API, Pharmaceutical Formulations and in Human Serum by RP-HPLC J. Chin. Chem. Soc., 57, 378-383.
7. Sultana N, Arayne MS, Shah SN and Safila Naveed (2010) Simultaneous determination of Prazosin, Atorvastatin, Rosuvastatin and Simvastatin in API, Dosage Formulations and Human serum by RP-HPLC. Journal of the Chinese Chemical Society, 57(6), 1286-1292. I
8. Sultana N, Arayne MS and Safila Naveed (2011) Validated Method for the Simultaneous Determination of Lisinopril, Pravastatin, Atorvastatin and Rosuvastatin in API, Formulations and Human Serum by RP-HPLC Chinese Journal of Chemistry 29, 1216-1220.DOI: 10.1002/cjoc.201190226.
9. Sultana N, Arayne MS and Safila Naveed (2011) simultaneous Determination of Enalapril and Statins In Pharmaceutical Formulations by RP- HPLC, Chilean chemical society 56(3),734-737.
10. Arayne MS, Sultana N, Arman Tabassum Saeeda Nadir Ali and Safila Naveed (2012). Simultaneous LC Determination of Rosuvastatin, Lisinopril, Captopril, and Enalapril in API, Pharmaceutical Dosage Formulations, and Human Serum Medicinal Chemistry Research 21:4542-4548 DOI 10.1007/s00044-012-9997-

Table 1 : % assay of different brands of atorvastatin

Brand Name	Serial no	Average wt of tablet mg	Wt for 100 ppm	Absorbance at 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
Lipiget	ATR- 6	18.8	18.8	0.093	62.00

Table 2 : Descriptive statistics of different brands of atorvastatin

	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			

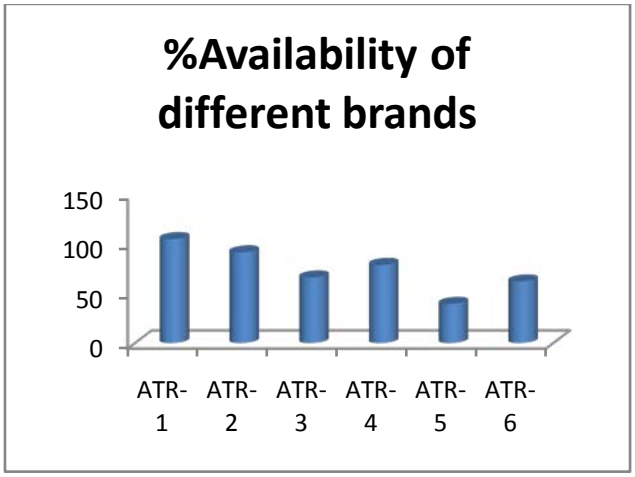

Figure 1

Table 5 : Multiple Comparisons of different brands of acetaminophen

(I) Brand Name	(J) Brand Name	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
ATR1	ATR2	13.30467*	.05871	.000	13.1835	13.4258
	ATR3	38.56733*	.05871	.000	38.4462	38.6885
	ATR4	25.96600*	.05871	.000	25.8448	26.0872
	ATR5	65.29267*	.05871	.000	65.1715	65.4138
	ATR6	42.53133*	.05871	.000	42.4102	42.6525
ATR2	ATR1	-13.30467*	.05871	.000	-13.4258	-13.1835
	ATR3	25.26267*	.05871	.000	25.1415	25.3838
	ATR4	12.66133*	.05871	.000	12.5402	12.7825
	ATR5	51.98800*	.05871	.000	51.8668	52.1092
	ATR6	29.22667*	.05871	.000	29.1055	29.3478
ATR3	ATR1	-38.56733*	.05871	.000	-38.6885	-38.4462
	ATR2	-25.26267*	.05871	.000	-25.3838	-25.1415
	ATR4	-12.60133*	.05871	.000	-12.7225	-12.4802
	ATR5	26.72533*	.05871	.000	26.6042	26.8465
	ATR6	3.96400*	.05871	.000	3.8428	4.0852
ATR4	ATR1	-25.96600*	.05871	.000	-26.0872	-25.8448
	ATR2	-12.66133*	.05871	.000	-12.7825	-12.5402
	ATR3	12.60133*	.05871	.000	12.4802	12.7225
	ATR5	39.32667*	.05871	.000	39.2055	39.4478
	ATR6	16.56533*	.05871	.000	16.4442	16.6865
ATR5	ATR1	-65.29267*	.05871	.000	-65.4138	-65.1715
	ATR2	-51.98800*	.05871	.000	-52.1092	-51.8668
	ATR3	-26.72533*	.05871	.000	-26.8465	-26.6042
	ATR4	-39.32667*	.05871	.000	-39.4478	-39.2055
	ATR6	-22.76133*	.05871	.000	-22.8825	-22.6402

ATR6	ATR1	-42.53133*	.05871	.000	-42.6525	-42.4102
	ATR2	-29.22667*	.05871	.000	-29.3478	-29.1055
	ATR3	-3.96400*	.05871	.000	-4.0852	-3.8428
	ATR4	-16.56533*	.05871	.000	-16.6865	-16.4442
	ATR5	22.76133*	.05871	.000	22.6402	22.8825

**. The mean difference is significant at the 0.05 level.*